Appendix A. Summary Tables

Table of Contents (N.B. Page numbers are links to the tables)

Abbreviations and acronyms used in tables. 8
Table 1.1.1. Type III Monitors vs. PSG: Study characteristics 10
Table 1.1.2. Type III Monitors vs. PSG: Study results 11
Table 1.2.1. Type IV Monitors (≥3 channels) vs. PSG: Study characteristics 13
Table 1.2.2. Type IV Monitors (2 channels) vs. PSG: Study characteristics 14
Table 1.2.3. Type IV Monitors (1 channel) vs. PSG: Study characteristics 15
Table1.3.1. Type IV Monitors (≥3 channels) vs. PSG: Study results 17
Table 1.3.2. Type IV Monitors (2 channels) vs. PSG: Study results 19
Table 1.3.3. Type IV Monitors (1 channel) vs. PSG: Study results 21
Table 1.4.1. Questionnaires vs. PSG: Study characteristics 24
Table 1.4.2. Questionnaires vs. PSG: Study results 25
Table 1.5.1. Clinical Prediction Rules vs. PSG: Study characteristics 27
Table 1.5.2. Clinical Prediction Rules vs. PSG: Study results 28
Table 3.1 Comparative studies of preoperative sleep apnea screening prior to surgical intervention: Study characteristics 30
Table 3.2 Duration of hospital stay (hr) in comparative studies of preoperative PSG testing 30
Table 3.3 Postsurgical outcomes in comparative studies of preoperative screening with PSG 31
Table 4.1 Multivariable analyses of AHI as a predictor of all-cause mortality: Study characteristics 32
Table 4.2. Results of multivariable analyses of AHI as a predictor of all-cause mortality 33
Table 4.3 Multivariable analyses of AHI as a predictor of cardiovascular events: Study characteristics 35
Table 4.4 Results of multivariable analyses of AHI as a predictor of cardiovascular events 36
Table 4.5 Multivariable analyses of AHI as a predictor of incident HTN: Study characteristics 37
Table 4.6 Results of multivariable analyses of AHI as a predictor of incident HTN 38
Table 4.7 Multivariable analyses of AHI as a predictor in Incident type 2 diabetes: Study characteristics 40
Table 4.8 Results of multivariable analyses of AHI as a predictor in Incident type 2 diabetes 40
Table 4.9 Multivariable analyses of AHI as a predictor of Quality of life SF-36: Study characteristics 41
Table 4.10 Results of multivariable analyses of AHI as a predictor of Quality of life (SF-36) 41
Table 5.1.1 Randomized clinical trials of CPAP vs. control: Study characteristics 42
Table 5.1.2 AHI (events/hr) in randomized controlled trials of CPAP vs. control 44
Table 5.1.3 ESS in randomized controlled trials of CPAP vs. control 45
Table 5.1.4a Arousal Index (events/hr)] in randomized controlled trials of CPAP vs. control 47
Table 5.1.4b Minimum 0_2 saturation (%) in randomized controlled trials of CPAP vs. control 48
Table 5.1.4c Sleep efficiency (% total sleep time) in randomized controlled trials of CPAP vs. control 49
Table 5.1.4d Slow wave sleep (% total sleep time or minutes) in randomized controlled trials of CPAP vs. control 50
Table 5.1.4e REM sleep (% total sleep time or minutes) in randomized controlled trials of CPAP vs. control 51

Table 5.1.5a Multiple Sleep Latency Test (min) in randomized controlled trials of CPAP vs. control 52
Table 5.1.5b Maintenance of wakefulness test (min) in randomized controlled trials of CPAP vs. control 53
Table 5.1.6a FOSQ in randomized controlled trials of CPAP vs. control 54
Table 5.1.6b Quality of life in randomized controlled trials of CPAP vs. control 55
Table 5.1.7 Neurocognitive and psychological tests in randomized controlled trials of CPAP vs. control 58
Table 5.1.8a Blood pressure measurements (mm Hg) in randomized controlled trials of CPAP vs. control 61
Table 5.1.8b HbA1C (%) in randomized controlled trials of CPAP vs. control 63
Table 5.2.1. Characteristics of randomized controlled trials comparing PAP with sham control 64
Table 5.2.2. AHI (events/hr) in randomized controlled trials of CPAP vs. sham control 66
Table 5.2.3. ESS in randomized controlled trials of CPAP vs. sham control 68
Table 5.2.4. Arousal index (events/hr) in randomized controlled trials of CPAP vs. sham control 70
Table 5.2.5. Sleep efficiency (%TST) in randomized controlled trials of CPAP vs. sham control 71
Table 5.2.6. Slow wave sleep (% TST) in randomized controlled trials of CPAP vs. sham control 72
Table 5.2.7. REM sleep (% TST) in randomized controlled trials of CPAP vs. sham control 73
Table 5.2.8. Maintenance of wakefulness test (min) in randomized controlled trials of CPAP vs. sham control 74
Table 5.2.9. FOSQ in randomized controlled trials of CPAP vs. sham control 75
Table 5.2.10. Quality of life in randomized controlled trials of CPAP vs. sham control 76
Table 5.2.11. Neuropsychological outcomes in randomized controlled trials of CPAP vs. sham control 77
Table 5.2.12. Blood pressure outcomes (mm Hg) in randomized controlled trials of CPAP vs. sham control 79
Table 5.3.1 Randomized controlled trials of oral vs. nasal CPAP: Study characteristics 82
Table 5.3.2 Compliance (mean hr/ night) in randomized controlled trials of oral vs. nasal CPAP 83
Table 5.3.3 ESS in randomized controlled trials of oral vs. nasal CPAP 84
Table 5.4.1 Randomized controlled trials of autoCPAP vs. CPAP: Study characteristics 85
Table 5.4.2 Compliance (mean hr/night) in randomized controlled trials of autoCPAP vs. CPAP 87
Table 5.4.3 AHI (events/hr) in randomized controlled trials of autoCPAP vs. CPAP 89
Table 5.4.4 ESS in randomized controlled trials of autoCPAP vs. CPAP 91
Table 5.4.5 Arousal Index (events/hr) in randomized controlled trials of autoCPAP vs. CPAP . 94
Table 5.4.6 Minimum O_2 saturation (%) in randomized controlled trials of autoPAP vs. CPAP 96
Table 5.4.7 Sleep efficiency (%) in randomized controlled trials of autoCPAP vs. CPAP 97
Table 5.4.8 REM sleep (%) in randomized controlled trials of autoCPAP vs. CPAP 98
Table 5.4.9 Stage 3 or 4 sleep (%) in randomized controlled trials of autoCPAP vs. CPAP 99
Table 5.4.10 Quality of life and functional outcomes in randomized controlled trials of autoCPAP vs. CPAP 100

Table 5.5.1 Characteristics of randomized controlled trials of bilevel CPAP vs. CPAP or autoCPAP 101
Table 5.5.2 Compliance (mean hr/night) in randomized controlled trials of bilevel CPAP vs. CPAP 102
Table 5.5.3 ESS in randomized controlled trials of bilevel CPAP vs. CPAP 103
Table 5.5.4 Quality of life and functional outcomes in randomized controlled trials of bilevel CPAP vs. CPAP 104
Table 5.7.1 Characteristics of randomized controlled trials of C-Flex™ vs. CPAP 105
Table 5.7.2 Compliance (mean hr/night) in randomized controlled trials of C-Flex™ vs. CPAP 106
Table 5.7.3 ESS in randomized controlled trials of C-Flex™ vs. CPAP 106
Table 5.8.1 Randomized controlled trials comparing different aspects of humidification with CPAP or autoCPAP: Study characteristics 107
Table 5.8.2 Compliance (mean hr/night) in randomized controlled trials comparing different aspects of humidification with CPAP or autoCPAP 108
Table 5.8.3 ESS in randomized controlled trials comparing different aspects of humidification with CPAP or autoCPAP 110
Table 5.9.1 Randomized controlled trials of mandibular devices vs. control: Study characteristics 112
Table 5.9.2 AHI (events/h) in randomized controlled trials of mandibular devices vs. control. 113
Table 5.9.3 ESS in randomized controlled trials of mandibular devices vs. control 115
Table 5.9.4a Minimum oxygen saturation (%) in randomized controlled trials of mandibular devices vs. control 116
Table 5.9.4b Arousal Index (events/h) in randomized controlled trials of mandibular devices vs. control 117
Table 5.9.4c Sleep Efficiency (%) in randomized controlled trials of mandibular devices vs. control 118
Table 5.9.4d Slow Wave Sleep (%) in randomized controlled trials of mandibular devices vs. control 119
Table 5.5.4e REM sleep (%) in randomized controlled trials of mandibular devices vs. control 120
Table 5.9.5 Quality of life outcomes in randomized controlled trials of mandibular devices vs. control 121
Table 5.10.1 Randomized controlled trials of mandibular advancement devices vs. inactive oral devices: Study characteristics 122
Table 5.10.2 AHI (events/hr) in randomized controlled trials of mandibular advancement devices vs. inactive oral devices 123
Table 5.10.3 ESS in randomized controlled trials of mandibular advancement devices vs. inactive oral devices 124
Table 5.10.4 Minimum oxygen saturation (%) in randomized controlled trials of mandibular advancement devices vs. inactive oral devices 125
Table 5.10.5 Arousal index (events/hr) in randomized controlled trials of mandibular advancement devices vs. inactive oral devices 126
Table 5.10.6 Sleep efficiency (%) in randomized controlled trials of mandibular advancement devices vs. inactive oral devices 127

Table 5.10.7 REM and slow wave sleep (%) in randomized controlled trials of mandibular advancement devices vs. inactive oral devices 128
Table 5.10.8 Other outcomes (see 5th column) in randomized controlled trials of mandibular advancement devices vs. inactive oral devices 129
Table 5.10.9 Functional Outcomes in randomized controlled trials of mandibular advancement devices vs. inactive oral devices 130
Table 5.11.1 Randomized controlled trials of mandibular advancement devices vs. mandibular advancement devices: Study characteristics 131
Table 5.11.2 AHI (events/hr) in randomized controlled trials of mandibular advancement devices vs. mandibular advancement devices 132
Table 5.11.3 AHI (events/hr) in randomized controlled trials of mandibular advancement devices vs. mandibular advancement devices 133
Table 5.11.4 ESS in randomized controlled trials of mandibular advancement devices vs. mandibular advancement devices 134
Table 5.11.5 other outcomes reported in randomized controlled trials of mandibular advancement devices vs. mandibular advancement devices 135
Table 5.11.6 Outcomes randomized controlled trials of mandibular advancement devices vs. tongue retaining devices 136
Table 5.11.7 Outcomes randomized controlled trials of tongue retaining devices vs. tongue retaining devices 137
Table 5.12.1 Randomized controlled trials of mandibular advancement devices vs. CPAP: Study characteristics 138
Table 5.12.2 Treatment response in randomized controlled trials of mandibular advancement devices vs. CPAP 139
Table 5.12.3 AHI (events/hr) in randomized controlled trials of mandibular advancement devices vs. CPAP 140
Table 5.12.4 ESS in randomized controlled trials of mandibular advancement devices vs. CPAP 142
Table 5.12.5a AI (events/hr) in randomized controlled trials of mandibular advancement devices vs. CPAP 143
Table 5.12.5b Minimum oxygen saturation (%) in randomized controlled trials of mandibular advancement devices vs. CPAP 144
Table 5.12.5c Sleep efficiency (%TST) in randomized controlled trials of mandibular advancement devices vs. CPAP 145
Table 5.12.5d Slow wave sleep (% TST) in randomized controlled trials of mandibular advancement devices vs. CPAP 146
Table 5.12.5e REM sleep (% TST) in randomized controlled trials of mandibular advancement devices vs. CPAP 147
Table 5.12.6 Wakefulness tests in randomized controlled trials of mandibular advancement devices vs. CPAP 148
Table 5.12.7a FOSQ in randomized controlled trials of mandibular advancement devices vs. CPAP 149
Table 5.12.7b Quality of life in randomized controlled trials of mandibular advancement devices vs. CPAP 150
Table 5.12.8 Cognitive function tests in randomized controlled trials of mandibular advancement devices vs. CPAP 152

Table 5.16.1 Randomized controlled trials of positional therapy vs. CPAP: Study characteristics 153
Table 5.16.2a AHI (events/hr) in randomized controlled trials of positional therapy vs. CPAP 154
Table 5.16.2b AHI ≤10 events/hr in randomized controlled trials of positional therapy 154
Table 5.16.3 ESS in randomized controlled trials of positional therapy vs. CPAP..... 155
Table 5.16.4 Other sleep study and related outcomes in randomized controlled trials of positional therapy vs. CPAP 155
Table 5.16.5 Quality of life in randomized controlled trials of Positional Therapy vs CPAP ... 156
Table 5.16.6 FOSQ in randomized controlled trials of positional therapy vs. CPAP 156
Table 5.16.7 Neurocognitive tests in randomized controlled trials of positional therapy vs. CPAP 157
Table 5.17.1 Randomized controlled trials of weight loss: Study characteristics 158
Table 5.17.2 Patients with OSA cure in 1 year in randomized controlled trials of weight loss . 158
Table 5.17.3 AHI (events/hr) in randomized controlled trials of weight loss 159
Table 5.17.4 ESS in randomized controlled trials of weight loss..... 159
Table 5.17.5 Minimum oxygen saturation (%) in randomized controlled trials of weight loss . 160
Table 5.17.6 Blood pressure (mm Hg) in randomized controlled trials of weight loss..... 160
Table 5.17.7 Hemoglobin A1c (%) in randomized controlled trials of weight loss 160
Table 5.17.8 Body weight (kg) in randomized controlled trials of weight loss..... 161
Table 5.18.1 Randomized controlled trials of oropharyngeal exercises: Study characteristics.. 162
Table 5.18.2 AHI (events/hr) in randomized controlled trials of oropharyngeal exercises..... 162
Table 5.18.3 ESS in randomized controlled trials of oropharyngeal exercises 163
Table 5.18.4 Minimum oxygen saturation (%) in randomized controlled trials of oropharyngeal exercises..... 163
Table 5.18.5 Sleep Efficiency (%) in randomized controlled trials of oropharyngeal exercises 164
Table 5.18.6 Other sleep study outcomes in randomized controlled trials of positional therapy vs. CPAP..... 164
Table 5.18.8 FOSQ in randomized controlled trials of oropharyngeal exercises..... 165
Table 5.18.9 Quality of life outcomes in randomized controlled trials of oropharyngeal exercises 165
Table 5.18.10 Neurocognitive tests in randomized controlled trials of oropharyngeal exercises 165
Table 5.19.1 Randomized controlled trials of palatal implants vs. control: Study characteristics 166
Table 5.19.2a. AHI (events/hr) in randomized controlled trials of palatal implant vs. Control . 166
Table 5.19.2b. 50% reduction in AHI to ≤ 20 events/hr in randomized controlled trials of palatal implant vs. control 166
Table 5.19.3 ESS in randomized controlled trials of palatal implant vs. control 167
Table 5.19.4 Minimum oxygen saturation in randomized controlled trials of palatal implant vs. control 167
Table 5.19.5. REM Sleep in randomized controlled trials of palatal implant vs. control..... 167
Table 5.19.6. FOSQ total in randomized controlled trials of palatal implant vs. control..... 167
Table 5.20.1 Studies of surgery vs. control: Study characteristics 168
Table 5.20.2 AHI or oxygen desaturation index (events/hr) in randomized controlled trials of surgery vs. control..... 169
Table 5.20.3 ESS in randomized controlled trials of surgery vs. control 170

Table 5.20.4 Minimum oxygen saturation (%) in randomized controlled trials of surgery vs. control 171
Table 5.20.5 Sleep stage changes (%) in randomized controlled trials of surgery vs. control ... 172
Table 5.20.6. FOSQ in randomized controlled trials of surgery vs. control 172
Table 5.20.7 Functional Outcomes in randomized controlled trials of surgery vs. control 173
Table 5.21.1 Studies of surgery vs. CPAP: Study characteristics 174
Table 5.21.2 Categorical outcomes in studies of surgery vs. CPAP 175
Table 5.21.3 Survival in studies of surgery vs. CPAP 175
Table 5.21.4 AHI or RDI in studies of surgery vs. CPAP 176
Table 5.21.5 ESS in studies of surgery vs. CPAP 177
Table 5.21.6 Other continuous outcomes in studies of surgery vs. CPAP 178
Table 5.21.7 Sleep stage in randomized controlled trials of surgery vs. CPAP 179
Table 5.21.8 Quality of life outcomes in randomized controlled trials of surgery vs. CPAP 179
Table 5.23.1. Randomized controlled trials of drug interventions: Study characteristics 180
Table 5.23.2 AHI (events/hr) in randomized controlled trials of drug interventions 181
Table 5.23.3 ESS in randomized controlled trials of drug interventions 182
Table 5.24.4 Arousal index (events/hr) in randomized controlled trials of drug interventions .. 182
Table 5.24.5 Sleep efficiency (%) in randomized controlled trials of drug interventions 183
Table 5.23.6 Slow wave sleep (%) in randomized controlled trials of drug interventions 184
Table 5.23.7 REM sleep (%) in randomized controlled trials of drug interventions 185
Table 5.23.8 Minimum oxygen saturation (%) in randomized controlled trials of drug interventions 186
Table 5.23.9 FOSQ in randomized controlled trials of drug interventions 186
Table 5.24.1 Randomized controlled trials of atrial overdrive pacing: Study characteristics ... 187
Table 5.24.2. AHI (events/hr) in randomized controlled trials of atrial overdrive pacing 187
Table 5.24.3. ESS in randomized Controlled trials of atrial overdrive pacing 188
Table 5.24.4. REM and Slow Wave Sleep (%) in randomized controlled trials of atrial overdrive pacing 188
Table 5.25.1 Positive airway pressure devices, reported major adverse events 189
Table 5.25.2 Mandibular advancement devices, reported major adverse events 190
Table 5.25.3 Surgical intervention (UPPP primarily), reported major adverse events 191
Table 5.25.4 Radiofrequency ablation, reported major adverse events 193
Table 5.25.5 Combination or various surgeries, reported major adverse events 194
Table 5.25.6 Surgical implant, reported major adverse events 195
Table 5.25.7 Bariatric surgery, reported major adverse events 195
Table 5.25.8 Weight loss diet, reported major adverse events 195
Table 5.25.9 Drugs, reported major adverse events 196
Table 6.1a Predictors of compliance with CPAP: Study characteristics 197
Table 6.1b Predictors of compliance with CPAP, multivariable analyses 198
Table 6.2a Mandibular advancement device as predictors of compliance: Study characteristics 200
Table 6.2b. Pre-treatment predictors of compliance with mandibular advancement device, multivariable analyses 200
Table 7.1 Randomized controlled trials of interventions to improve compliance with CPAP use: Study characteristics 201

Table 7.2 Compliance (hr/night) in randomized controlled trials of interventions to improve CPAP use 204
Table 7.3 Non-compliance outcome in randomized controlled trials of interventions to improve CPAP use 207

Abbreviations and acronyms used in tables.

Abbreviation / Acronym	Definition
AHI	apnea-hypopnea index in events/hour of sleep
AOP	atrial overdrive pacing
ASA	American Society of Anesthesiologists
AUC	area under the curve
Auto	automated scoring
autoCPAP	autotitrating positive airway pressure
BDI	Beck Depression Inventory
Block Design	Block Design and Digit Symbol Substitution
BMI	body mass index
bpm	beats per minute
Calgary	Calgary Sleep Apnea Quality of Life Index
C-flex™	splinted airway pressure
CHF	congestive heart failure
CI	confidence interval
CM	conservative management (sleep hygiene and weight control)
CMS collar	cervicomandibular support collar
COPD	chronic obstructive pulmonary disease
CPAP	continuous positive airway pressure
CT	conservative treatment
CVD	cardiovascular disease
DBP	diastolic blood pressure
Diff	difference
DM	diabetes mellitus (Type 2 Diabetes)
ED	emergency department
ESS	Epworth Sleepiness Scale (no units)
FOSQ	Functional Outcomes of Sleep Questionnaire
GA	geniotubercle advancement
GAHM	genioglossus advancement with hyoid myotomy/suspension
GERD	gastroesophageal reflux disease
GHQ-28	general health questionnaire
GrenobleSAQOL	Grenoble Sleep Apnea Quality of Life test
HADS	Hospital Anxiety and Depression Scale
HR	hazard ratio
HS	hyoid suspension (hyothyroidopexy)
HTN	hypertension
IQR	interquartile range
ISI	Insomnia Severity Index
LAUP	laser-assisted uvulopalatoplasty
LOA	limits of agreement
MAD	mandibular advancement device
MCS	Mental Component Summary (SF-36)
MLHFQ	Minnesota Living with Heart Failure questionnaire
MMO	maxillomandibular advancement osteotomy
MMSE	Mini Mental Status Examination
MSLT	Multiple Sleep Latency Test
nd	no data
NHP	Nottingham Health Profile
O2 desat	oxygen desaturation
OR	odds ratio
OSA	obstructive sleep apnea
OSLER	Oxford sleep resistance
P Btw	P value of difference between two interventions
PASAT	Paced Auditory Serial Addition Test
PCS	Physical Component Summary (SF-36)
PL	parallel design
PMID	Pubmed identifier (also known as unique identifier)
PSG	polysomnography; STOP

Abbreviation / Acronym	Definition
QLSESQ	Quality of Life Enjoyment and Satisfaction Questionnaire
RCT	randomized controlled trial
RDI	respiratory disturbance index
Resp dz	respiratory disease
RFA	radiofrequency ablation
RFVTR	radiofrequency volumetric tissue reduction
RH	reinforced education by the homecare team
ROC	receiver-operator characteristic curve
RP	reinforced education by the prescriber
RR	relative risk
SACS	sleep apnea clinical score
SAHS	sleep apnea-hypopnea syndrome-related symptoms questionnaire
SAQLI	Sleep Apnea Quality of Life Index
SBP	systolic blood pressure
SD	standard deviation
SDB	sleep disordered breathing
SF-36	Short Form (36) Health Survey
SH	standard education by the homecare network
SHEP	shoulder head elevation pillow
SHHS	Sleep Heart Health Study
SP	standard education by the prescriber
SQ	Scottish National Sleep Laboratory symptom questionnaire
STOP	Snoring, tiredness during daytime, observed apnea, and high blood pressure
STOP-Bang	STOP with BMI, age, neck circumference, and gender variables
TAP	transpalatal advancement pharyngoplasty
TASB	thoracic anti-supine band
TC	total cholesterol
TCA	tricyclic antidepressants
TCRFTVR	temperature controlled radiofrequency tissue volume reduction of the soft palate
Tg	triglycerides
TMJ	temporomandibular joint
TSD	tongue stabilizing device
Tx	treatment
UMACL	University of Wales mood adjective list energetic arousal score
UPP	uvulopalatoplasty
UPPP	uvulopalatopharyngoplasty
VLCD	very low calorie diet
WAIS	Wechsler Adult Intelligence Scale
WHR	waist-hip ratio
WMS	Wechsler Memory Scale
WSCS	Wisconsin Sleep Cohort Study
XO	crossover design

Table 1.1.1. Type III Monitors vs. PSG: Study characteristics

Study PMID	Participants	Country (Enrollment Years)	N	Baseline AHI (SD) [Range]	Baseline ESS (SD)	Mean Age, y	Male, %	Mean BMI, kg/m^2	Setting	Sleep Apnea Definition	Denominator	Quality Issues
Garcia-Diaz, 2007[60] 17356086	Suspected sleep apnea-hypopnea syndrome patients	Spain (nd)	65	30 (33) [nd]	12 (3.7)	54	87%	30.1	Sleep lab & Home	nd	Total recording time (RDI)	
Santos-Silva, 2009[61] 19480230	Suspected OSA and healthy subjects	Brazil (nd)	82	23 (34) [nd]	10.4 (5.8)	47	57%	28	Sleep lab & Home	nd	Total recording time	No clear population description – baseline severity by AHI
To, 2009[62] 19210658	Suspected OSA referred to respiratory clinic	China (2005)	184	40	10.4	49	75%	28.7	Sleep lab	AHI > 5	Total recording time	B-A plots are not interpretable; no clear population description
Tonelli de Oliveira, 2009[63] 19201709	Referred for sleep center	Brazil (2004-2006)	157	30 (28)	11 (5.0)	45	73%	29.1	Sleep lab & Home	AHI ≥ 5	Total recording time	Analytical problem – no adjustment for multiple measures on same patient

Respiratory events across all studies were of at least 10 seconds duration. As mentioned in the header row, respiratory events were defined identically in for the portable monitors as with laboratory-based PSG. Studies are ordered by decreasing number of analyzed people.

Table 1.1.2. Type III Monitors vs. PSG: Study results

Author, Year PMID	Index Test (vs. PSG)	N	Setting	Bland-Altman Metric	Bland-Altman Result, Events/hr	ROC Analysis Threshold, Events/hr Index	ROC Analysis Threshold, Events/hr PSG	Sensitivity, % (95% CI)	Specificity, % (95% CI)	AUC	Quality
Garcia-Diaz, 2007[60] 17356086	Respiratory Polygraph – Apnoescreen II in Lab (Obs A)	62	Sleep lab (& home)	95% LOA	2.8 (-18, 23)	RDI≥10	AHI≥10	94.6 (87.3,100)	96 (88.3,100)	0.977	A
						RDI≥15	AHI≥15	100	96.7 (90.2,100)	0.998	
						RDI≥30	AHI≥30	95.8 (87.8,100)	94.7 (87.6,100)	0.986	
	Respiratory Polygraph – Apnoescreen II in Lab (Obs B)				1.03 (-19, 21)	RDI≥10	AHI≥10	94.6 (87.3,100)	88 (75.2,100)	0.974	
						RDI≥15	AHI≥15	100	96.7 (90.2,100)	0.997	
						RDI≥30	AHI≥30	95.8 (87.8,100)	94.7 (87.6,100)	0.987	
	Respiratory Polygraph – Apnoescreen II at Home (Obs A)				3.1 (-30, 36)	RDI≥10	AHI≥10	86.4 (75.4,97.5)	100	0.969	
						RDI≥15	AHI≥15	87.5 (76,98.9)	96.7 (90.2,100)	0.972	
						RDI≥30	AHI≥30	91.7 (80.6,100)	94.7 (87.6,100)	0.986	
	Respiratory Polygraph – Apnoescreen II at Home (Obs B)				1.6 (-31, 34)	RDI≥10	AHI≥10	83.8 (71.9,95.6)	92 (81.3,100)	0.976	
						RDI≥15	AHI≥15	84.4 (71.8,96.9)	96.7 (90.2,100)	0.977	
						RDI≥30	AHI≥30	95.8 (87.8,100)	94.7 (87.6,100)	0.985	
Santos-Silva, 2009[61] 19480230	STD at-home vs. PSG in-lab	80	Sleep Lab & Home	95% LOA	-0.7 (-24, 22.6)	≥5	≥5	93 (nd)	59 (nd)	0.90	A
						≥15	≥15	85 (nd)	80 (nd)	0.92	
						≥30	≥30	77 (nd)	93 (nd)	0.95	
	STD in-lab (done with PSG) vs. PSG in-lab				-4.0 (-26.6, 18.6)	≥5	≥5	92 (nd)	48 (nd)	0.91	
						≥15	≥15	94 (nd)	71 (nd)	0.93	
						≥30	≥30	86 (nd)	79 (nd)	0.95	
	STD at-home vs. PSG in-lab (done with STD)				1.6 (-22.2, 25.4)	≥5	≥5	95 (nd)	62 (nd)	0.95	
						≥15	≥15	86 (nd)	78 (nd)	0.95	
						≥30	≥30	74 (nd)	96 (nd)	0.96	
	STD in-lab (done with PSG) vs. PSG in-lab (done with STD)				-1.1 (-24.9, 22.8)	≥5	≥5	98 (nd)	62 (nd)	0.97	
						≥15	≥15	97 (nd)	74 (nd)	0.98	
						≥30	≥30	96 (nd)	92 (nd)	0.98	

Author, Year PMID	Index Test (vs. PSG)	N	Setting	Bland-Altman		ROC Analysis					Quality
				Metric	Result, Events/hr	Threshold, Events/hr Index	PSG	Sensitivity, % (95% CI)	Specificity, % (95% CI)	AUC	
To, 2009[62] 19210658	ARES Unicorder vs. PSG	141	Hospital	nd	Data not interpretable from figure	≥5 at 4% O_2 desat	≥ 5	84 (77,90)	100	0.96	B
						≥5 at 3% O_2 desat	≥5	89 (84,94)	100	0.97	
						≥5 at 1% O_2 desat	≥5	97 (94,99)	63 (55,71)	0.98	
Tonelli de Oliveira, 2009[63] 19201709	Somnocheck-lab vs. PSG	149	Sleep lab & Home	95% LOA	2.6 (-17.7, 22.8)						B
	Somnocheck-Home vs. PSG				3.2 (-28, 34.3)	≥7	AHI≥5	96.15 (92.5,99.8)	64.7 (42.0,87.4)	0.96	
						≥9	AHI≥10	90.7 (82.7,95.2)	82.9 (67.3,91.9)	0.92	
						≥9	AHI≥15	81.3 (71.1,88.5)	88.4 (78.8,94.0)	0.91	
						≥33	AHI≥30	80 (68.3,91.7)	92.1 (86,98.2)	0.92	

Table 1.2.1. Type IV Monitors (≥3 channels) vs. PSG: Study characteristics

Study PMID	Participants	Country (Enrollment Years)	N	Baseline AHI (SD) [Range]	Baseline ESS (SD)	Mean Age, y	Male, %	Mean BMI, kg/m^2	Setting	Sleep Apnea Definition	Denominator	Quality Issues
Ayappa, 2008[64] 18350959	Referred to specialized center	US (2005-2006)	80	nd	8.8 (nd)	46	78%	30	Sleep lab & Home	nd	Total sleep time as well as total recording time	Baseline AHI not reported
Goodrich, 2009[70] 18083629	Symptoms suggestive of OSA & GERD	US (nd)	50	[5–105]	nd	44	73%	nd	Sleep lab	nd	Total recording time (RDI)	No data on test reader blinding
Pang, 2007[75] 17903588	Referred to sleep center	US (nd)	37	35 (20) [nd]	13.9	50	32%	34.6	Sleep lab	nd	Total sleep time*	Unclear results reporting; Unclear population description
Schafer, 1997[78] 9154670	Suspected sleep-related breathing disorders	Germany (nd)	114	29 (24) [nd]	nd	56	88%	30.8	Sleep lab & Home	RDI ≥10	Total recording time	Nonconsecutive subjects
Smith, 2007[79] 18036089	Chronic heart failure	UK (nd)	20	26 (22) [nd]	8 (4.0)	61	70%	29	Sleep lab & Home	AHI >20	Total recording time	OSA cut-off different for PSG device
Yagi, 2009[84] 18635324	Suspected sleep apnea syndrome	Japan (2005-2006)	22	44 (21) [nd]	nd	53	77%	25.7	Sleep lab	AHI ≥15	Total recording time	Incomplete reporting of population, OSA severity, methods, or analyses

* As described, the device should only be capable of using the total recording time

Table 1.2.2. Type IV Monitors (2 channels) vs. PSG: Study characteristics

Study PMID	Participants	Country (Enrollment Years)	N	Baseline AHI (SD) [Range]	Baseline ESS (SD)	Mean Age, y	Male, %	Mean BMI, kg/m^2	Setting	Sleep Apnea Definition	Denominator	Quality Issues
Abraham, 2006[65] 17033271	Heart failure	US & UK (nd)	50	[0-92]	10.6 (4.4)	56	68%	32.6	Sleep lab & Home	RDI ≥5	Total sleep time	Significant difference among sites; Home test data not presented; Unclear criteria for tests
Chen, 2009[66] 19052790	Suspected sleep disordered breathing patients	Canada (nd)	54	30 (26) [1–86]	nd	49	64%	32.2	Sleep lab	OSA: AHI≥ 5	Total sleep time	
Clark, 2009[67] 19222876	Suspected sleep disordered breathing patients	UK (nd)	67	22 (23) [0–87]	13.3 (5.2)	51	76%	35.0	Home	CPAP Tx needed: AHI ≥ 15	Total recording time (RDI)	B-A plots are not interpretable; no clear population description
Heneghan, 2008[72] 18853941	Suspected OSA	Ireland (nd)	63	nd	11.3	51	88%	30.9	Sleep lab	AHI≥15	Total recording time	
Pepin, 2009[76] 19028140	Referred for sleep center	France (nd)	34	20 (19) [nd]	10 (6.0)	47	63%	25.4	Sleep lab	AHI >20	Total recording time	Unclear population description
Szyszko, 2009[80] 18971289	Suspected OSA	Argentina (nd)	20	24 (26) [5–119]	10.9 (5.2)	49	50%	41.3	Sleep lab	AHI ≥10	Total recording time	
White, 1994[82] 7923843	Referred for UPPP	UK (nd)	37	nd	nd	37	68%	nd	Sleep lab	AHI ≥10	Total sleep time	Unclear description of population and tests; Discrepancy in results reporting

Table 1.2.3. Type IV Monitors (1 channel) vs. PSG: Study characteristics

Study PMID	Participants	Country (Enrollment Years)	N	Baseline AHI (SD) [Range]	Baseline ESS (SD)	Mean Age, y	Male, %	Mean BMI, kg/m^2	Setting	Sleep Apnea Definition	Denominator	Quality Issues
de Almeida, 2006[68] 16502297	Patients referred to sleep center for suspected sleep-related breathing disorders	Canada (nd)	35	19 (22) [nd]	nd	44	77%	31.1	Sleep lab	AHI >5	Total recording time (RDI)	16% of sample was excluded without reason
Erman, 2007[69] 17694728	Patients with type 2 diabetes mellitus	USA (nd)	68	nd	nd	57	49%	32.6	Sleep lab & Home	nd	Total recording time (RDI)	
Heneghan, 2008[71] 18595434	Suspected OSA and healthy male subjects	Ireland (nd)	98	33 (nd) [nd]	11.9 (nd)	42	100%	33.9	Sleep lab	AHI≥15	Total recording time	Results not interpretable
Nakano, 2008[73] 18480104	Patients referred for sleep disorders	Japan (nd)	100	30 [10-65]	nd	45.3*	80%	26.9*	Sleep lab & Home	nd	Total recording time	
Nigro, 2009[74] 18830731	Suspected OSA	Argentina (nd)	166	14 [4-29]†	nd	51	77%	28.3	Sleep lab	AHI ≥5	Total recording time	Unclear description of population
Watkins, 2009[81] 19786903	Commercial motor drivers at high risk for OSA	USA (Sept 2007 – Oct 2008)	159	19 (nd) [1–117]	nd	nd	nd	nd	Sleep lab & Community	AHI ≥ 5	Total recording time	No clear population description; 78% drop outs; no clear description of PSG
Reda, 2001[77] 11593166	Sleep-related breathing disorders	UK (nd)	59	nd	nd	Range: 20-70	nd	nd	Sleep lab	AHI ≥15	Total recording time	Unclear population description; Test readers not blinded

Study PMID	Participants	Country (Enrollment Years)	N	Baseline AHI (SD) [Range]	Baseline ESS (SD)	Mean Age, y	Male, %	Mean BMI, kg/m^2	Setting	Sleep Apnea Definition	Denominator	Quality Issues
White, 1994[82] 7923843	Referred for UPPP	UK (nd)	37	nd	nd	37	68%	nd	Sleep lab	AHI ≥10	Total sleep time	Unclear description of population and tests; Discrepancy in results reporting
Wong, 2008[83] 18411561	Referred for sleep center	Australia (nd)	34	32 (27) [0-100]	11.9 (4.7)	42	97%	30.2	Sleep lab & Home	AHI ≥10	Total recording time	Unclear description of population

* Average of the mean values of the two centers of the study
† Median and interquartile range

Table1.3.1. Type IV Monitors (≥3 channels) vs. PSG: Study results

Author Year PMID	Index Test (vs PSG)	N	Setting	Bland-Altman Metric	Bland-Altman Result, Events/hr	ROC Analysis Threshold, Events/hr Index	ROC Analysis Threshold, Events/hr PSG	Sensitivity, % (95% CI)	Specificity, % (95% CI)	AUC	Quality
Ayappa 2008[64] 18350959	ARES* in-Lab vs PSG	73	Sleep lab (& home)	95% LOA	0.7 (-1.2, 2.6)	AHI >5 4% O_2 des	AHI >5 4% O_2 des	0.98 (0.88, 1)	0.76 (0.52, 0.91)		A
						AHI >5 4% O_2 des	AHI >10 4% O_2 des	0.97 (0.84, 1)	0.78 (0.6, 0.89)		
						AHI >5 4% O_2 des	AHI >15 4% O_2 des	0.91 (0.75, 0.98)	0.92 (0.78, 0.98)		
	ARES in-Lab vs PSG (RDI)	73			3.3 (0.8, 5.9)	AHI >10 1% O_2 des	RDI >10	0.95 (0.86, 0.99)	0.73 (0.39, 0.93)		
						AHI ≥15 1% O_2 des	RDI≥15	0.94 (0.84, 0.99)	0.89 (0.65, 0.98)		
	ARES at-home vs PSG	67			5.2 (1.0, 9.4)	AHI >5 4% O_2 des	AHI >5 4% O_2 des	0.92 (0.8, 0.97)	0.67 (0.41, 0.86)		
						AHI >5 4% O_2 des	AHI >10 4% O_2 des	0.89 (0.72, 0.96)	0.72 (0.53, 0.86)		
						AHI >5 4% O_2 des	AHI >15 4% O_2 des	0.76 (0.57, 0.88)	0.82 (0.65, 0.93)		
	ARES at-home vs PSG (RDI)	67			10.3 (5.9, 14.6)	AHI >10 1% O_2 des	RDI >10	0.9 (0.78, 0.96)	0.78 (0.4, 0.96)		
						AHI ≥15 1% O_2 des	RDI≥15	0.84 (0.71, 0.93)	0.81 (0.54, 0.95)		
Goodrich 2009[70] 18083629	Lifeshirt	48	Lab	95% LOA	1.02 (-16.4, 16.4)	≥5	≥5	85 (nd)	67 (nd)	0.76	B
						≥10	≥10	92 (nd)	88 (nd)	0.90	
						≥15	≥15	87 (nd)	82 (nd)	0.84	
						≥20	≥20	85 (nd)	94 (nd)	0.90	
						≥25	≥25	100 (nd)	97 (nd)	0.99	
						≥30	≥30	88 (nd)	100 (nd)	0.94	
Yagi 2009[84] 18635324	Apnomonitor vs PSG	22	Sleep lab			≥15	≥15	95			C
Pang 2007[75] 17903588	WatchPAT	32	Sleep Lab			>5	>5	94 (nd)	80 (nd)		C
						>15	>15	96 (nd)	79 (nd)		
						>35	>35	83 (nd)	72 (nd)		
Smith 2007[79] 18036089	Embletta in-Lab	20	Sleep lab & Home	95% LOA	6 (-11,24)						B
	Embletta at-home	20	Sleep lab & Home		12 (-25,49)	AHI≥10	AHI ≥15	87.5 (nd)	58.3		
						AHI≥20	AHI ≥15	75 (nd)	50		

Author Year PMID	Index Test (vs PSG)	N	Setting	Bland-Altman		ROC Analysis				AUC	Quality
				Metric	Result, Events/hr	Threshold, Events/hr Index	PSG	Sensitivity, % (95% CI)	Specificity, % (95% CI)		
Schafer 1997[78] 9154670	MESAM 4	114	Sleep lab & Home	nd	Data not interpretable from figure	≥5	≥5	96 (nd)	15 (nd)		B
						≥10	≥10	95 (nd)	41 (nd)		
						≥15	≥15	83 (nd)	62 (nd)		
						≥20	≥20	68 (nd)	74 (nd)		
						≥25	≥25	60 (nd)	85 (nd)		

* ARES: Apnea Risk Evaluation System Unicorder

Table 1.3.2. Type IV Monitors (2 channels) vs. PSG: Study results

Author Year PMID	Index Test (vs PSG)	N	Setting	Bland-Altman Metric	Bland-Altman Result, Events/hr	ROC Analysis Threshold, Events/hr		Sensitivity, % (95% CI)	Specificity, % (95% CI)	AUC	Quality
Pepin 2009[76] 19028140	ECG/nasal pressure holter monitoring visual	19	Sleep lab	95% CI	5.8 (-3.9, 15.5)	>35	>20	57 (nd)	100 (nd)	0.97	B
	ECG/nasal pressure holter monitoring automated	19	Sleep lab		2.3 (-18.9, 23.4)	>35	>20	71 (nd)	100 (nd)	0.85	
Chen 2009[66] 19052790	ApneaLink (AASM criteria*)	50	Sleep lab	95% LOA	-6.3 (-25.5, 12.9)	AHI≥5	AHI≥5	97.7 (nd)	66.7 (nd)	0.964	A
						AHI≥10	AHI≥10	95.0 (nd)	90.0 (nd)	0.978	
						AHI≥15	AHI≥15	87.5 (nd)	88.9 (nd)	0.944	
						AHI≥20	AHI≥20	88.0 (nd)	88.0 (nd)	0.944	
						AHI≥30	AHI≥30	88.2 (nd)	93.9 (nd)	0.954	
	ApneaLink (Sandman setting†)				-0.5 (-17.9, 16.9)	AHI≥5	AHI≥5	93.2 (nd)	83.3 (nd)	0.951	
						AHI≥10	AHI≥10	97.5 (nd)	90.0 (nd)	0.983	
						AHI≥15	AHI≥15	90.6 (nd)	77.8 (nd)	0.944	
						AHI≥20	AHI≥20	92.0 (nd)	84.0 (nd)	0.934	
						AHI≥30	AHI≥30	94.1 (nd)	81.8 (nd)	0.955	
Clark 2009[67] 19222876	ApneaLink‡	50	Home	nd	Data not interpretable from figure	AHI≥15	AHI≥15	92 (nd)	96.7 (nd)		B
Abraham 2006[65] 17033271	Home Cardiorespiratory system (ClearPath System Nx-301)	50	Sleep lab			RDI≥5	RDI≥5	92 (nd)	52 (nd)		B
						RDI≥10	RDI≥10	88 (nd)	63 (nd)		
						RDI≥15	RDI≥15	67 (nd)	78 (nd)		
Heneghan 2008[72] 18853941	ECG-Oximetry analysis	59	Sleep lab	95% LOA	-0.9 /hr (-18, 16.2)	≥5	≥5	93.8 (86.9,100)	100		A
						≥10	≥10	81.6 (69.3,93.9)	90.5 (77.9,100)		
						≥15	≥15	74.2 (58.8,89.6)	96.4 (89.6,100)		
	Oximetry	59	Sleep lab		1.1 /hr (-16.5, 18.4)						
Heneghan 2008[71] 18595434	Holter ECG analysis algorithm	92	Sleep lab	nd	Data not interpretable from figure	≥15	≥15	92 (nd)	69 (nd)		B
						≥5 - <15	≥5 - <15	60§ (nd)	86 (nd)		
						< 5	< 5	37 (nd)	95 (nd)		
Szyszko 2009[80] 18971289	Holter Monitor	20	Sleep lab	95% LOA	4.7 (-30.1, 39.4)	RDI ≥10	AHI ≥10	78.5 (48.2,94.2)	83.3 (25.8,89.7)	0.81	A
White 1994[82] 7923843	O_2 saturation & snoring sound vs PSG	37	Sleep lab			nd	AHI≥10	62	100		C
						nd	AHI≥15	86	78		
						nd	AHI≥20	100	76		

* Apnea: Reduction of inspiratory airflow by 80% to 100% over 10 secs (max 80 ss); Hypopnea: Reduction of tidal breathing of 50% from baseline tidal breathing lasting (Max100 secs)
† Sandman Sleep Diagnostic System setting - Apnea: 85% or more reduction of normal flow that lasts (max 100 s); Hypopnea: 40% reduction of normal flow lasting 10 s (max 120 s)
‡ Using home-based PSG (Embletta)
§ Calculated from data provided

Table 1.3.3. Type IV Monitors (1 channel) vs. PSG: Study results

Author Year PMID	Index Test (vs PSG)	N	Setting	Bland-Altman		ROC Analysis					Quality
				Metric	Result, Events/hr	Threshold, Events/hr		Sensitivity, % (95% CI)	Specificity, % (95% CI)	AUC	
Erman 2007[69] 17694728	ApneaLink	58	Lab	95% LOA	~ -2 (-22, 18)*	AHI >5	AHI >5	85.4 (nd)	50.0 (nd)	0.863	A
						AHI >10	AHI >10	82.1 (nd)	83.9 (nd)	0.862	
						AHI >15	AHI >15	90.9 (nd)	94.6 (nd)	0.977	
						AHI >20	AHI >20	83.3 (nd)	92.7 (nd)	0.967	
de Almeida 2006[68] 16502297	Sleep Check	30	Sleep lab	95% LOA	0 (-26.6, 26.6)	>5	>5	86.4	75	0.886	B
						>10	>10	85.7	87.5	0.915	
						>15	>15	83.5	83.5	0.898	
						>20	>20	88.9	81	0.910	
Nakano 2008[73] 18480104	SOMNIE single-channel airflow monitor	100	Home	95% LOA	-9.5 (-30.4,11.4)	>5.3	>5	96 (91,100)	82 (59,100)	0.95	A
						>11.4	>15	91 (84,98)	82 (70,95)	0.96	
						>19.6	>30	89 (80,97)	96 (90,100)	0.98	
			Female			>5.3	>5	88 (nd)	67 (nd)	0.88	
						>11.4	>15	75 (nd)	83 (nd)	0.89	
						>19.6	>30	100	94 (nd)	1.0	
			BMI <25 kg/m^2			>5.3	>5	97 (nd)	71 (nd)	0.94	
						>11.4	>15	78 (nd)	89 (nd)	0.92	
						>19.6	>30	91 (nd)	92 (nd)	0.97	
			AHI < 15			>5.3	>5	83 (nd)	82 (nd)	0.81	
Watkins 2009[81] 19786903	RUSleeping RTS vs PSG	34	Sleep lab & Community			>5	>15	100	42		C
						>10	>15	100	71		
						>15	>15	70	83		
						>20	>15	70	83		
						>30	>15	43	96		

Author Year PMID	Index Test (vs PSG)	N	Setting	Bland-Altman Metric	Bland-Altman Result, Events/hr	ROC Analysis Threshold, Events/hr		Sensitivity, % (95% CI)	Specificity, % (95% CI)	AUC	Quality
Wong 2008[83] 18411561	FlowWizard in lab vs PSG	31	Sleep lab	95% LOA	1.8 (-32.4, 36.0)	AHI>18	AHI≥10	96	71	0.95	A
	FlowWizard at home (3 night average) vs PSG	31	Sleep lab & Home		7.1(-14.8, 29.0)	AHI>8	AHI≥10	100	43	0.96	
						AHI>12		96	71		
						AHI>18		92	86		
						AHI>21		88	100		
						AHI>21	AHI≥30	100	50	0.85	
						AHI>28		91	75		
						AHI>45		36	90		
						AHI>59		18	100		
						AHI from first night on FlowWizard	AHI≥30			0.89	
	FlowWizard at home (1 night) vs PSG	31	Sleep lab & Home			AHI from first night on FlowWizard	AHI≥10			0.92	
	MAPI v PSG	31	Sleep lab & Home				AHI≥10			0.68	
	Combined FlowWizard (home, 3 night) & MAPI v PSG	31	Sleep lab & Home				AHI≥10			0.96	
Nigro 2009[74] 18830731	O_2 saturation (WristOx 3100)	154	Sleep lab			ADI2† >12.2	AHI ≥5	100 (96.4,100)	57.69 (43.2,71.3)	0.959	B
						ADI2 >19.3	AHI ≥5	89.22 (81.5,94.5)	94.23 (84.0,98.7)		
						ADI5 >4.3	AHI ≥5	92.75 (52.6,72.1)	100 (93.1,100)	0.907	
						ADI2 >12.2	AHI ≥10	100 (95.8,100)	44.12 (32.1,56.7)	0.957	
						ADI3 >10.5	AHI ≥10	88.37 (79.6,94.3)	94.12 (85.6,98.3)	0.965	
						ADI5 >4.3	AHI ≥10	74.42 (63.9,83.2)	100 (94.7,100)	0.930	
						ADI3 >4.4	AHI ≥15	100 (95.0,100)	49.38 (38.1,60.7)	0.945	
						ADI3 >13.4	AHI ≥15	87.67 (77.9,94.2)	90.12 (81.5,95.6)		
						ADI3 >32	AHI ≥15	42.47 (31.0,54.6)	100 (95.5,100)		

Author Year PMID	Index Test (vs PSG)	N	Setting	Bland-Altman		ROC Analysis				AUC	Quality
				Metric	Result, Events/hr	Threshold, Events/hr		Sensitivity, % (95% CI)	Specificity, % (95% CI)		
White 1994[82] 7923843	O_2 saturation vs PSG	37	Sleep lab			nd	AHI≥10	30	100		C
						nd	AHI≥15	71	94		
						nd	AHI≥20	100	94		
Reda 2001[77] 11593166	Pharyngoesophageal monitoring	59	Sleep lab	95% LOA	0.22 (-8.68, 9.02)	<15	<15	100 (nd)	100 (nd)		C
						15-20	15-20	80 (nd)	96 (nd)		
				95% CI	(-0.93, 1.38)	20-40	20-40	90 (nd)	97 (nd)		
						>40	>40	100 (nd)	100 (nd)		

* Estimated from Figure of plot in the publication, using the Engauge Digitizer software program
† ADI - Adjusted O_2 desaturation index (ADI): mean number of O_2 desaturations per hour of analyzed recording ≥2%, 3%, 5% (ADI2, ADI3, ADI5)

Table 1.4.1. Questionnaires vs. PSG: Study characteristics

Study PMID	Participants	Country (Years)	N	Baseline AHI (SD) [Range]	Baseline ESS (SD)	Mean Age, y	Male, %	Mean BMI, kg/m^2	Setting	Sleep Apnea Definition	Quality Issues
Chung, 2008[85] 18431116	**Preoperative**	Canada (nd)	2127	20 (6) [nd]	nd	55	50	30	Hospital	AHI>5	Selection bias
Chung, 2008[86] 18431117	Preoperative	Canada (nd)	2127	20 (6) [nd]	nd	55	50	30	Hospital	AHI>5	Selection bias
Kapuniai, 1988[87] 3227223	Sleep disorder center	US (nd)	53	nd	nd	46	79	nd	Sleep lab	AI / AHI >5	PSG results not reported
Netzer, 1999[88] 10507956	General population visiting primary care physician	US (nd)	1008	High-risk group: 21 (18) [0, 101] Low-risk group: 5 (7) [0, 37]	nd	49	42	29	Home	RDI ≥5	Probable selection bias
Sharma, 2006[89] 17085831	Attending the medical outpatient department	India (2000-02)	180	nd	nd	40	80	28.2	Sleep lab and hospital	AHI >5	Modified questionnaire not validated, 42% dropout rate

Table 1.4.2. Questionnaires vs. PSG: Study results

Study PMID	Index test	Reference test	N	Setting	Bland-Altman		ROC Analysis					Quality
					Metric[A]	Result	Threshold, Events/hr		Sensitivity (95% CI)	Specificity (95% CI)	AUC	
							Index	PSG				
Chung, 2008[85] 18431116	STOP	PSG	177	Sleep lab			High vs. low	>5	65.6 (56.4, 73.9)	60 (45.9, 73.0)	0.703	C
								>15	74.3 (62.4, 84.0)	53.3 (43.4, 63.0)	0.722	
								>30	79.5 (63.5, 90.7)	48.6 (40.0, 63.0)	0.769	
	STOP-Bang						High vs. low	>5	83.6 (75.8, 89.7)	56.4 (42.3, 69.7)	0.806	
								>15	92.9 (84.1, 97.6)	43 (33.5, 52.9)	0.782	
								>30	100 (91.0, 100.0)	37 (28.9, 45.6)	0.822	
Chung, 2008[86] 18431117	Berlin	PSG	211	Sleep lab			High vs. low	>5	68.9 (59.8, 76.9)	56.4 (42.3, 69.7)	0.69	C
								>15	78.6 (67.1, 87.5)	50.5 (40.6, 62.3)	0.672	
								>30	87.2 (72.6, 95.7)	46.4 (37.9, 55.1)	0.668	
	ASA checklist						High vs. low	>5	72.1 (63.3, 79.9)	38.2 (25.4, 52.3)	0.783	
								>15	78.6 (67.1, 87.5)	37.4 (28.2, 47.3)	0.73	
								>30	87.2 (72.6, 95.7)	36.2 (28.2, 44.8)	0.617	
Kapuniai, 1988[87] 3227223	Apnea score derived from the Hawaii Sleep Questionnaire*	PSG	53	Sleep lab			≥3	>5	59 (nd)	69 (nd)		B
							≥2 (no adenoidectomy score)	>5	70 (nd)	65 (nd)		
							≥2 (no adenoidectomy score)	>10	78 (nd)	67 (nd)		
Netzer, 1999[88] 10507956	Berlin	PSG	100	Home			High-risk (high risk in 2/3 categories) vs. low-risk †	≤ 5	77 (nd)	89 (nd)		C
								>5	86 (nd)	77 (nd)		
								>15	54 (nd)	97 (nd)		
								>30	17 (nd)	97 (nd)		
Sharma, 2006[89] 17085831	Berlin Questionnaire,‡ modified	PSG	104	Sleep lab & Hospital			High risk vs. low risk	>5	86 (nd)	95 (nd)		C

* The HSQ includes questions on characteristics in sleep apnea patients: (a) stopping breathing during sleep, (b) loud snoring, and (c) waking from sleep gasping or short of breath. Additional questions on sex, age, height, weight, sleep history and history of tonsillectomy or adenoidectomy. The final model included self-reports of loud snoring, breathing cessation during sleep and adenoidectomy.

† High Risk: classified as “high risk” in 2 of 3 symptom categories - (a) snoring (b) wake time sleepiness and drowsy driving (c) hr/o high blood pressure or BMI >30 kg/m^2; Low Risk: all others.

‡ The Berlin Questionnaire was customized to the Indian setting (re: questions on driving) but the scoring remained the same. The screening questionnaire used was not a validated one.

Table 1.5.1. Clinical Prediction Rules vs. PSG: Study characteristics

Study PMID	Participants	Country (Years)	N	Baseline AHI (SD) [Range]	Baseline ESS (SD)	Mean Age, y	Male, %	Mean BMI, kg/m^2	Setting	Sleep Apnea Definition	Quality Issues
Crocker, 1990[90] 2368960	Referred for suspected abnormal breathing	Australia (1987-88)	114	nd	nd	51	82	30.4	Sleep lab	AHI >15	Baseline AHI severity not reported
Gurubhagavatula, 2001[91] 11734444	Referred for suspected OSA	US (nd)	421	26 (30) [nd]	nd	47	68	32.4	Sleep lab	RDI ≥5	
Kushida, 1997[92] 9341055	Referred for sleep disorders	US (nd)	423	35 [nd]	10.9	47	75	32	Sleep lab	RDI ≥5	Selection bias; 29% dropout rate
Onen, 2008[93] 18775037	Elderly (≥70 y) referred to a sleep center	France (2005-06)	121	nd	nd	79	50	29.4	Sleep lab & Hospital	AHI ≥15	Incomplete ROC data; other thresholds not reported
Rodsutti, 2004[94] 15283004	Referred for suspected sleep-disordered breathing	Australia (2003)	243	nd	nd	51	63	32.8	Sleep lab	AHI ≥5	
Rowley, 2000[95] 11083602	Referred for sleep-disordered breathing	US (1996-97)	425	19 (7-52) *	nd	Median 47	52	37.1	Sleep lab	AHI ≥10	
Zerah-Lancner, 2000[96] 11112139	Referred for snoring and suspected sleep apnea	France (nd)	101	Group with AHI <15: 6 (4) Group with AHI≥15: 42 (24)	nd	nd	nd	28.8	Sleep lab	AHI ≥15	Unclear description of population

* Median and inter-quartile range

Table 1.5.2. Clinical Prediction Rules vs. PSG: Study results

Study PMID	Index test	Reference test	N	Setting	Subgroup	ROC Analysis Threshold, Events/hr Index	PSG	Sensitivity, % (95% CI)	Specificity, % (95% CI)	AUC	Quality
Crocker, 1990[90] 2368960	Statistical model *	PSG	105	Sleep lab		Probability of OSA >0.15	>15	92 (nd)	51 (nd)		B
Gurubhagavatula, 2001[91] 11734444	Clinical prediction rule,† derived	PSG	359	Sleep lab		Upper bound= 0.58 Lower bound= 0.14 ODI threshold= 5.02	≥5	94.1 (nd)	66.7 (nd)		A
						Upper bound = 0.9 Lower bound = 0.38 ODI threshold = 21	≥30	83.3 (nd)	94.7 (nd)		
Kushida, 1997[92] 9341055	Morphometric model‡	PSG	300	Sleep lab		≥70	≥5	97.6 (95, 98.9)	100 (92,100)	0.996	C
Onen, 2008[93] 18775037	Observation-based Nocturnal Sleep Inventory (ONSI)§	PSG	115	Hospital		≥2 snoring episodes or ≥1 apnea episode	AHI≥15	89.7 (82, 97)	81.4 (70,93)		B
						≥5 snoring or ≥1 apnea	AHI≥15	56 (44, 68)	100		
						≥3 snoring or ≥1 apnea	AHI≥15	74 (63, 84)	93 (85,100)		
Rodsutti, 2004[94] 15283004	Clinical prediction rule,** derived	PSG	243	Sleep lab		< 2.5	≥5	0 (nd)	89 (nd)	0.789	A
						2.5 - < 4.2	≥5	44 (nd)	85 (nd)		
						≥4.2	≥5	76 (nd)	60 (nd)		
Rowley, 2000[95] 11083602	Model #1 ††	PSG	370	Sleep lab	All	0.15	≥10	84 (nd)	39 (nd)	0.669	A
						0.95	≥20	33 (nd)	90 (nd)	0.7	
					Men	0.15	≥10			0.761	
					Women	0.15	≥10			0.633	
	Model #2 ‡‡				All	0.20	≥10	96 (nd)	13 (nd)	0.695	
						0.95	≥20	34 (nd)	87 (nd)	0.722	
					Men	0.2	≥10			0.801	
					Women	0.2	≥10			0.626	
	Model #3 §§				All	10	≥10	76 (nd)	54 (nd)	0.696	
						35	≥20	34 (nd)	89 (nd)	0.733	
					Men	10	≥10			0.707	
					Women	10	≥10			0.648	
	Model #4 ***				All	0.5	≥10	87 (nd)	35 (nd)	0.736	
						0.85	≥20	39 (nd)	93 (nd)	0.757	
					Men	0.5	≥10			0.801	
					Women	0.5	≥10			0.611	

Study PMID	Index test	Reference test	N	Setting	Subgroup	ROC Analysis Threshold, Events/hr Index	PSG	Sensitivity, % (95% CI)	Specificity, % (95% CI)	AUC	Quality
Zerah-Lancner, 2000[96] 11112139	Based on Pulmonary function data†††	PSG	101	Sleep Lab		0.5	≥15	100 (nd)	84 (nd)		B

Bland-Altman column omitted. No study reported Bland-Altman data.

* Derived by logistic regression on data from a 24-item questionnaire and clinical features.

† Combination of Multivariable Apnea Prediction (MAP) questionnaire score and oximetry results. MAP score predicts apnea risk using a score between 0 and 1, with 0 representing low risk and 1 representing high risk. Oximetry desaturation index (ODI) using a 3% drop (ODI3) as well as a 4% drop (ODI4) in oxygen saturation. Optimal model parameters obtained by the bootstrapping technique.

‡ Model: P + (Mx - Mn) + 3 X OJ + 3 X [Max (BMI -25, 0)] X (NC / BMI)

P = palatal height (in millimeters); Mx is the maxillary intermolar distance (in millimeters) between the mesial surfaces of the crowns of the maxillary second molars; Mn is the mandibular intermolar distance (in millimeters) between the mesial surfaces of the crowns of the mandibular second molars; OJ is the overjet (in millimeters) or the horizontal overlap of the crowns of the maxillary and mandibular right central incisors; BMI is the body mass index (kg/m2; ideal BMI < 25); Max (BMI -25, 0) refers to the larger of the two quantities: BMI - 25, or zero. If BMI is <= 25, then [Max (BMI - 25, 0)] is zero; if BMI >25, then BMI - 25 is inserted into the formula; NC is neck circumference (in centimeters) measured at the level of the cricothyroid membrane.

§ Nurse observations made in five standardized hourly bedside visits over the course of one night.

** Sum of the individual scores for age, sex, snoring, stops breathing, and BMI; range = 0 -7.3.

†† Clinical prediction model #1: Probability of predicting AHI ≥10 = $1/ (1 + e^{-(-13.9+0.06a+2.98b+0.23c+1.35d)})$ where a = age; b= I if witnessed apneas present, 0 if witnessed apneas absent; c = BMI; d = 1 if patient has hypertension, 0 if hypertension absent.

‡‡ Clinical prediction model #2: Probability of predicting AHI ≥10 = $e^x/ (1+e^x)$ where, x = -10.5132 + 0.9164*sex + 0.0470*age + 0.1869*BMI+1.932*snoring; where sex = 1 for male, 0 for female, snoring = 1 for present, 0 for absent.

§§ Clinical prediction model #3: Probability of predicting AHI ≥10 = $(10^{(-2.132 + 0.069*NC + 0.31*H+ 0.206'*HS+0.224*PR)} + 1)$ where NC=neck circumference; H=1 if hypertension, 0 if hypertension absent, HS=1 if habitual snorer, 0 if not, PR = 1 if reports nocturnal choking/gasping, 0 if no nocturnal choking/gasping.

*** Clinical prediction model #4: Probability of predicting AHI ≥10 = $e^x/ (1+e^x)$ where, x = -8.160+1.299*Index1+O.163*BMI-0.025*BMI*Index1+0.032*age +1.278*sex where, sex=1 if male, 0 if female, index1 = the mean of non-missing values for frequency of snorting/gasping; loud snoring; breathing stops/chokes.

††† Probability (p) of having a polysomnography positive for SAS: logit (p)= -136 sGrs + 2.5 (100 - SaO_2) + 4.2 where specific respiratory conductance (sGrs) (in $cmH_20^{-1} * s^{-1}$) = respiratory conductance (Grs) / functional reserve capacity (FRC) SaO_2 = daytime arterial oxygen saturation in %. The estimated value of p was derived from logit (p)= $log_e(p/1-p)$, from 0 to 1 range.

Table 3.1 Comparative studies of preoperative sleep apnea screening prior to surgical intervention: Study characteristics

Study PMID	Interventions	Mean age, yr	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Other quality issues
Hallowell, 2007[98] 17950355	Mandatory PSG	43	13	51	Patients who have undergone bariatric surgery	US (1998-2005)	Selection bias; discrepancy in reporting of results
	PSG based on ESS or clinical suspicion						
Chung, 2008[86] 18431117	PSG	55	51	30.1	All pre-op patients in general surgery, gynecology, orthopedics, urology, plastic surgery, ophthalmology, or neurosurgery	Canada (nd)	Selection bias in participants who underwent PSG
	No PSG						

Table 3.2 Duration of hospital stay (hr) in comparative studies of preoperative PSG testing

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Diff	95% CI	P Btw	Dropout, %	Study quality
Hallowell, 2007[98] 17950355	nd	nd	Immediate postoperative (retrospective chart review)	Mandatory PSG	318	nd	74.4 (2.4)	-9.6	nd	nd	0	C
				PSG only after clinical indications	576	nd	84.0 (4.8)					
Chung, 2008[86] 18431117	20 (6) [nd]	nd	30 d (prospective case series)	Accepted preoperative PSG	211	nd	Median 44.8 (IQR: 0.2–352.8)	+15.5 (difference of medians)	nd	NS	0	C
				Refused preoperative PSG	205	nd	Median 29.3 (IQR: 0.1–299.8)					

Table 3.3 Postsurgical outcomes in comparative studies of preoperative screening with PSG

Study PMID	Outcome	Baseline AHI (SD) [range]	Baseline ESS (SD)	Duration (design)	Interventions	n Event	N Total	Outcome metric	Result*	95% CI	P Btw	Dropout, %	Study quality
Hallowell, 2007[98] 17950355	ICU admission	nd	nd	Immediate postoperative (retrospective chart review)	Mandatory PSG	11	318	RR	0.62	0.32, 1.22	nd	0	C
					Indicated PSG	32	576						
	Respiratory related ICU admission				Mandatory PSG	1	318	RR	0.16	0.02, 1.27	nd		
					Indicated PSG	11	576						
Chung, 2008[86] 18431117	ICU admission	20 (6) [nd]	nd	30 d (case series)	Preop PSG	13	211	RR	3.16	1.05, 9.52	nd	0	C
					No Preop PSG	4	205						
	Total complications				Preop PSG	48	211	RR	1.55	1.03, 2.35	0.03		
					No Preop PSG	30	205						
	Respiratory complication				Preop PSG	39	211	RR	1.52	0.95, 2.41	0.08		
					No Preop PSG	25	205						
	Cardiac complication				Preop PSG	12	211	RR	1.94	0.74, 5.08	0.11		
					No Preop PSG	6	205						
	Neurologic complication				Preop PSG	2	211	RR	0.65	0.11, 3.84	0.68		
					No Preop PSG	3	205						
	Prolonged O_2 therapy				Preop PSG	24	211	RR	1.46	0.80, 2.66	0.22		
					No Preop PSG	16	205						
	Additional monitoring				Preop PSG	9	211	RR	1.46	0.53, 4.02	0.46		
					No Preop PSG	6	205						
	Readmission within 30 d				Preop PSG	4	211	RR	0.78	0.21, 2.85	0.75		
					No Preop PSG	5	205						
	ED visit within 30 d				Preop PSG	1	211	RR	0.24	0.03, 2.15	0.21		
					No Preop PSG	4	205						

* Top row intervention vs. bottom row intervention. Calculated from reported data.

Table 4.1 Multivariable analyses of AHI as a predictor of all-cause mortality: Study characteristics

Study PMID	Design Country (Study years)	Eligibility	N (followup)	Factor	Value	Quality
Lavie 2005[99] 15738297	Retrospective Israel (1991-2000)	Men, >20 yr, OSA symptoms	13,853 (4.7 yr)	**Male**	100%	A
				Age	48 yr	
				BMI (kg/m^2)	28.8	
Punjabi 2009[100] 19688045	Prospective US (1995-1998)	≥40 yr, no Tx	6441 (8.2 yr)	**Male**	47%	B
				Age	63 yr	
				BMI	28.4	
Young 2008[102] 18714778	Prospective US (1988-nd)	General population	1522 (14 yr)	**Male**	55%	A
				Age	48 yr	
				BMI	28.6	
Lavie 1995[101] 7610310	Retrospective Israel (1976-1988)	Men, apnea index ≥10	1140 (2-14 yr)	**Male**	100%	A
				Age	48 yr	
				BMI	nd	

Table 4.2. Results of multivariable analyses of AHI as a predictor of all-cause mortality

Study PMID	Baseline AHI	n/	N	Adjusted HR	95% CI	P Trend	Other Predictors Significant	P	NS	nd P*	NS Univariable†	Interactions
Lavie 2005[99] 15738297	≤10	34/	3227	Ref		0.0001				Age BMI		nd
	11-20	88/	4154	1.52	NS							
	21-30	65/	2601	1.34	NS							
	31-40	50/	1204	2.13	1.36-3.34							
	>40	126/	2667	2.59	1.73-3.87							
Punjabi 2009[100] SHHS 19688045	**All**						Age	<0.05	Cholesterol	Sex Race BMI Smoking BP HTN Diabetes CVD		No substantive difference with addition of other predictors
	<5	477/	3429	Ref		<0.05‡						
	5-15	320/	1797	0.93	0.80-1.08							
	15-30	165/	727	1.17	0.97-1.42							
	≥30	86/	341	1.46	1.14-1.86							
	Men≤70§											Interaction of Age x AHI significant P<0.005 Interaction of Sex x AHI implied
	<5	91/	985	Ref		<0.05**						
	5-15	82/	694	1.24	0.90-1.71							
	15-30	47/	322	1.45	0.98-2.14							
	≥30	28/	168	2.09	1.31-3.33							
	Men>70											
	<5	125/	277	Ref		NS						
	5-15	111/	282	0.92	0.70-1.20							
	15-30	67/	140	1.23	0.90-1.68							
	≥30	36/	75	1.27	0.86-1.86							
	Women											
	<5	261/	2167	Ref		NS						
	5-15	126/	821	0.83	0.66-1.04							
	15-30	51/	265	1.01	0.73-1.38							
	≥30	22/	99	1.40	0.89-2.22							
Young, 2008[102] WSCS 18714778	<5	46/	1157	Ref		0.008			Age Sex BMI			nd
	5-15	16/	220	1.6	0.9-2.8							
	15-30	6/	82	1.4	0.6-3.3							
	≥30	12/	63	3.0	1.4-6.3							
Lavie 1995[101] 7610310	Per unit††	51/	1140	OR=1.012	1.001 - 1.024	0.04	Older age	0.0001	Diabetes			No substantive difference with addition of comorbidities
							Higher BMI	0.006				
							HTN	0.009				
							CVD	<0.04				
							Lung dz	<0.01				

* Included in multivariable analysis. No data on whether statistically significant independent predictor.
† Not statistically significant in univariable analysis. Not included in multivariable analysis.
‡ Implied

§ Results also reported for all men combined, and women divided above and below age 70 yr.
‡ Implied
†† Analyzed in a multivariable logistic regression with apnea index (continuous) included as a predictor.

Table 4.3 Multivariable analyses of AHI as a predictor of cardiovascular events: Study characteristics

Study PMID	Design Country (Study years)	Eligibility	N (followup)	Factor	Value	Quality
CVD Death						
Marin 2005[4] 15781100	Prospective Spain (1992-1994)	Men, healthy w/ SDB	1651 (10 yr)	**Male**	100%	A
				Age	50 yr	
				BMI (kg/m^2)	28.7	
Young, 2008[102] 18714778	Prospective US (1988-nd)	General population	1522 (14 yr)	**Male**	55%	A
				Age	48 yr	
				BMI	28.6	
Nonfatal CVD						
Marin 2005[4] 15781100	Prospective Spain (1992-1994)	Men, healthy w/ SDB	1651 (10 yr)	**Male**	100%	A
				Age	50 yr	
				BMI	28.7	
Stroke						
Arzt 2005[103] 16141444	Prospective US (≥1988)	30-60 yr, no stroke	1475 (4, 8, 12 yr)	**Male**	55%	B
				Age	47 yr	
				BMI	30	

Table 4.4 Results of multivariable analyses of AHI as a predictor of cardiovascular events

Study PMID	Baseline AHI	n/	N	Adjusted HR	95% CI	P trend	Other Predictors Significant	P	NS	nd P*	NS Univariable†	Interactions
CVD Death												
Marin, 2005[4] 15781100	"Healthy"	12/	264	Ref		nd	Older age	0.001	HTN		BMI (implied)	No substantive difference in AHI with or without CVD and HTN in model
	<5	22/	377	1.03	0.31, 1.84		CVD	0.02	Diabetes			
	5-30	36/	403	1.15	0.34, 2.69		Higher SBP	0.04	Dyslipidemia			
	≥30	50/	235	2.87	1.17, 7.51		Smoker	0.04	Alcohol use			
	CPAP	24/	372	1.05	0.39, 2.21				DBP			
									Glucose			
									TC & Tg			
									Prescriptions‡			
Young, 2008[102] WSCS 18714778	<5	12/	1157	Ref		0.12			Age			nd
	5-15	6/	220	1.8	0.7, 4.9				Sex			
	15-30	2/	82	1.2	0.3, 5.8				BMI			
	≥30	5/	63	2.9	0.8, 10.0							
Nonfatal CVD												
Marin, 2005[4] 15781100	"Healthy"	8/	264	Ref		nd	Older age	0.001	HTN		BMI (implied)	No substantive difference in AHI with or without CVD and HTN in model
	<5	13/	377	1.32	0.64, 3.01		CVD	0.005	Diabetes			
	5-30	22/	403	1.57	0.62, 3.16				Dyslipidemia			
	≥30	25/	235	3.17	1.12, 7.52				Smoking			
	CPAP	13/	372	1.42	0.52, 3.40				Alcohol use			
									BP			
									Glucose			
									TC & Tg			
									Prescriptions§			
Stroke												
Arzt, 2005[103] 16141444	<5	9/	1121	Ref		nd				Age		AHI≥20 significant w/o BMI in model
	5-20	1/	255	0.29	0.04, 2.36					Sex		
	≥20	4/	99	3.08	0.74, 13.0					BMI		

* Included in multivariable analysis. No data on whether statistically significant independent predictor.
† Not statistically significant in univariable analysis. Not included in multivariable analysis.
‡ Antihypertensive, lipid-lowering, and antidiabetic drugs.
§ Antihypertensive, lipid-lowering, and antidiabetic drugs.

Table 4.5 Multivariable analyses of AHI as a predictor of incident HTN: Study characteristics

Study PMID	Design Country (Study years)	Eligibility	N (followup)	Factor	Value	Quality
O'Connor 2009[104] 19264976	Prospective US (1995-1998)	≥40 y	2470 (5 yr)	**Male**	45%	A
				Age	60 yr	
				BMI (kg/m^2)	27.9	
Peppard 2000[9] 10805822	Prospective US (1989-1995)	No CVD	709 (4, 8 yr)	**Male**	46%	B
				Age	47 yr	
				BMI	29	

Table 4.6 Results of multivariable analyses of AHI as a predictor of incident HTN

Study PMID	Baseline AHI	n/	N	Adjusted OR	95% CI	P Trend	Other Predictors Significant	P	NS	nd P*	NS Univariable†	Interactions
O'Connor 2009[104] SHHS 19264976	**All**									Age Sex Race BMI WHR Neck girth		AHI significant without BMI in model. No substantive change with WHR or girth
	<5	**296/**	**1510**	**Ref**		NS						
	5-15	156/	629	0.94	0.73-1.22							
	15-30	77/	234	1.09	0.77-1.54							
	≥30	33/	97	1.50	0.91-2.46							
	Men									Age Race BMI		AHI x sex interaction term NS P=0.09
	<5	nd	**505**	**Ref**		nd						
	5-15	nd	341	0.96	0.68-1.36							
	15-30	nd	155	0.89	0.57-1.39							
	≥30	nd	56	1.10	0.57-2.10							
	Women											
	<5	nd	**950**	**Ref**		nd						
	5-15	nd	261	0.83	0.59-1.18							
	15-30	nd	72	1.59	0.95-2.64							
	≥30	nd	31	2.27	1.07-4.80							
	BMI≤27.3									Age Sex Race BMI		AHI x BMI interaction term NS P=0.36
	<5	nd	**887**	**Ref**		nd						
	5-15	nd	213	0.89	0.59-1.34							
	15-30	nd	58	0.93	0.46-1.90							
	≥30	nd	21	2.71	1.24-5.93							
	BMI>27.3											
	<5	nd	541	Ref		nd						
	5-15	nd	378	0.92	0.67-1.27							
	15-30	nd	164	1.13	0.76-1.68							
	≥30	nd	65	1.18	0.64-2.19							
	Age≤59 y									Sex Race BMI		No difference in association stratified by age
	<5	nd	**879**	**Ref**		nd						
	5-15	nd	262	1.02	0.70-1.50							
	15-30	nd	96	1.79	1.08-2.95							
	≥30	nd	33	1.47	0.64-3.37							
	Age>59 y											
	<5	nd	576	Ref		nd						
	5-15	nd	340	0.85	0.62-1.16							
	15-30	nd	131	0.82	0.53-1.26							
	≥30	nd	54	1.53	0.84-2.79							

Study PMID	Baseline AHI	n/	N	Adjusted OR	95% CI	P Trend	Other Predictors Significant P	NS	nd P*	NS Univariable†	Interactions
O'Connor SHHS 2009[104] continued	**ESS≤11**										AHI x ESS interaction term NS P=0.11
	<5	nd	**1189**	**Ref**		nd			Age		
	5-15	nd	472	0.83	0.63-1.09				Sex		
	15-30	nd	178	0.90	0.62-1.31				Race		
	≥30	nd	58	1.57	0.87-2.83				BMI		
	ESS>11										
	<5	nd	221	Ref		nd					
	5-15	nd	119	1.31	0.72-2.38						
	15-30	nd	47	2.32	1.09-4.97						
	≥30	nd	27	1.50	0.58-3.85						
Peppard, 2000[9] WSCS 10805822	0	**32/**	**187**	**Ref**		0.002			Baseline HTN		No substantive changes in association with addition of predictors. No interaction terms were significant.
	<5	142/	507	1.42	1.13-1.78				Age		
	5-15	64/	132	2.03	1.29-3.17				Sex		
	≥15	40/	67	2.89	1.46-5.64				BMI		
									Neck girth		
									Waist girth		
									Alcohol use		
									Smoking		

* Included in multivariable analysis. No data on whether statistically significant independent predictor.
† Not statistically significant in univariable analysis. Not included in multivariable analysis.

Table 4.7 Multivariable analyses of AHI as a predictor in Incident type 2 diabetes: Study characteristics

Study PMID	Design Country (Study years)	Eligibility	N (followup)	Factor	Value	Quality
Reichmuth 2005[105] 16192452	Prospective US (1988)	30-60 yr, no DM	978 (4 yr)	**Male**	56%	B
				Age	49 yr	
				BMI (kg/m^2)	28.9	
Botros 2009[106] 19958890	Prospective US (2000-2005)	SDB, no DM	544 (2.7 yr)	**Male**	93%	A
				Age	62 yr	
				BMI	33.2	

Table 4.8 Results of multivariable analyses of AHI as a predictor in Incident type 2 diabetes

Study PMID	Baseline AHI	n/	N	Adjusted OR/HR	95% CI	P trend	Other Predictors Significant	P	NS	nd P*	NS Univariable†	Interactions
Reichmuth 2005[105] WSCS 16192452	<5	nd	nd	**Ref (OR)**		nd				Age, sex, waist girth		AHI significant w/o waist girth in the model
	5-15	nd	nd	1.56	0.80-3.02							
	≥15	nd	nd	1.62	0.67-3.65							
Botros 2009[106] 19958890	<8	6/	142	Ref (HR)		0.008	Glucose	<0.001	Age Sex Race BMI‡			AHI similar with or without adjustment
	≥8	55/	402	1.43	1.10-1.86							

* Included in multivariable analysis. No data on whether statistically significant independent predictor.
† Not statistically significant in univariable analysis. Not included in multivariable analysis.
‡ Change in BMI during follow-up was statistically significant

Table 4.9 Multivariable analyses of AHI as a predictor of Quality of life SF-36: Study characteristics

Study PMID	Design Country (Study years)	Eligibility	N (followup)	Factor	Value	Quality
Silva 2009[107] 19725256	Prospective US (1995)	All	3078 (5 yr)	**Male**	45%	A
				Age	62 yr	
				BMI (kg/m^2)	28.7	

Table 4.10 Results of multivariable analyses of AHI as a predictor of Quality of life (SF-36)

Study PMID	Baseline AHI	N	Score*	Adjusted RR	95% CI	P Trend	Other Predictors Significant	P	NS	nd P†	NS Univariable‡	Interactions
Silva 2009[107] 19725256	**PCS**			**Continuous**			Age, sleeping pills	<0.001	BMI			nd
	<5	1662	49/48	1.008	nd	NS		0.003	CHD			
	5-15	893	48/46						Resp dz			
	15-30	339	47/45						Smoking			
	≥30	154	45/44						Sex			
	MCS			**Continuous**			Smoking	0.02	Age			
	<5	1662	54/55	0.98	nd	NS			BMI			
	5-15	893	54/55						CHD			
	15-30	339	55/54						Resp dz			
	≥30	154	55/56						Sex			

* Baseline / Final
† Included in multivariable analysis. No data on whether statistically significant independent predictor.
‡ Not statistically significant in univariable analysis. Not included in multivariable analysis.

Table 5.1.1 Randomized clinical trials of CPAP vs. control: Study characteristics

Study PMID	Interventions	CPAP pressure* (type)	Mean Age, yr	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Other quality issues
Ballester 1999[108] 9927363	CPAP +conservative measures Conservative measures	Auto (Separate)	53	88	32.7		Spain (nd)	No power calculation
Barnes 2004[129] 15201136	CPAP Placebo	nd (nd)	47	80	31.1		Australia (nd)	
Barnes 2002[120] 11897643	CPAP Placebo	nd (nd)	46	86	30.9		Australia (nd)	
Chakravorty 2002[109] 12449179	CPAP Lifestyle intervention	Auto (Separate)	50	nd	37		UK (1998-1999)	No power calculation
Comondore 2009[121] 18795367	CPAP No treatment	Auto (nd)	56	69	31.1		Canada (nd)	Multiple comparisons in a small pilot study
Drager 2007[110] 17556718	C-flex CPAP No treatment	Manual (Separate)	46	100	29.8	Severe OSA patients free of co-morbidities	Brazil (2004-2006)	
Engleman 1994[122] 7906330	CPAP Placebo	Manual (Separate)	49	74	33		UK (nd)	Baseline data not reported, no wash out period, nd on blinding
Engleman 1996[123] 8843528	CPAP Placebo	Manual (Separate)	51	85	36		UK (nd)	No power calculation
Engleman 1997[124] 9059469	CPAP Placebo	Manual (Separate)	52	85	29.8		UK (nd)	Baseline data not reported, no wash out period, nd on blinding
Engleman 1998[125] 9708223	CPAP Placebo	Manual (Separate)	47	91	30		UK (nd)	No adverse event data
Engleman 1999[126] 9927358	CPAP Placebo	Manual (Separate)	44	62	30		UK (nd)	
Faccenda 2001[127] 11179104	CPAP Placebo	Auto (Separate)	50	81	30		UK (nd)	No wash out period, but no measurements were made until 26 days after crossover; no power calculations reported.
Ip 2004[111] 14551167	CPAP No treatment	Manual (Unclear)	43	100	29.4	Very healthy	Hong Kong (nd)	

Study PMID	Interventions	CPAP pressure* (type)	Mean Age, yr	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Other quality issues
Kajaste 2004[112] 15033131	CPAP No treatment	Manual (Separate)	49	100	43.8	Obese male	Finland (nd)	No power calculation
Kaneko 2003[113] 12660387	CPAP Optimal drug treatment	Manual (Separate)	56	88	31.4	Symptomatic, stable, optimally treated CHF	Canada (nd)	No power calculation
Lam 2007[119] 17121868	CPAP + conservative measures Conservative measures	nd (nd)	47	79	27.3		Hong Kong (nd)	
Lojander 1996[114] 8681614 Lojander 1999[115] 10188139	CPAP Conservative measures	Manual (Separate)	51	93	31.1		Finland (1987-1992)	Large drop out; expert panel decided patients would be more suitable for nasal CPAP but no objective criteria stated
Mansfield 2004[116] 14597482	CPAP No treatment	Manual (Separate)	58	95	33.5	Symptomatic, stable, optimally treated CHF	Australia (nd)	No power calculation
McArdle 2001[128] 11704596	CPAP Placebo	nd (Separate)	53	87	31		Australia (nd)	
Monasterio 2001[117] 11587974	CPAP + conservative measures Conservative measures	Manual (Separate)	54	86	29.4		Spain (nd)	Did not enroll enough to meet power calculations
Redline 1998[118] 9517603	CPAP Conservative measures	Manual (Separate)	48	52	33		US (nd)	Power calculation: needed sample size -112; no. analyzed- 97

* Method for choosing CPAP pressure: Manual (during sleep study); Auto (determined with AutoCPAP); Algorithm (by an algorithm); nd (no data reported); NA (not applicable, eg if AutoCPAP is the intervention). In parentheses: Split (CPAP introduced in a split night study); Separate (CPAP introduced on a separate full night than the diagnostic sleep study).

Table 5.1.2 AHI (events/hr) in randomized controlled trials of CPAP vs. control.

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI*	P Btw	Dropout, %	Study quality
Lam 2007[119] 17121868	19 (17) [>5]	12.0 (8.8)	10 wk (PL)	CPAP + conservative measures	34	23.8 (16.7)	2.8 (9.7)	-22.2	-27.6, -16.7	<0.001	0	B
				Conservative measures	33	19.3 (16.7)	20.5 (21.9)					
Monasterio 2001[117] 11587974	21 (5) [>10]	13.2 (4.3)	6 mo (PL)	CPAP + conservative measures	66	20.0 (6.0)	6.0 (8.0)	-10	-12.8, -7.2	<0.001	12	C
				Conservative measures	59	21 (6.0)	17.0 (10.0)					
Chakravorty 2002[109] 12449179	35 (19) [>15]	14.0 (4.2)	3 mo (PL)	AutoCPAP	32	55 (28.7)	8 (28)	-46	-59.0, -32.9	<0.001	25	C
				Lifestyle intervention	21	35 (19.1)	34 (21)					
Mansfield 2004[116] 14597482	27 (21) [>5]	8.8 (0.9)	3 mo (PL)	CPAP	19	25 (17.9)	2.9 (3.5)	-13.7	-24.4, -3.0	0.012	27	C
				No treatment	21	26.6 (20.6)	18.2 (12.8)					
Ip 2004[111] 14551167	46 (15) [>15]	11.1 (6.2)	1 mo (PL)	CPAP	14	47.7 (15.3)	1.7 (1.8)	-16.8	-27.9, -5.7†	0.003	7	C
				No treatment	14	45.1 (14.3)	15.9 (15.5)					
Kaneko 2003[113] 12660387	45 (5) [>20]	5.7 (0.9)	1 mo (PL)	CPAP	12	37.1 (22.2)	8.3 (9.9)	-28.3	-45.2, -11.4‡	0.001	0	C
				Optimal drug treatment	12	45.2 (18.4)	44.7 (23.6)					
Barnes 2004[129] 15201136	21 (12) [>5]	10.7 (3.5)	3 mo (XO)	CPAP	80	21.3 (11.6)	4.8 (4.5)	-15.5	-18.7, -12.2	<0.001	23	B
				Placebo			20.3 (9.8)					

* Estimated from reported data.
† Estimated from reported P value.
‡ Estimated from reported P value.

Table 5.1.3 ESS in randomized controlled trials of CPAP vs. control

Study PMID	Baseline AHI (SD) [min]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI*	P Btw	Dropout, %	Study quality
Ballester 1999[108] 9927363	58 (20) [>15]	11.4 (5.0)	3 mo (PL)	AutoCPAP + conservative measures	68	12.1 (8.2)	5.6 (nd)	-5.7	-8.1, -3.3	<0.001	0	B
				Conservative measures	37	11.4 (3.6)	10.6 (nd)					
Redline 1998[118] 9517603	12 (10) [>5]	10.6 (5.6)	10 wk (PL)	CPAP	51	10.4 (4.3)	nd	-1.1	-2.5, 0.3	nd	15	B
				Conservative measures	46	10.6 (5.6)	nd					
Lam 2007[119] 17121868	19 (17) [>5]	12.0 (8.8)	10 wk (PL)	CPAP + conservative measures	34	12 (8.8)	7 (8.8)	-3	-5.7, -0.2†	0.034	0	B
				Conservative measures	33	12 (8.8)	10 (8.8)					
Drager 2007[110] 17556718	65 (22) [>30]	13.0 (5.0)	4 mo (PL)	C-Flex	12	14.0 (4.0)	7.0 (2.0)	-7	-10.2, -3.7	<0.001	0	B
				No treatment	12	13.0 (5.0)	13.0 (4.0)					
Monasterio 2001[117] 11587974	21 (5) [>10]	13.2 (4.3)	6 mo (PL)	CPAP + conservative measures	66	12.1 (4.9)	9.6 (5.5)	-1.1	-2.9, 0.7	NS	12	C
				Conservative measures	59	13.2 (4.3)	11.8 (5.2)					
Chakravorty 2002[109] 12449179	35 (19) [>15]	14.0(4.2)	3 mo (PL)	AutoCPAP	32	16 (5.6)	8 (6.4)	-5.0	-7.9, -2.1	0.001	25	C
				Lifestyle intervention	21	14 (4.2)	11 (5.0)					
Mansfield 2004[116] 14597482	27 (21) [>5]	8.8 (0.9)	3 mo (PL)	CPAP	19	9.5 (3.9)	6.9 (4.5)	-4.2‡	-7.4, -1.0§	0.01	27	C
				No treatment	21	8.8 (3.9)	9.9 (4.5)					
Barnes 2004[129] 15201136	21 (12) [>5]	10.7 (3.5)	3 mo (XO)	CPAP	80	10.7 (3.6)	9.2 (3.6)	-1	-2.1, 0.1	NS	23	B
				Placebo			10.2 (3.6)					
Faccenda 2001[127] 11179104	35 (15-129) [>15]	15 (6-24)	1 mo (XO)	AutoCPAP	68	nd	10.1 (0.7)	-2.0	-3.2, -0.8**	0.001	5	B
				Placebo			12.5 (0.8)					

Study PMID	Baseline AHI (SD) [min]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI*	P Btw	Dropout, %	Study quality
Engleman 1999[126] 9927358	10 (nd) [>5]	13.0 (3.0)	4 wk (XO)	CPAP	34	13.0 (3.0)	8.0 (4.0)	-3	-4.8, -1.2††	0.001	8	B
				Placebo			11.0 (4.0)					
Engleman 1998[125] 9708223	43 (nd) [>15]	12.0 (4.0)	4wk (XO)	CPAP	23	12.0 (4.0)	6.0 (3.0)	-6	-9.5, -2.4‡‡	0.001	0	B
				Placebo			12.0 (4.0)					
Barnes 2002[120] 11897643	13 (6) [>5]	11.3 (5.0)	8 wk (XO)	CPAP	28	11.2 (5.0)	-2.7§§	-0.6	nd	NS	33	C
				Placebo			-2.1***					
Engleman 1997[124] 9059469	11 (4) [>5]	nd	4 wk (XO)	CPAP	16	nd	10.1 (5.6)	0.1	-3.5, 3.7	NS	11	C
				Placebo			10.0 (4.8)					

* Estimated from reported data
† Estimated from reported P value.
‡ Based on reported within-group changes.
§ Estimated from reported P value.
** Estimated from reported P value.
†† Estimated from reported P value.
‡‡ Estimated from reported P value.
§§ Reported change.
*** Reported change.

Table 5.1.4a Arousal Index (events/hr)] in randomized controlled trials of CPAP vs. control

Study PMID	Baseline AHI (SD) [min]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI*	P Btw	Dropout, %	Study quality
Lam 2007[119] 17121868	19 (17) [>5]	12.0 (8.8)	10 wk (PL)	CPAP + conservative measures	34	21.6 (14.9)	16.3 (15.7)	-10.6	-16.3, -4.83	<0.001	0	B
				Conservative measures	33	23.5 (19.3)	28.8 (21.9)					
Chakravorty 2002[109] 12449179	35 (19) [>15]	14.0 (4.2)	3 mo (PL)	AutoCPAP	32	64.0 (28.0)	38.9 (28.6)	-9.8	-25.4, 4.9	nd	25	C
				Lifestyle intervention	21	52.2 (28.5)	36.9 (21.5)					
Ip 2004[111] 14551167	46 (15) [>15)	11.1 (6.2)	1 mo (PL)	CPAP	14	33.4 (17.2)	17.5 (10.7)	-17.6	-29.3, -5.9	0.003	7	C
				No treatment	14	33.8 (15.0)	35.5 (17.7)					
Kaneko 2003[113] 12660387	45 (5) [>20]	5.7 (0.9)	1 mo (PL)	CPAP	12	31.4 (21.1)	12.6 (5.9)	-18.0	-33.7, -2.3	0.025	0	C
				Optimal drug treatment	12	42.9 (19.1)	42.3 (21.5)					
Barnes 2004[129] 15201136	21 (12) [>5]	10.7 (3.5)	3 mo (XO)	CPAP	80	22.0 (10.7)	18.3 (8.0)	-6.9	-9.9, -3.8	<0.001	23	B
				Placebo			25.2 (9.8)					
McArdle 2001[128] 11704596	40 (25-65) [>15]	14.0 (10-17)	1 mo (XO)	CPAP	22	nd	21.0	-24.0	-38.3, -9.7†	<0.001	4	B
				Placebo			45.0					

* Estimated from reported data.
† Estimated from reported P value.

Table 5.1.4b Minimum 0_2 saturation (%) in randomized controlled trials of CPAP vs. control

Study PMID	Baseline AHI (SD) [min]	Baseline ESS (SD)	Duration (Design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI*	P Btw	Dropout, %	Study quality
Lam 2007[119] 17121868	19 (17) [>5]	12.0 (8.8)	10 wk (PL)	CPAP + conservative measures	34	75.0 (12.3)	87.2 (25.4)	10.9	4.2, 17.7	0.002	0	B
				Conservative measures	33	76.1 (22.8)	77.4 (17.5)					
Mansfield 2004[116] 14597482	27 (21) [>5]	8.8 (0.9)	3 mo (PL)	CPAP	19	79.6 (11.3)	91.1 (3.9)	11.5	2.9, 20.1	0.008	27	C
				No treatment	21	77.2 (17.8)	77.2 (16.0)					
Ip 2004[111] 14551167	46 (15) [>15)	11.1 (6.2)	1 mo (PL)	CPAP	14	64.9 (11.9)	91.4 (2.6)	26.6	17.4, 35,8	<0.001	7	C
				No treatment	14	66.6 (12.2)	66.5 (15.0)					
Kaneko 2003[113] 12660387	45 (5) [>20]	5.7 (0.9)	1 mo (PL)	CPAP	12	82.3 (4.2)	89.6 (3.8)	8.8	2.2, 15.3	0.009	0	C
				Optimal drug treatment	12	78.4 (7.6)	76.9 (12.4)					
Barnes 2004[129] 15201136	21 (12) [>5]	10.7 (3.5)	3 mo (XO)	CPAP	80	86.7 (5.4)	91.9 (2.7)	6.5	4.9, 8.0	<0.001	23	B
				Placebo			85.4 (5.4)					

* Estimated from reported data

Table 5.1.4c Sleep efficiency (% total sleep time) in randomized controlled trials of CPAP vs. control

Study PMID	Baseline AHI (SD) [min]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI*	P Btw	Dropout, %	Study quality
Barnes 2004[129] 15201136	21 (12) [>5]	10.7 (3.5)	3 mo (XO)	CPAP	80	79.5 (9.83)	82.1 (7.15)	1.4	-1.4, 4.2	NS	23%	B
				Placebo tablets		79.5 (9.83)	80.7 (8.04)					
Chakravorty 2002[109] 12449179	35 (19) [>15]	14.0 (4.2)	3 mo (PL)	AutoCPAP	32	67.7 (18.2)	67.5 (15.7)	-3	-10.8, 4.8	nd	25	C
				Lifestyle intervention	21	71.6 (12.8)	74.4 (11.1)					

* Estimated from reported data

Table 5.1.4d Slow wave sleep (% total sleep time or minutes) in randomized controlled trials of CPAP vs. control

Study PMID	Baseline AHI (SD) [min]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI*	P Btw	Dropout, %	Study quality
Chakravorty 2002[109] 12449179	35 (19) [>15]	14.0 (4.2)	3 mo (PL)	AutoCPAP	32	16.6% (nd)	21.0 (nd)	-1	nd	nd	25	C
				Lifestyle intervention	21	18.7% (nd)	22.0 (nd)					
				AutoCPAP	32	64.7 min (50.2)	69.5 (50.1)	0.7	-26.7, 28.1	nd		
				Lifestyle intervention	21	81.2 min (52.5)	85.3 (46.6)					
Mansfield 2004[116] 14597482	27 (21) [>5]	8.8 (0.9)	3 mo (PL)	CPAP	19	5% (4.4)	7.0 (8.7)	4.0	0.1, 7.9	0.046	27	C
				No treatment	21	6% (4.6)	4.0 (4.6)					
Kaneko 2003[113] 12660387	45 (5) [>20]	5.7 (0.9)	1 mo (PL)	CPAP	12	10.0% (9.0)	12.7 (11.4)	3.2	-5.5, 11.9	NS	0	C
				Optimal drug treatment	12	8.5% (10.4)	8.0 (3.5)					
McArdle 2001[128] 11704596	40 (25-65) [>15]	14 (10-17)	1 mo (XO)	CPAP	22	nd (min)	41.0 (nd)	18	4.9, 31.1†	0.007	4	B
				Placebo			23.0 (nd)					
Barnes 2004[129] 15201136	21 (12) [>5]	10.7 (3.5)	3 mo (XO)	CPAP	80	17.9% (10.7)	20.7 (9.8)	2.2	-1.1, 5.5	NS	23	B
				Placebo			18.5 (10.7)					

* Estimated from reported data.
† Estimated from reported P value.

Table 5.1.4e REM sleep (% total sleep time or minutes) in randomized controlled trials of CPAP vs. control

Study PMID	Baseline AHI (SD) [min]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI*	P Btw	Dropout, %	Study quality
Chakravorty 2002[109] 12449179	35 (19) [>15]	14.0 (4.2)	3 mo (PL)	AutoCPAP	32	20.7% (nd)	24.9 (nd)	nd	nd	nd	25	C
				Lifestyle intervention	21	20.1% (nd)	23.9 (nd)					
				AutoCPAP	32	80.6 min (39.3)	81.9 (35.8)	-4.1	-27.2, 19.0	nd		
				Lifestyle intervention	21	87.1 min (40.5)	92.5 (47.8)					
Mansfield 2004[116] 14597482	27 (21) [>5]	8.8 (0.9)	3 mo (PL)	CPAP	19	14.0% (4.4)	13.0 (8.7)	0	-4,8, 4.8	NS	27	C
				No treatment	21	12.0% (9.2)	11.0 (4.6)					
Kaneko 2003[113] 12660387	45 (5) [>20]	5.7 (0.9)	1 mo (PL)	CPAP	12	7.7% (5.5)	12.2 (7.3)	5.9	-0.1, 11.9	NS	0	C
				Optimal drug treatment	12	13.2% (6.2)	11.6 (9.4)					
McArdle 2001[128] 11704596	40 (25-65) [>15]	14 (10-17)	1 mo (XO)	CPAP	22	nd (min)	86.0 (30.0)	12	-2.3, 26.3†	NS	4	B
				Placebo			74.0 (29.0)					
Barnes 2004[129] 15201136	21 (12) [>5]	10.7 (3.5)	3 mo (XO)	CPAP	80	18.8% (6.2)	18.9 (4.4)	0	-1.8, 1.8	NS	23	B
				Placebo			18.9 (5.3)					

* Estimated from reported data.
† Estimated from reported P value.

Table 5.1.5a Multiple Sleep Latency Test (min) in randomized controlled trials of CPAP vs. control

Study PMID	Baseline AHI (SD) [min]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI*	P Btw	Dropout, %	Study quality
Redline 1998[118] 9517603	12 (10) [>5]	10.6 (5.6)	10 wk (PL)	CPAP	51	9.9 (4.8)	nd	0.39	-14.4, 15.2	nd	15	B
				Conservative measures	46	10.3 (5.0)	nd					
Monasterio 2001[117] 11587974	21 (5) [>10]	13.2 (4.3)	6 mo (PL)	CPAP + Conservative measures	40	10. (5.0)	10.0 (5.0)	0	-1.8, 1.8	NS	12	C
				Conservative measures		11.0 (5.0)	11.0 (5.0)					
Engleman 1998[125] 9708223	43 (nd) [>15]	12.0 (4.0)	4wk (XO)	CPAP	23	nd	9.2 (3.9)	2.4	0.8, 4.0	<0.001	0	B
				Placebo			6.8 (4.3)					
Engleman 1994[122] 7906330	28 (7-129) [>5]	nd	1 mo (XO)	CPAP	32	nd	7.2 (4.0)	1.1	0.1, 2.1†	0.03	9	C
				Placebo			6.1 (4.0)					
Barnes 2002[120] 11897643	13 (6) [>5]	11.3 (5.0)	8 wk (XO)	CPAP	28	12.5 (4.8)	-1.8‡	-1.0	nd	NS	33	C
				Placebo			-0.8§					
Engleman 1997[124] 9059469	11 (4) [>5]	nd	4 wk (XO)	CPAP	16	nd	10.0 (4.8)	0.1	-3.6, 3.9	NS	11	C
				Placebo			9.9 (6.0)					

* Estimated from reported data
† Estimated from reported P value
‡ Reported change
§ Reported change

Table 5.1.5b Maintenance of wakefulness test (min) in randomized controlled trials of CPAP vs. control

Study PMID	Baseline AHI (SD) [min]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Engleman 1999[126] 9927358	10 (nd) [>5]	13.0 (3.0)	4 wk (XO)	CPAP	34	nd	16.2 (10.6)	1.8	-4.2, 7.8*	NS	8	B
				Placebo tablet			14.4 (8.5)					

* Estimated from reported data.

Table 5.1.6a FOSQ in randomized controlled trials of CPAP vs. control

Study PMID	Baseline AHI (SD) [min]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI*	P Btw	Dropout, %	Study quality
Monasterio 2001[117] 11587974	21 (5) [>10]	13.2 (4.3)	6 mo (PL)	CPAP + conservative measures	66	101 (18)†	106 (20) ‡	3	-3.6, 9.6	NS	12	C
				Conservative measures	59	100 (15) §	102 (21) **					
Barnes 2004[129] 15201136	21 (12) [>5]	10.7 (3.5)	3 mo (XO)	CPAP	80	3.1 (0.9)††	3.3 (0.9) ‡‡	0	-0.3, 0.3	NS	27	B
				Placebo			3.3 (0.9) §§					
Faccenda 2001[127] 11179104	35 (15-129) [>15]	15 (6-24)	1 mo (XO)	AutoCPAP	68	nd	12.4 (4.1)***	+0.8	-0.2, 1.4†††	NS	5	B
				Placebo			11.6 (5.7) ‡‡‡					
Barnes 2002[120] 11897643	13 (6) [>5]	11.3 (5.0)	8 wk (XO)	CPAP	28	0.8 (0.1)§§§	+0.07****	+0.01	nd	NS	33	C
				Placebo			+0.06††††					

* Estimated from reported data.
† Total summed score of FOSQ responses.
‡ Total summed score of FOSQ responses.
§ Total summed score of FOSQ responses.
** Total summed score of FOSQ responses.
†† Weighted average of FOSQ subscale scores.
‡‡ Weighted average of FOSQ subscale scores.
§§ Weighted average of FOSQ subscale scores.
*** Summed score of FOSQ subscale averages.
††† Estimated from reported P value.
‡‡‡ Summed score of FOSQ subscale averages.
§§§ Ratio of total summed score over maximum possible score.
**** Reported change.
†††† Reported change.

Table 5.1.6b Quality of life in randomized controlled trials of CPAP vs. control

Study PMID	Baseline Test (SD)	Duration (design)	Interventions	No. analyzed	Outcome	Favors	If Significant Difference Net difference	95% CI*	Test range "Worst"	"Best"	P Btw	Study quality
Ballester 1999[108] 9927363	AHI 58 (20)	3 mo (PL)	AutoCPAP + CM	68	SAHS-related symptoms questionnaire	AutoCPAP	-12.3	-14.6, -9.9	15	-16	<0.001	B
	ESS 11.4 (5.0)		CM	37	NHP – Emotional reactions	0						
					NHP - Sleep	0						
					NHP - Physical	0						
					NHP – Social isolation	0†	-3.7	-11.2, 3.8	0	100	0.33	
					NHP – Pain	0						
					NHP - Energy	AutoCPAP	-20.6	-33.1, -8.1	0	100	<0.001	
Lam 2007[119] 17121868	AHI 19 (17)	10 wk (PL)	CPAP + CM	34	SAQLI summary score (A-D)[a]	CPAP	1	0.7, 1.2	0	7	<0.001	B
	ESS 12 (8.8)		CM	33	SAQLI summary score (A-E)[a]	CPAP	nd	nd	0	7	<0.05	
					SF-36 Physical function	CPAP	6.9	1.6, 12.1‡	0	100	<0.05	
					SF-36 Bodily Pain	CPAP	11.7		0	100	<0.05	
Monasterio 2001[117] 11587974	AHI 21 (5)	6 mo (PL)	CPAP + CM	66	SAHS related symptoms	CPAP	-5	-6.4, -3.6	8	32	<0.001	C
	ESS 13.2 (4.3)		CM	59	NHP	0					NS	
Mansfield 2004[116] 14597482	AHI 27 (21)	3 mo (PL)	CPAP	19	SF-36 role-physical	0					NS	C
	ESS 8.8 (0.9)		No treatment	21	SF-36 vitality	CPAP	20	5.2, 34.8	0	100	0.008	
					SF-36 mental health	0					NS	

Study PMID	Baseline Test (SD)	Duration (design)	Interventions	No. analyzed	Outcome	Favors	If Significant Difference Net difference	95% CI*	Test range "Worst"	"Best"	P Btw	Study quality
Barnes 2002[120] 11897643	AHI 13 (6) ESS 11.3 (5.0)	8 wk (XO)	CPAP Placebo	28	SF-36 physical functioning	0					NS	B
					SF-36 mental health	0					NS	
Barnes 2004[129] 15201136	AHI 21 (12) ESS 10.7 (3.5)	3 mo (XO)	CPAP Placebo	80	SF-36 mean score	0					NS§	B
Engleman 1994[122] 7906330	AHI 28 (7-129) ESS nd	1 mo (XO)	CPAP Placebo	32	GHQ 28 total score	CPAP	-3.4	-5.6, -1.2**	0	28	0.003	C
Engleman 1997[124] 9059469	AHI 11 (4) ESS nd	4 wk (XO)	CPAP Placebo	16	GHQ 28 total score	0					NS	C
Engleman 1998[125] 9708223	AHI 43 (nd) ESS 12.0 (nd)	4 wk (XO)	CPAP Placebo	23	UMACL Energetic Arousal Score	0					NS	B
					GHQ-28	0					NS	
					NHP Part 2 score	0					NS	
Engleman 1999[126] 9927358	AHI 10 (nd) ESS 13.0 (3.0)	4 wk (XO)	CPAP Placebo	34	SF-36 Role-physical	CPAP	17	0.9, 33.0	0	100	0.038	B
					SF-36 mental health	0					NS	
					SF-36 Vitality	CPAP	12	2.6, 24.1	0	100	0.014	
					UMACL Energetic Arousal Score	0					NS	
					NHP Part 2 score	0					NS	

* Estimated from reported data.
† Contrary to the reported P-value for this outcome (P=0.03), our calculations showed no statistical significance (P=0.33).
‡ Estimated from reported P value.
§ Our estimated does not match with reported statistical significance.
** Estimated from reported P value.

Table 5.1.7 Neurocognitive and psychological tests in randomized controlled trials of CPAP vs. control

Study PMID	Baseline Test (SD)	Duration (design)	Interventions	No. analyzed	Outcome	Favors	If Significant Difference Net Difference	95% CI	Test Range "Worst"	Test Range "Best"	P Btw	Study quality
Monasterio 2001[117] 11587974	AHI 21 (5)	6 mo (PL)	CPAP + CM	66	Attention - digit symbol (WAIS) SS	0					NS	C
	ESS 13.2 (4.3)		CM	59	Attention - digits forward and backward (WAIS) SS	0					NS	
					Attention - mental control (WMS) p	0					NS	
					Memory - verbal paired associated (WMS) p	0					NS	
					Memory - visual memory (WMS), SS	0					NS	
					Executive function - Verbal fluency, p	0					NS	
					Executive function - Block Design (WAIS), SS	0					NS	
					Trailmaking A (sec)	0					NS	
					Trailmaking B (sec)	0					NS	
					PASAT 4-s,	0					NS	
					PASAT 3-s	0					NS	
					PASAT 2-s	0					NS	
					PASAT 1-s	0					NS	
					Vigilance - Steer-clear, % hits	0					NS	
Lojander 1996,1999[115 114] 8681614, 10188139	nd	12 mo (PL)	CPAP + CM	23	Wechsler Verbal	0					NS	C
			CM	21	Wechsler Performance	0					NS	
					Wechsler Memory	0					NS	
Barnes 2004[129] 15201136	AHI 21 (12) ESS 10.7 (3.5)	3 mo (XO)	CPAP Placebo	80	Beck Depression Inventory	0					NS	B

Study PMID	Baseline Test (SD)	Duration (design)	Interventions	No. analyzed	Outcome	Favors	If Significant Difference Net Difference	95% CI	Test Range "Worst"	Test Range "Best"	P Btw	Study quality
Engleman 1999[126] 9927358	AHI 10 (nd) ESS 13 (3)	4 wk (XO)	CPAP Placebo	34	SteerClear	0					NS	B
					Trailmaking A and B	0					NS	
					Digit symbol	CPAP	0.5*	nd			0.004	
					Block Design score	0					NS	
					Performance IQ score	0					NS	
					HADS anxiety score	0					NS	
					HADS depression score	CPAP	0.41†		0	21	0.003	
					PASAT 2-s	CPAP	0.36‡				0.02	
Barnes 2002[120] 11897643	AHI 13 (6) [>5] ESS 11.3 (5.0)	8 wk (XO)	CPAP Placebo	28	Word pair memory recall	0					NS	B
					WMS-R visual reproduction	0					NS	
					Trailmaking A (sec)	0					NS	
					Trailmaking B (sec)	0					NS	
					Digital symbol substitution test	0					NS	
					Controlled oral word association test	CPAP	+2.7	0.43, 4.97§			0.02	
					Psychomotor vigilance task	0					NS	
					Stroop color association test	0					NS	
					POMS	0					NS	
					Mood- Beck depression inventory	0					NS	
Engleman 1998[125] 9708223	AHI 43 (nd) ESS 12.0 (nd)	4 wk (XO)	CPAP Placebo	23	SteerClear	0					NS	B
					Trailmaking B	0					NS	
					Digit symbol substitution	0					NS	
					Block Design	0					NS	
					Performance IQ decrement	0					NS	
					HADS anxiety score	0					NS	
					Rapid visual information processing	0					NS	
					HADS depression score	0					NS	
					PASAT 2-s	0					NS	

Study PMID	Baseline Test (SD)	Duration (design)	Interventions	No. analyzed	Outcome	Favors	If Significant Difference Net Difference	95% CI	Test Range "Worst"	Test Range "Best"	P Btw	Study quality
Engleman 1994[122] 7906330	AHI 28 (7-129)	1 mo (XO)	CPAP	32	IQ decrement score	CPAP	-3.2	-6.3, -0.1**	NA	NA	0.04	C
	ESS nd		Placebo		Trailmaking B (sec)	CPAP	-9	-16.5, -1.4††	NA	NA	0.02	
					PASAT	0					NS	
					HADS anxiety score	CPAP	-1.2	-2.2, -0.2	0	21	0.02	
					HADS depression score	CPAP	-1.9	-3.1, -0.7‡‡	0	21	0.002	
Engleman 1997[124] 9059469	AHI 11 (4)	4 wk (XO)	CPAP	16	IQ decrement score	0					NS	C
	ESS nd		Placebo		Trailmaking B (sec)	CPAP	-13.6	-25.1, -2.1	NA	NA	0.02	
					PASAT	0					NS	
					Verbal fluency total words	0					NS	
					HADS anxiety score	0					NS	
					HADS depression score	CPAP	-1.6	-3.0, -0.2	0	21	0.03	

* Reported Effect size (final difference/standard deviation of difference)
† Reported Effect size (final difference/standard deviation of difference)
‡ Reported Effect size (final difference/standard deviation of difference)
§ Estimated from reported P value.
** Estimated from reported P value.
†† Estimated from reported P value.
‡‡ Estimated from reported P value.

Table 5.1.8a Blood pressure measurements (mm Hg) in randomized controlled trials of CPAP vs. control

Study PMID	Baseline AHI (SD) [min]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI*	P Btw	Dropout, %	Study quality
Daytime Systolic Blood Pressure												
Drager 2007[110] 17556718	65 (22) [>30]	13.0 (5.0)	4 mo (PL)	C-Flex	12	122 (5)	119 (9)	-1	-8.2, 6.2	NS	0	B
				No treatment	12	124 (11)	122 (9)					
Monasterio 2001[117] 11587974	21 (5) [>10]	13.2 (4.3)	6 mo (PL)	CPAP + conservative measures	66	126.0 (17.0)	122.0 (22.0)	-2	-8.4, 4.4	NS	12	C
				Conservative measures	59	132.0 (17.0)	130.0 (16.0)					
Kaneko 2003[113] 12660387	45 (5) [>20]	5.7 (0.9)	1 mo (PL)	CPAP	12	126 (20.8)	116 (17.3)	-16	-34.4, 2.4	NS	0	C
				Optimal drug treatment	12	128 (24.2)	134 (27.7)					
Barnes 2002[120] 11897643	13 (6) [>5]	11.3 (5.0)	8 wk (XO)	CPAP	28	132.0 (11.0)	-0.7 (25.6)†	-2.1	-11.2, 7.0	0.65	33	C
				Placebo			2.2 (9.8)‡					
Comondore 2009[121] 18795367	28 (nd) [>15]	6.8 (nd)	4 wk (XO)	AutoCPAP	13	139.3 (nd)	131.9 (nd)	-3.6	-18.5, 11.3	0.50	0	C
				No treatment			133.6 (nd)					
Engleman 1996[123] 8843528	49 (32) [>5]	nd	3 wk (XO)	CPAP	13	nd	138.0 (14.4)	-0.1	-10.8, 8.7	nd	19	C
				Placebo			139.0 (10.8)					
Nightime Systolic Blood Pressure												
Drager 2007[110] 17556718	65 (22) [>30]	13.0 (5.0)	4 mo (PL)	C-Flex	12	108.0 (9.0)	105.0 (10.0)	-4	-11.6, 3.6	NS	0	B
				No treatment		109 (10.0)	113.0 (9.0)					
Daytime Diastolic Blood Pressure												
Drager 2007[110] 17556718	65 (22) [>30]	13.0 (5.0)	4 mo (PL)	C-Flex	12	79.0 (4.0)	75.0 (7.0)	-1	-4.6, 6.6	NS	0	B
				No treatment	12	78.0 (9.0)	75.0 (6.0)					

Study PMID	Baseline AHI (SD) [min]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI*	P Btw	Dropout, %	Study quality
Kaneko 2003[113] 12660387	45 (5) [>20]	5.7 (0.9)	1 mo (PL)	CPAP	12	62.0 (13.9)	59.0 (6.9)	-1	-10.8, 8.8	NS	0	C
				Optimal drug treatment	12	60.0 (13.9)	58.0 (10.4)					
Monasterio 2001[117] 11587974	21 (5) [>10]	13.2 (4.3)	6 mo (PL)	CPAP + conservative measures	66	81.0 (12.0)	80.0 (10.0)	-1	-4.9, 2.9	NS	12	C
				Conservative measures	59	84.0 (11.0)	84.0 (11v)					
Barnes 2002[120] 11897643	13 (6) [>5]	11.3 (5.0)	8 wk (XO)	CPAP	28	84.0 (7.8)	-0.5 (25.6) §	-2.6	-11.7, -6.5	0.57	33	C
				Placebo			+2.1 (9.8)**					
Comondore 2009[121] 18795367	28 (nd) [>15]	6.8 (nd)	4 wk (XO)	AutoCPAP	13	82.7 (nd)	79.0 (nd)	-0.7	-8.5, 7.1	0.84	0	C
				No treatment		84.8 (nd)	81.8 (nd)					
Engleman 1996[123] 8843528	49 (32) [>5]	nd	3 wk (XO)	CPAP	13	nd	84.0 (3.0)	-2	-4.3, 0.3	nd	19	C
				Placebo		nd	86.0 (3.0)					
Nightime Diastolic Blood Pressure												
Drager 2007[110] 17556718	65 (22) [>30]	13.0 (5.0)	4 mo (PL)	C-Flex	12	67.0 (8.0)	63.0 (8.0)	-1	-7.7, 5.7	NS	0	B
				No treatment	12	69.0 (7.0)	66.0 (10.0)					

* Estimated from reported data.
† Reported change.
‡ Reported change
§ Reported change.
** Reported change.

Table 5.1.8b HbA1C (%) in randomized controlled trials of CPAP vs. control

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Comondore 2009[121] 18795367	28 (nd) [>15]	6.8 (nd)	4 wk (XO)	AutoCPAP	13	5.91 (nd)	5.94 (nd)	0.04	-0.27, 0.34	NS	0	C
				No treatment		5.85 (nd)	5.85 (nd)					

Table 5.2.1. Characteristics of randomized controlled trials comparing PAP with sham control

Author Year PMID	Interventions	CPAP Pressure* (Type)	Mean Age, y	Male, %	Mean BMI, kg/m^2	Other Patient Characteristics	Country (Enrollment Years)	Other Quality Issues
Arias 2005[130] 16009798	CPAP Sham CPAP	Auto (separate)	52	100	30.5		Spain (nd)	
Barbe 2001[131] 11388814	CPAP Sham CPAP	Manual (separate)	53	91	29	Non-sleepy	Spain (1999-2000)	N <30
Becker 2003[132] 12515745	CPAP Sham CPAP	Manual (separate)	53	91	33.4	67% with HTN	Germany (nd)	No power calculation, no allocation concealment, high dropout rate
Campos-Rodriguez 2006[133] 16778262	CPAP Sham CPAP	Manual (separate)	57	60	34.8	30-70 yr with primary HTN and on treatment	Spain (nd)	Unclear randomization
Coughlin 2007[134] 17251237	CPAP Sham CPAP	Auto (split)	49	100	36.1	Healthy obese males	UK (nd)	
Cross 2008[135] 18390635	CPAP Sham CPAP	Auto (separate)	48	96	37	22% on aspirin, statins, or beta blockers	UK (nd)	
Egea 2008[136] 17904420	CPAP Sham CPAP	Manual (split)	64	94	31.1	Stable heart failure patients with sleep apnea	Spain (nd)	PSG results included 17% central sleep apnea subjects, but sleepiness and QoL measures only included OSA subjects
Haensel 2007[137] 17503102	CPAP Sham CPAP	Manual (separate)	49	80	33.4		US (nd)	relatively small samples, no power calculation
Henke 2001[138] 11282765	CPAP Sham CPAP	Manual (separate)	50	56	42.6		US (nd)	No power calculation; one-way cross over
Hui 2006[139] 16928705	CPAP Sham CPAP	Auto (separate)	51	80	27.2		Hong Kong (nd)	Underpowered; Non-ITT analyses; likely selection bias; questionable patient blinding
Jenkinson 1999[140] 10382693 Hack 2000[141] 10679542	CPAP Sham CPAP	Auto (separate)	49	100	35.1		UK (1997-98)	
Loredo 1999[142] 10593774 Yu 1999[143] 10504011 Bardwell 2001[144] 11485111 Profant 2003[145] 12571548	CPAP Sham CPAP	Manual (separate)	48	75	31.3		US (nd)	

Author Year PMID	Interventions	CPAP Pressure* (Type)	Mean Age, y	Male, %	Mean BMI, kg/m^2	Other Patient Characteristics	Country (Enrollment Years)	Other Quality Issues
Loredo 2006[146] 16676791 Bardwell 2001[144] 11485111	CPAP Sham CPAP	Manual (separate)	48	83	31.8		US (2002-04)	Poorly reported results, with much missing data, incomplete analyses
Marshall 2005[148] 15860720	CPAP Sham CPAP	Manual (separate)	51	76	31.5		New Zealand (2001-03)	Allocation concealment: yes – assessors; no - patients
Mills 2006[149] 16357087 Lim 2007[150] 17694727	CPAP Sham CPAP	Manual (separate)	48	85	31.9		US (nd)	No power calculation
Montserrat 2001[151] 11520724	CPAP Sham CPAP	Manual (separate)	54	91	32.0		Spain (nd)	Needed sample size 48 but had only 45
Norman 2006[152] 16585412	CPAP Sham CPAP	Manual (separate)	50	85	30.8			No power calculation
Robinson 2006[153] 16455835	CPAP Sham CPAP	Auto (split)	54	89	33.2	HTN with significant OSA, but without sufficient daytime hypersomnolence	UK (nd)	
Siccolli 2008[154] 19014075	CPAP Sham CPAP	Auto (separate)	48	100	35.2		UK (nd)	
Smith 2007[155] 17470670	CPAP Sham CPAP	Auto (split)	61	88	31	CHF	UK (nd)	
Spicuzza 2006[156] 16963674	CPAP Sham CPAP	Manual (separate)	56	80	32.1		Italy (nd)	
West 2007[157] 17557769	CPAP Sham CPAP	Auto (split)	56	100	37.8	Diabetes mellitus	UK (2004-05)	

* Method for choosing CPAP pressure: Manual (during sleep study); Auto (determined with AutoPAP); Algorithm (by an algorithm); nd (no data reported); NA (not applicable, eg if AutoPAP is the intervention). In parentheses: split (CPAP introduced in a split night study); separate (CPAP introduced on a separate full night than the diagnostic sleep study).

Table 5.2.2. AHI (events/hr) in randomized controlled trials of CPAP vs. sham control

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study Quality
Egea 2008[136] 17904420	35 (17) [>10]	7.3 (4.5)	3 mo (PL)	CPAP	27	43.7 (22.9)	10.8 (11.4)	-25.6	-36.5, -14.6*	<0.0001†	18	B
				Sham CPAP	29	35.3 (16.7)	28 (24.8)					
Haensel 2007[137] 17503102	58 (30) [≥15]	nd	2 wk (PL)	CPAP	25	65.9 (28.6)	3.5 (3.4)	-58.3	-74.9, -41.7‡	<0.001	0	B
				Sham CPAP	25	57.5 (32.1)	53.4 (32.9)					
Loredo 1999[142] 10593774 Yu 1999[143] 10504011 Bardwell 2001[144] 11485111 Profant 2003[145] 12571548	44 (25) [RDI≥20]	nd	1 wk (PL)	CPAP	23	56.4 (24.1)	3.3 (3.8)	-37.2	-51.6, -22.7§	<0.001	14	B
				Sham CPAP	18	44.2 (25.3)	28.3 (22.7)					
Mills 2006[149] 16357087 Lim 2007[150] 17694727	61 (33) [>15]	nd	2 wk (PL)	CPAP	17	65.0 (34)	2.56 (2.4)	-58.5	-84.0, -33.0**	nd	nd	B
				Sham CPAP	16	61.2 (41)	57.3 (41)					
Loredo 2006[146] 16676791 Bardwell 2001[144] 11485111	57 (32) [≥15]	12.3 (6.7)	2 wk (PL)	CPAP	22	65.9 (28.6)	3.0 (4.7)	-57.9	-76.2, -39.6††	<0.001	nd	C
				Sham CPAP	19	57.5 (32.1)	52.5 (37.5)					
Norman 2006[152] 16585412	54 (30) [>15]	12.0 (6.6)	2 wk (PL)	CPAP	18	66.1 (29.1)	3.4 (3.0)	-58.9	-79.2, -38.6‡‡	<0.05	nd	C
				Sham CPAP	15	53.9 (29.8)	50.1 (32.1)					
Becker 2003[132] 12515745	65.0 (26.7) [≥5]	14.1 (3.2)	9 wk (PL	CPAP	16	62.5 (17.8)	3.4 (3.1)	-27.5	-43.4, -11.6§§	0.001	47	C
				Sham CPAP	16	65.0 (26.7)	33.4 (29.2)					
Spicuzza 2006[156] 16963674	59 (17) [>5]	nd	1 mo (PL)	CPAP	15	55.3 (11.9)	2.1 (0.3)	-51.0	-62.0, -40.0***	<0.005	nd	C
				Sham CPAP	10	59.2 (17.3)	57.0 (8.6)					

* Estimated from reported data.
† Estimated from reported data.
‡ Estimated from reported data.
§ Estimated from reported data.
** Estimated from reported data.
†† Estimated from reported data.
‡‡ Estimated from reported data.
§§ Estimated from reported data
*** Estimated from reported data.

Table 5.2.3. ESS in randomized controlled trials of CPAP vs. sham control

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI	P Btw	Dropout %	Study Quality
West 2007[157] 17557769	nd	14 (3.5)	3 mo (PL)	AutoCPAP	19	15 (3.5)	-6.6 (4.5)*	-4.0	-7.0, -0.9	0.01	5	A
				Sham CPAP	21	17 (3.5)	-2.6 (4.9)†					
Coughlin 2007[134] 17251237	40 (14) [>15]	14 (4.9)	6 wk (XO)	AutoCPAP	34	14 (4.9)	nd	-3.1	-4.5, -1.7	<0.01	3	A
				Sham CPAP	34	14 (4.9)						
Robinson 2006[153] 16455835	nd	5.3 (IRQ 3.0-7.0)	1 mo (XO)	AutoCPAP	32	5.3 (nd)	-1.4 (nd)‡	-1.1	-2.0, -0.17§	<0.02	9	A
				Sham CPAP	32	5.3 (nd)	-0.3 (nd)**					
Smith 2007[155] 17470670	36 (23) [≥15]	10 (5)	6 wk (XO)	AutoCPAP	23	10 (5)	7 (4)	-1.0	-1.9, 0	0.04	12	A
				Sham CPAP	23	10 (5)	8 (5)					
Jenkinson 1999[140] 10382693 Hack 2000[141] 10679542	nd	17.0 (nd)	4 wk (PL)	AutoCPAP	52	15.5 (nd)	7.0 (nd)	-7.0	-10.5, -3.5 ††	<0.0001	6	B
				Sham CPAP	49	15.0 (nd)	13.0 (nd)					
Siccolli 2008[154] 19014075	nd	15.2 (4.0)	4 wk (PL)	AutoCPAP	50	15.8 (4.0)	6.8 (5.1)	-5.9	-7.8, -3.95	<0.0001	3	B
				Sham CPAP	49	15.0 (4.0)	11.9 (5.9)					
Campos-Rodriguez 2006[133] 16778262	60 (22) [≥10]	13.6 (3.6)	4 wk (PL)	CPAP	34	15.0 (3.9)	11.2 (3.0)	-2.4	-4.0, -0.81 ‡‡	0.003	6	B
				Sham CPAP	34	13.6 (3.6)	12.2 (2.2)					
Barbe 2001[131] 11388814	57 (15) [≥30]	7.0 (2)	6 wk (PL)	CPAP	29	7 (2.2)	8 (3.2)	+1.0	-1.0, 3.0§§	NS	2	B
				Sham CPAP	25	7 (2.0)	8 (5.0)					
Hui 2006[139] 16928705	30 (16) [≥5]	10.7 (3.3)	3 mo (PL)	AutoCPAP	23	10.2 (4.8)	7.0 (4.8)	-0.04	-2.94, 2.86	NS	18	B
				Sham CPAP	23	11.2 (5.5)	8.1 (5.0)					
Egea 2008[136] 17904420	35 (17) [>10]	7.3 (4.5)	3 mo (PL)	CPAP	20	8.6 (3.6)	5.0 (3.6)	-1.9	-4.1, 0.3***	NS	18	B
				Sham CPAP	25	6.9 (4.0)	5.2 (4.0)					
Montserrat 2001[151] 11520724	54 (19) [>10]	16.9 (5.6)	6 wk (PL)	CPAP	23	16.1 (4.8)	6.7 (3.4)	-7.21	-10.1, -4.4 †††	<0.001	6	B
				Sham CPAP	22	16.9 (6.0)	14 (5.5)					
Loredo 2006[146] 16676791 Bardwell 2001[144] 11485111	58 (32) [≥15]	12.3 (6.7)	2 wk (PL)	CPAP	22	11.6 (4.9)	8.2 (4.4)	-1.7	-5.2, 1.8‡‡‡	NS	nd	B
				Sham CPAP	19	12.3 (6.7)	10.6 (6.4)					
Marshall 2005[148] 15860720	22 (nd) [nd]	12.5 (4.3)	3 wk (XO)	CPAP	29	12.5 (4.3)	9.7 (3.8)	-2.4	-4.2, -0.6	0.04	6	B
				Sham CPAP	29	12.5 (4.3)	12.0 (3.8)					

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI	P Btw	Dropout %	Study Quality
Becker 2003[132] 12515745	65 (27) [≥5]	14.1 (3.2)	9 wk (PL)	CPAP	16	14.4 (2.5)	5.1 (3.8)	-4.1	-6.8, -1.4 §§§	0.009	47	C
				Sham CPAP	16	14.1 (3.2)	8.9 (5.0)					

* Change from baseline (SD)
† Change from baseline (SD)
‡ Change from baseline (SD)
§ Estimated from reported P value
** Change from baseline (SD)
†† Estimated from reported data.
‡‡ Estimated from reported data.
§§ Estimated from reported data.
*** Estimated from reported data.
††† Estimated from reported data.
‡‡‡ Estimated from reported data.
§§§ Estimated from reported data

Table 5.2.4. Arousal index (events/hr) in randomized controlled trials of CPAP vs. sham control

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study Quality
Loredo 1999[142] 10593774 Yu 1999[143] 10504011 Bardwell 2001[144] 11485111 Profant 2003[145] 12571548	44 (25) [RDI≥20]	nd	1 wk (PL)	CPAP	23	55.1 (24.4)	1.4 (9.5)	-38.6	-53.5, -23.7*	0.001	14	B
				Sham CPAP	18	48.6 (28.2)	33.5 (23.2)					
Loredo 2006[146] 16676791 Bardwell 2001[144] 11485111	58 (32) [≥15]	12.3 (6.7)	2 wk (PL)	CPAP	22	41 (28.4)	10.5 (1.0)	-27.2	-45.9, -8.4†	<0.001	nd	C
				Sham CPAP	19	43.8 (32.6)	40.5 (8.0)					
Becker 2003[132] 12515745	65 (27) [≥5]	14.1 (3.2)	9 wk (PL)	CPAP	16	58.7 (21.9)	24.1 (9.8)	-13.8	-30.2, 2.6‡	nd	47	C
				Sham CPAP	16	62.0 (28.0)	41.2 (27.2)					

* Estimated from reported data.
† Estimated from reported data.
‡ Estimated from reported data

Table 5.2.5. Sleep efficiency (%TST) in randomized controlled trials of CPAP vs. sham control

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study Quality
Haensel 2007[137] 17503102	58 (30) [≥15]	nd	2 wk (PL)	CPAP	25	80.3 (2.3)	87.5 (1.5)	3.3	2.3, 4.3*	NS	0	B
				Sham CPAP	25	82.0 (1.6)	85.9 (1.6)					
Loredo 1999[142] 10593774 Yu 1999[143] 10504011 Bardwell 2001[144] 11485111 Profant 2003[145] 12571548	44 (25) [RDI≥20]	nd	1 wk (PL)	CPAP	23	83.7 (10.7)	88.1 (8.6)	2.9	-4.1, 9.9†	NS	14	B
				Sham CPAP	18	82.2 (11.8)	83.7 (12.9)					

* Estimated from reported data.
† Estimated from reported data.

Table 5.2.6. Slow wave sleep (% TST) in randomized controlled trials of CPAP vs. sham control

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study Quality
Egea 2008[136] 17904420	35 (17) [>10]	7.3 (4.5)	3 mo (PL)	CPAP	27	7.9 (8.3)	7.2 (10.4)	3.2	-1.9, 8.3*	NS	18	B
				Sham CPAP	29	9.7 (10.2)	5.8 (9.7)					
Loredo 1999[142] 10593774 Yu 1999[143] 10504011 Bardwell 2001[144] 11485111 Profant 2003[145] 12571548	44 (25) [RDI≥20]	nd	1 wk (PL)	CPAP	23	7.4 (8.7)	12.5 (10.6)	-1.6	-8.7, 5.5†	NS	14	B
				Sham CPAP	18	6.3 (8.6)	13.0 (14.5)					
Loredo 2006[146] 16676791 Bardwell 2001[144] 11485111	58 (32) [≥15]	12.3 (6.7)	2 wk (PL)	CPAP	22	5.0 (6.9)	7.1 (6.2)	1.5	-2.2, 5.2‡	NS	nd	B
				Sham CPAP	19	4.1 (5.1)	4.7 (5.8)					
Becker 2003[132] 12515745	65 (27) [≥5]	14.1 (3.2)	9 wk (PL	CPAP	16	6.2 (7.2)	15.2 (7.1)	3.4	-1.8, 8.6§	NS	47	C
				Sham CPAP	16	6.0 (8.4)	11.6 (6.7)					

* Estimated from reported data.
† Estimated from reported data.
‡ Estimated from reported data.
§ Estimated from reported data

Table 5.2.7. REM sleep (% TST) in randomized controlled trials of CPAP vs. sham control

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. Analyzed	Baseline (SD)	Final (SD)	Net Diff or Diff*	95% CI	P Btw	Dropout, %	Study Quality
Egea 2008[136] 17904420	35 (17) [>10]	7.3 (4.5)	3 mo (PL)	CPAP	27	15.7 (9.9)	12.2 (6.2)	-2.8	-6.9, 1.3†	NS	18	B
				Sham CPAP	29	12.9 (7.0)	12.2 (7.0)					
Loredo 1999[142] 10593774 Yu 1999[143] 10504011 Bardwell 2001[144] 11485111 Profant 2003[145] 12571548	44 (25) [RDI≥20]	nd	1 wk (PL)	CPAP	23	19.0 (7.9)	26.2 (7.0)	5.7	0.85, 10.6‡	NS	14	B
				Sham CPAP	18	17.7 (8.0)	19.2 (8.3)					
Loredo 2006[146] 16676791 Bardwell 2001[144] 11485111	58 (32) [≥15]	12.3 (6.7)	2 wk (PL)	CPAP	22	14.3 (6.9)	22 (9.4)	7.5	3.5, 11.5§	<0.05	nd	C
				Sham CPAP	19	15.3 (4.8)	15.5 (4.4)					
Becker 2003[132] 12515745	65 (27) [≥5]	14.1 (3.2)	9 wk (PL)	CPAP	16	11.4 (6.8)	22.3 (5.7)	4.1	-0.8, 9.0**	NS	47%	C
				Sham CPAP	16	14.3 (6.3)	21.1 (8.8)					

* In crossover studies, if only data on the final values and the difference in final values are reported (as opposed to changes from baseline and net change), these data are italicized.
† Estimated from reported data.
‡ Estimated from reported data.
§ Estimated from reported data.
** Estimated from reported data

Table 5.2.8. Maintenance of wakefulness test (min) in randomized controlled trials of CPAP vs. sham control

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. Analyzed	Baseline (SD)	Change (SD)	Net Diff	95% CI	P Btw	Dropout, %	Study Quality
West 2007[157] 17557769	nd	14 (3.5)	3 mo (PL)	AutoCPAP	19	22 (13)*	+10.6 (14)	+15.3	6.5, 24	0.001	5	A
				Sham	21	32 (11)†	-4.7 (12)					
Jenkinson 1999[140] 10382693 Hack 2000[141] 10679542	nd	17.0 (nd)	4 Wk (PL)	AutoCPAP	52	23 (nd)	32.9 (nd)	+6.8	2.0, 11.5‡	0.005	6	B
				Sham	49	20 (nd)	23.5 (nd)					
Marshall 2005[148] 15860720	22 (nd) [nd]	12.5 (4.3)	3 wk (XO)	CPAP	29	20.9 (2.5)	23.1 (10.8)	+5.2	-0.6, 11	0.09	6	B
				Sham	29	20.9 (2.5)	17.9 (10.8)					

* Significantly different between group at baseline
† Significantly different between group at baseline
‡ Estimated from reported data.

Table 5.2.9. FOSQ in randomized controlled trials of CPAP vs. sham control

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. Analyzed	Baseline (SD)	Final (SD)	Net Diff	95% CI	P Btw	Dropout, %	Study Quality
Barbe 2001[131] 11388814	57 (15) [≥30]	7.0 (2)	6 wk (PL)	CPAP	29	102 (16)	108 (11)	+4.0	-3.3, 11.3*	NS	2	B
				Sham CPAP	25	107 (15)	110 (10)					
Montserrat 2001[151] 11520724	54 (19) [>10]	16.9 (5.6)	6 wk (PL)	CPAP	23	85 (22)	109 (13)	+10.48	-2.6, 23.6†	NS	6	B
				Sham CPAP	22	86 (28)	101 (22)					
Marshall 2005[148] 15860720	22 (nd) [nd]	12.5 (4.3)	3 wk (XO)	CPAP	29	12.6 (1.6)	13.6 (1.8)	-0.3	-1.1, 0.5	NS	6	B
				Sham CPAP	29	12.6 (1.6)	13.3 (1.8)					

* Estimated from reported data.
† Estimated from reported data.

Table 5.2.10. Quality of life in randomized controlled trials of CPAP vs. sham control

Author Year PMID	Baseline AHI (SD)	Baseline ESS (SD)	Duration (Design)	Interventions	No. Analyzed	Outcome	Favors*	If Significant Difference Net Diff	95 CI	Test Range "Worst"	"Best"	P Btw	Dropout, %	Study Quality
Smith 2007[155] 17470670	36 (23) [≥15]	10 (5)	6 wk (XO)	AutoCPAP	23	SF-36 PCS	0					NS	12	A
				Sham	23									
						SF-36 MCS	0					NS		
Siccolli 2008[154] 19014075	nd	15.2 (4.0)	4 wk (PL)	AutoCPAP	50	SF-36 PCS	CPAP	8.2	0.4, 16.0†	0	100	0.01	3	B
				Sham CPAP	49									
						SF-36 MCS	CPAP	10.8	2.8, 18.8‡	0	100	0.002		
						Calgary SAQLI total score	CPAP	0.9	0.4, 1.4§	0	7	0.001		
Egea 2008[136] 17904420	35 (17) [>10]	7.3 (4.5)	3 mo (PL)	CPAP	20	SF-36 PCS	0					NS	18	B
				Sham CPAP	25									
						SF-36 MCS	0					NS		
Barbe 2001[131] 11388814	57 (15) [≥30]	7.0 (2)	6 wk (PL)	CPAP	29	SF-36 PCS	0					NS	2	B
				Sham CPAP	25									
						SF-36 MCS	0							
Montserrat 2001[151] 11520724	54 (19) [>10]	16.9 (5.6)	6 wk (PL)	CPAP	23	SF-36 PCS	0					NS	6	B
				Sham CPAP	22									
						SF-36 MCS	0					NS		
Marshall 2005[148] 15860720	22 (nd) [nd]	12.5 (4.3)	3 wk (XO)	CPAP	29	SF-36 PCS	0					NS	6	B
				Sham CPAP	29									
						SF-36 MCS	0					NS		

* The noted intervention statistically significantly favors the patient (net better score on test). 0 = no difference.
† Estimated from reported data.
‡ Estimated from reported data.
§ Estimated from reported data.

Table 5.2.11. Neuropsychological outcomes in randomized controlled trials of CPAP vs. sham control

Author Year PMID	Baseline AHI (SD)	Baseline ESS (SD)	Duration (Design)	Interventions	No. Analyzed	Outcome	Favors*	If Significant Difference Net Diff	95 CI	Test Range "Worst"	"Best"	P Btw	Dropout, %	Study Quality
Barbe 2001[131] 11388814	57 (15) [≥30]	7.0 (2)	6 wk (PL)	CPAP	29	Trial Making A test	0					NS	2	B
				Sham CPAP	25									
						Trial Making B test	0					NS		
						WAIS- Digital symbols	0					NS		
						WAIS- block design	0					NS		
						WAIS- digit span	0					NS		
						WMS- mental control	0					NS		
						WMS- verbal paired associated	0					NS		
						PASAT 1	0					NS		
						PASAT 2	0					NS		
						PASAT 3	0					NS		
						PASAT 4	0					NS		
Haensel 2007[137] 17503102	58 (30) [≥15]	nd	2 wk (PL)	CPAP	25	POMS total score	0					NS	0	B
				Sham CPAP	25									
Loredo 1999[142] 10593774 Yu 1999[143] 10504011 Bardwell 2001[144] 11485111 Profant 2003[145] 12571548	44 (25) [RDI≥20]	nd	11 d (PL)	CPAP	23	POMS- TMD	0					NS	14	B
				Sham CPAP	18									
						All Cognitive tests	0					NS		
						MOS	0					NS		
Loredo 2006[146] 16676791 Bardwell 2001[144] 11485111	58 (32) [≥15]	12.3 (6.7)	2 wk (PL)	CPAP	22	BSI GSI	0					NS	nd	B
				Sham CPAP	19									
						BSI Depression	0					NS		
Mills 2006[149] 16357087 Lim 2007[150] 17694727	61 (33) [>15]	nd	2 wk (PL)	CPAP	17	All neuropsychological tests except the one below	0					NS	nd	B
				Sham CPAP	14									
						Digit Vigilance	CPAP	-15.3	nd			0.02		

Author Year PMID	Baseline AHI (SD)	Baseline ESS (SD)	Duration (Design)	Interventions	No. Analyzed	Outcome	Favors*	If Significant Difference Net Diff	95 CI	Test Range "Worst"	"Best"	P Btw	Dropout, %	Study Quality
Marshall 2005[148] 15860720	22 (nd) [nd]	12.5 (4.3)	3 wk (XO)	CPAP	29	Hospital Anxiety and Depression scale	0					NS	6	B
				Sham CPAP										
Henke 2001[138] 11282765	68 (25) [>10]	16.0 (4.8)	2 wk (PL)	CPAP	27	Trial Making A test	0					NS	0	C
				Sham CPAP	18									
						Trial Making B test	0					NS		
						WAIS- Digital symbols	0					NS		
						WAIS- complex figure	0					NS		
						WAIS- digit span	0					NS		
						Hits on steer clear test	0					NS		

* The noted intervention statistically significantly favors the patient (net better score on test). 0 = no difference.

Table 5.2.12. Blood pressure outcomes (mm Hg) in randomized controlled trials of CPAP vs. sham control

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. Analyzed	Baseline (SD)	Final (SD)	Net Diff	95% CI	P Btw	Dropout, %	Study Quality
MAP												
Coughlin 2007[134] 17251237	40 (14) [>15]	14 (4.9)	6 wk (XO)	AutoCPAP	34	nd	103.1 (8.7)	-5.5	-8.2, -2.8	<0.01	3	A
				Sham	34		108.6 (9.9)					
Robinson 2006[153] 16455835	nd	5.3 (IRQ 3.0-7.0)	1 mo (XO)	AutoCPAP	32	106 (14)	105.6 (13.2)	+1.1*	-2.9, +5.1	NS	9	A
				Sham	32	109 (13)	107.6 (13.6)					
Campos-Rodriguez 2006[133] 16778262	60 (22) [≥10]	13.6 (3.6)	4 wk (PL)	CPAP	34	100.8 (10.7)	99.8 (10.1)	-0.8	-3.1, 4.9	NS	6	B
				Sham CPAP	34	98.9 (10.0)	98.9 (11.2)					
Hui 2006[139] 16928705	30 (16) [≥5]	10.7 (3.3)	3 mo (PL)	AutoCPAP	23	98.9 (10.1)	96.9 (10.1)	-2.2	-6.2, +1.9	NS	18	B
				Sham CPAP	23	98.1 (10.1)	98.3 (11.5)					
Norman 2006[152] 16585412	54 (30) [>15]	12.0 (6.6)	2 wk (PL)	CPAP	18	Change (SD): -3.1 (5.5)		-6.4	-11.1, -1.7†	<0.05	nd	C
				Sham CPAP	15	Change (SD): +3.3 (7.2)						
Becker 2003[132] 12515745	65 (27) [≥5]	14.1 (3.2)	9 wk (PL)	CPAP	16	103.6 (16.1)	93.6 (11.3)	-11.3	-20, -2.7	0.01	47	C
				Sham CPAP	16	103.5 (12.1)	104.8 (10.6)					
SBP												
Coughlin 2007[3194 /id} 17251237	40 (14) [>15]	14 (4.9)	6 wk (XO)	AutoCPAP	34	nd	135.7 (11.7)	-6.7	-10, -1.7	<0.01	3	A
				Sham	34		142.4 (14.0)					
Barbe 2001[131] 11388814	57 (15) [≥30]	7.0 (2)	6 wk (PL)	CPAP	29	130 (10.8)	127 (10.8)	-2	-8.5, 4.5‡	NS	2	B
				Sham CPAP	25	127 (10.0)	124 (10.0)					
Hui 2006[139] 16928705	30 (16) [≥5]	10.7 (3.3)	3 mo (PL)	AutoCPAP	23	129.1 (14.4)	126.8 (14.4)	-2.5	-8.2, +3.2	NS	18	B
				Sham CPAP	23	127.7 (14.4)	128.0 (16.3					

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. Analyzed	Baseline (SD)	Final (SD)	Net Diff	95% CI	P Btw	Dropout, %	Study Quality
Egea 2008[136] 17904420	35 (17) [>10]	7.3 (4.5)	3 mo (PL)	CPAP	20	124.3 (18.8)	124.3 (21.9)	+1.6	-8.9, 12.1§	NS	18	B
				Sham CPAP	25	125.0 (13.5)	123.4 (14)					
Mills 2006[149] 16357087 Lim 2007[150] 17694727	61 (33) [>15]	nd	2 wk (PL)	CPAP	17	155.2 (18.6)	145.1 (21.0)	-8.0	-22.4, 6.4**	nd	nd	B
				Sham CPAP	16	149.0 (23.2)	146.9 (21.2)					
Cross 2008[135] 18390635	63.0 (26) [>15]	nd	6 wk (XO)	AutoCPAP	27	143.0 (17.1)	141 (16.1)	-3.8	-10.5, 2.9††	0.07	13	B
				Sham CPAP	27	143.0 (17.1)	144.8 (19.2)					
Norman 2006[152] 16585412	54 (30) [>15]	12.0 (6.6)	2 wk (PL)	CPAP	18	Change (SD): -2.2 (5.5)		-5.7	-11.2, -0.2‡‡	<0.05	nd	C
				Sham CPAP	15	Change (SD): +3.5 (9.7)						
Becker 2003[132] 12515745	65 (27) [≥5]	14.1 (3.2)	9 wk (PL	CPAP	16	140.1 (17.6)	132.1 (15.7)	-10.3	-20.6, 0.1	0.05	47	C
				Sham CPAP	16	141.0 (13.8)	143.2 (11.2)					
Arias 2005[130] 16009798	44 (28) [≥10]	nd	12 wk (XO)	AutoCPAP	25	127 (50)	127 (40)	0	-18, 18§§	NS	7	C
				Sham CPAP	25	127 (50)	127 (60)					
DBP												
Coughlin 2007[134] 17251237	40 (14) [>15]	14 (4.9)	6 wk (XO)	AutoCPAP	34	nd	86.8 (8.7)	-4.9	-8.0, -1.8	<0.01	3	A
				Sham	34		91.7 (9.3)					
Barbe 2001[131] 11388814	57 (15) [≥30]	7.0 (2)	6 wk (PL)	CPAP	29	82(5.4)	81 (5.4)	-1	-5.4, 3.4***	NS	2	B
				Sham CPAP	25	80 (10.0)	80 (10.0)					
Hui 2006[139] 16928705	30 (16) [≥5]	10.7 (3.3)	3 mo (PL)	AutoCPAP	23	84.3 (10.1)	82.3 (9.6)	-1.8	-5.3, +1.8	NS	18	B
				Sham CPAP	23	83.6 (10.1)	83.4 (9.1)					

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. Analyzed	Baseline (SD)	Final (SD)	Net Diff	95% CI	P Btw	Dropout, %	Study Quality
Egea 2008[136] 17904420	35 (17) [>10]	7.3 (4.5)	3 mo (PL)	CPAP	20	75.6 (10.3)	76.0 (12.5)	-0.8	-8.9, 7.3†††	NS	18	B
				Sham CPAP	25	75.8 (12)	77.0 (18.5)					
Mills 2006[149] 16357087 Lim 2007[150] 17694727	61 (33) [>15]	nd	2 wk (PL)	CPAP	17	84.2 (10.7	79.5 (13.2)	-4.0	-12.5, 4.5‡‡‡	nd	nd	B
				Sham CPAP	16	83.6 (14.0)	82.9 (12.4)					
Cross 2008[135] 18390635	63.0 (26) [>15]	nd	6 wk (XO)	AutoCPAP	27	80.4 (10.5)	82.3 (9.9)	0	-3.5, 3.5§§§	NS	13	B
				Sham CPAP	27	80.4 (10.5)	82.3 (8.8)					
Norman 2006[152] 16585412	54 (30) [>15]	12.0 (6.6)	2 wk (PL)	CPAP	18	Change (SD): -2.6 (4.7)		-5.2	-9.3, -1.1****	<0.05	nd	C
				Sham CPAP	15	Change (SD): +2.6 (6.5)						
Becker 2003[132] 12515745	65 (27) [≥5]	14.1 (3.2)	9 wk (PL	CPAP	16	86.4 (16.1)	75.8 (11.6)	-11.2	-19.5, -2.8	0.01	47	C
				Sham CPAP	16	85.4 (12.3)	85.9 (10.6)					
Arias 2005[130] 16009798	44 (28) [≥10]	nd	12 wk (XO)	AutoCPAP	25	79 (25)	78 (25)	0	-11, 11††††	NS	7	C
				Sham CPAP	25	79 (25)	78 (30)					

* Median
† Estimated from reported data.
‡ Estimated from reported data.
§ Estimated from reported data.
** Estimated from reported data.
†† Estimated from reported data.
‡‡ Estimated from reported data.
§§ Estimated from reported data.
*** Estimated from reported data.
††† Estimated from reported data.
‡‡‡ Estimated from reported data.
§§§ Estimated from reported data.
**** Estimated from reported data.
†††† Estimated from reported data.

Table 5.3.1 Randomized controlled trials of oral vs. nasal CPAP: Study characteristics

Study PMID	Interventions	CPAP pressure* (type)	Mean age, y	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Other quality issues
Anderson 2003[158] 14572126	oral CPAP nasal CPAP	manual (both)	46	nd	43	high BMI	New Zealand (nd)	small sample
Mortimore 1998[159] 9741373	oral CPAP nasal CPAP	manual (separate?)	52	nd	32	-	UK (nd)	study inclusion criteria not stated
Khanna 2003[160] 14592306	oral CPAP nasal CPAP	manual (separate)	52	63	34.6	-	US (2000-01)	incomplete reporting

* Method for choosing CPAP pressure: Manual (during sleep study); Auto (determined with AutoCPAP); Algorithm (by an algorithm); nd (no data reported); NA (not applicable, eg if AutoCPAP is the intervention). In parentheses: Split (CPAP introduced in a split night study); Separate (CPAP introduced on a separate full night than the diagnostic sleep study).

Table 5.3.2 Compliance (mean hr/ night) in randomized controlled trials of oral vs. nasal CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Change (final)	Net diff or diff	95% CI	P Btw	Dropout, %	Study quality
Anderson 2003[158] 14572126	85 (36) [>20]	17 (2.3)	1 mo (XO)	oral CPAP	21	3.5	-0.3	-1.1, 0.5*	0.50	16	B
				nasal CPAP	21	3.8					
Mortimore 1998[159] 9741373	35 (23) [nd]	nd	1 mo (XO)	oral CPAP	20	4.3	-1.0	-1.8, -0.3	0.01	0	C
				nasal CPAP	20	5.3					
Khanna 2003[160] 14592306	60† (39) [>15]	13.3 (3.6)	1 mo (PL)	oral CPAP	21	5.8	0	-0.73, 0.73‡	NS	29	C
				nasal CPAP	17	5.8					
			2 mo (PL)	oral CPAP	15	5.8	0.1	-1.2, 1.4§	NS		
				nasal CPAP	12	5.7					

* Estimated from reported P value
† RDI
‡ Estimated from reported data
§ Estimated from reported data

Table 5.3.3 ESS in randomized controlled trials of oral vs. nasal CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or diff	95% CI	P Btw	Dropout, %	Study quality
Anderson 2003[158] 14572126	85 (36) [>20]	17 (2.3)	1 mo (XO)	oral CPAP	21	17 (2.3)	-10.0	0.7	-1.7, 3.1	0.20	16	B
				nasal CPAP	21	17 (2.3)	-11.0					
Mortimore 1998[159] 9741373	35 (23) [nd]	nd	1 mo (XO)	oral CPAP	20	nd	9.8	1.6	0.38, 2.82*	<0.01	0	C
				nasal CPAP	20	nd	8.2					

* Estimated from reported P value

Table 5.4.1 Randomized controlled trials of autoCPAP vs. CPAP: Study characteristics

Study PMID	Interventions	CPAP Pressure* (type)	Mean Age, y	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Other quality issues
Damjanovic 2009[161] 19129293	autoCPAP CPAP	auto/manual (separate)	57	78	31.1	-	Germany (nd)	
Meurice 2007[164] 17638595	autoCPAP CPAP	auto/manual (separate)	55	nd	30.8	-	France (nd)	pt recruitment unclear
Patruno 2007[167] 17494789	autoCPAP CPAP	manual (separate)	48	81	36.5	some with HTN	Italy (nd)	incomplete reporting
Planes 2003[180] 12683473	autoCPAP CPAP	manual (separate)	54	77	32.4	-	France (1998-99)	pt recruitment unclear
Series 1997[178] 9341056	autoCPAP est./meas. CPAP	manual (separate)	36-65 (range)	nd	36.4	-	Canada (1995-96)	potential selection bias
Fietze 2007[162] 17337881	autoCPAP CPAP	auto/manual (separate)	54	95	30.9	-	Germany (nd)	incomplete reporting; pt selection unclear
Resta 2004[175] 15679008	autoCPAP CPAP	manual (nd)	33	90	36.7	-	Italy (nd)	incomplete reporting
Hukins 2004[170] 15683142	autoCPAP CPAP	manual (nd)	50	87	35.2	-	Australia (nd)	-
Randerath 2001[177] 11254519	autoCPAP CPAP	manual (separate)	55	87	32.4	-	Germany	-
Massie 2003[173] 12406840	autoCPAP CPAP	manual (both)	49	82	32	-	Australia, UK, U.S.	incomplete reporting
To 2008[168] 18197915	autoCPAP CPAP	auto/manual (separate?)	46	nd	28.7	severe OSA	China (nd)	-
Nussbaumer 2006[166] 16537862	autoCPAP CPAP	manual (separate)	49	90	31.1	-	Switzerland (nd)	-
Senn 2003[176] Switzerland 14525804	autoCPAP (2 modes) CPAP	auto/manual (separate)	53	79	33.3	-	Switzerland (nd)	-
Nolan 2007[165] 17326544	autoCPAP CPAP	auto/manual (separate?)	53	90	29.9	-	Ireland (nd)	-
Noseda 2004[174] 15249439	autoCPAP CPAP	manual (separate)	49	96	32.3	high variability in pressure required during 2 wk autoCPAP run-in	Belgium (nd)	-
Hudgel 2000[169] 10947032	autoCPAP CPAP	auto/manual (both)	46	54	42	-	U.S.	incomplete reporting; 35% drop out

Study PMID	Interventions	CPAP Pressure* (type)	Mean Age, y	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Other quality issues
Marrone 2004[172] 15165530	autoCPAP CPAP	auto/manual (separate)	53	95	32.9	-	Italy	small sample & no power calc
Galetke 2008[163] 17148931	autoCPAP CPAP	auto/manual (separate)	56	80	29.3	-	Germany (nd)	incomplete reporting; small sample & no power calc
Hussain 2004[171] 15072173	autoCPAP CPAP	manual (separate)	45	90	35.9	-	Pakistan and Canada (nd)	pt recruitment method unclear; small sample & no power calc
Teschler 2000[179] 10885414	autoCPAP CPAP	manual/auto (separate)	52	100	33.8	-	Germany (nd)	incomplete reporting; small sample; ?power calc

* Method for choosing CPAP pressure: manual (during sleep study), auto (determined with AutoCPAP); Algorithm (by an algorithm); nd = no data reported; NA = not applicable (e.g., if AutoCPAP is the intervention). In parentheses: Split (CPAP introduced in a split night study), Separate (CPAP introduced on a separate full night than the diagnostic sleep study).

Table 5.4.2 Compliance (mean hr/night) in randomized controlled trials of autoCPAP vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or diff	P Btw	Dropout, %	Study quality
Damjanovic 2009[161] 19129293	44 (25) [≥15]	8.8 (5.2)	3 mo (PL)	autoCPAP	46	5.4	0	-0.7, 0.7	nd	8	B
				CPAP	46	5.4					
			9 mo (PL)	autoCPAP	34	5.2	0.1	-0.9, 1.1	nd	22	
				CPAP	44	5.1					
Meurice 2007[164] 17638595	55 (10) [nd]	11.8 (4.9)	3 mo (PL)	autoCPAP (AutoSet)	15	6.0	-0.1	-0.786, 0.586	nd	15	B
				CPAP	14	6.1					
			6 mo (PL)	autoCPAP (AutoSet)	15	6.1	-0.4	-1.28, 0.48	nd	15	
				CPAP	14	6.5					
Patruno 2007[167] 17494789	46 (14) [>20]	15 (2.7)	3 mo (PL)	autoCPAP	15	6.2	0.2	-0.25, 0.65	nd	23	C
				CPAP	16	6.0					
Planes 2003[180] 12683473	59 (17) [≥30]	15.1 (3.9)	2 mo (PL)	autoCPAP	16	4.5	-0.8	nd	NS	14	C
				CPAP	14	5.3					
Series 1997[178] 9341056	44 (20) [nd]	15.5 (4.5)	0.75 mo (PL)	autoCPAP est.	12	nd*	-	-	NS	0	C
				CPAP	12	nd					
				autoCPAP meas.	12	nd†	-	-	NS		
				CPAP	12	nd					
Fietze 2007[162] 17337881	42 (26) [≥10]	nd	1.5 mo (PL)	autoCPAP	20	5.0	0.8	nd	NS	0	C
				CPAP	21	4.2					
Resta 2004[175] 15679008	47 (11) [>30]	13.9 (3.2)	1 mo (PL)	autoCPAP	10	5.2	-0.1	-1.12, 0.92	nd	0	C
				CPAP	10	5.3					
Hukins 2004[170] 15683142	56 (nd)	12.5 (nd)	1–2 mo (XO)	autoCPAP	46	5.05	0.19	-0.062, 0.442‡	0.14	16	B
				CPAP	46	4.86					
Randerath 2001[177] 11254519	35 (26) [≥10]	11.1 (5.1)	1.5 mo (XO)	autoCPAP	52 (46?)	5.26	0	-0.44, 0.44	nd	12	B
				CPAP	52 (46?)	5.26					
Massie 2003[173] 12406840	nd [≥15]	nd	1.5 mo (XO)	autoCPAP	44	5.1	0.58	0.18, 0.99§	0.005	4	B
				CPAP	44	4.52					
To 2008[168] 18197915	54 (nd) [>30]	13.4 (nd)	1 mo (XO)	autoCPAP	41	4.3	0.5	0.02, 0.98**	0.04	5	B
				CPAP	41	3.8					
			2 mo (XO)	autoCPAP	41	4.4	0.7	0.17, 1.23††	0.01		
				CPAP	41	3.7					

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or diff	P Btw	Dropout, %	Study quality
Nussbaumer 2006[166] 16537862	41 (20) [>10]	12.7 (3.3)	1 mo (XO)	autoCPAP	30	5.1	0.3	-0.29, 0.89	nd	12	B
				CPAP	30	4.8					
Senn 2003[176] Switzerland 14525804	46 (23) [>10]	14.2 (3.8)	1 mo (XO)	autoCPAP (Autoset T)	29	5.5	-0.1	nd	NS	7	B
				autoCPAP (AutoAdjust)	29	5.5	-0.1	nd	NS		
				CPAP	29	5.6					
Nolan 2007[165] 17326544	15 (8) [≥5)	12.3 (4.0)	2 mo (XO)	autoCPAP	29	4.9	0	nd	0.94	15	B
				CPAP	29	4.9					
Noseda 2004[174] 15249439	51 (25) [>20]	10.7 (2.4)	2 mo (XO)	autoCPAP	24	5.3	-0.2	-0.89, 0.49	nd	11	B
				CPAP	24	5.5					
Hudgel 2000[169] 10947032	30 (25) [nd]	16.0 (5.0)	3 mo (XO)	autoCPAP	14	6.0	0.5	0.02, 0.98‡‡	<0.04	35	C
				CPAP	19	5.5					
Marrone 2004[172] 15165530	68 (12) [30]	16.3 (5.0)	1 mo (XO)	autoCPAP	22	4.9	0.5	-0.26, 1.26	nd	0	C
				CPAP	22	4.4					
Galetke 2008[163] 17148931	33 (19) [>10]	10.3 (5.7)	2 mo (XO)	autoCPAP	20	6.37	-0.01	-0.82, 0.8	nd	0?	C
				CPAP	20	6.38					
Hussain 2004[171] 15072173	47 (36) [>15]	11.1 (6.4)	1 mo (XO)	autoCPAP	10	4.3	0.6	-0.84, 2.04	nd	0	C
				CPAP	10	3.7					
Teschler 2000[179] 10885414	53 (26) [>20]	nd	2 mo (XO)	autoCPAP	10	6.3	0.2	-0.7, 1.1	nd	0?	C
				CPAP	10	6.1					

* directions of changes were not reported in the study
† directions of changes were not reported in the study
‡ Estimated from reported P value
§ Estimated from reported P value
** Estimated from reported P value
†† Estimated from reported P value
‡‡ Estimated from reported P value

Table 5.4.3 AHI (events/hr) in randomized controlled trials of autoCPAP vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or diff	95% CI*	P Btw	Dropout, %	Study quality
Damjanovic 2009[161] 19129293	44 (25) [≥15]	8.8 (5.2)	3 mo (PL)	autoCPAP	46	41.8 (23.7)	-37.0	1.8	-7.14, 10.74	nd	8	B
				CPAP	46	45.5 (24.4)	-38.8					
			9 mo (PL)	autoCPAP	34	41.8 (23.7)?	-38.2	1.9	-6.86, 10.66	nd	22	
				CPAP	44	45.5 (24.4)?	-40.1					
Meurice 2007[164] 17638595	55 (10) [nd]	11.8 (4.9)	6 mo (PL)	autoCPAP (AutoSet)	15	53.4 (15.1)	-51.1	2.6	-8.88, 14.08	nd	15	B
				CPAP	14	56.1 (21.4)	-53.7					
Patruno 2007[167] 17494789	46 (14) [>20]	15 (2.7)	3 mo (PL)	autoCPAP	15	47.3 (14.7)	-41.3	2.7	-7.01, 12.41	nd	23	C
				CPAP	16	46.0 (14.6)	-44.0					
Planes 2003[180] 12683473	59 (17) [≥30]	15.1 (3.9)	2 mo (PL)	autoCPAP	16	57.5 (16.5)	-49.9	0.7	-10.06, 11.46	nd	14	C
				CPAP	14	61.0 (17.4)	-50.6					
Series 1997[178] 9341056	44 (20) [nd]	15.5 (4.5)	0.75 mo (PL)	autoCPAP est.	12	61.5 (27.9)	nd†	-	-	NS	0	C
				CPAP	12	50.1 (14.5)	nd					
				autoCPAP meas.	12	46.8 (22.3)	nd‡	-	-	NS		
				CPAP	12	50.1 (14.5)	nd					
Fietze 2007[162] 17337881	42 (26) [≥10]	nd	1.5 mo (PL)	autoCPAP	20	43.3 (30.2)	-38.9	0.5	-1.19, 2.19	nd	0	C
				CPAP	21	40.4 (26.1)	-36.5					
Resta 2004[175] 15679008	47 (11) [>30]	13.9 (3.2)	1 mo (PL)	autoCPAP	10	48.0 (14.3)	-39.7	-2.8	-12.96, 7.36	nd	0	C
				CPAP	10	45.3 (10.7)	-36.9					
Randerath 2001[177] 11254519	35 (26) [≥10]	11.1 (5.1)	1.5 mo (XO)	autoCPAP	52 (46?)	35.1 (26)	-30.1	0.7	-0.88, 2.28	nd	12	B
				CPAP	52 (46?)	35.1 (26)	-30.8					

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or diff	95% CI*	P Btw	Dropout, %	Study quality
Massie 2003[173] 12406840	nd [≥15]	nd	1.5 mo (XO)	autoCPAP	44	nd	nd	-1.1	-2.89, 0.69	nd	4	B
				CPAP	44	nd	nd					
Nussbaumer 2006[166] 16537862	41 (20) [>10]	12.7 (3.3)	1 mo (XO)	autoCPAP	30	41.1 (19.7)	-36.5	-0.8	-1.7, 3.3§	nd	12	B
				CPAP	30	41.2 (19.7)	-35.7					
Senn 2003[176] Switzerland 14525804	46 (23) [>10]	14.2 (3.8)	1 mo (XO)	autoCPAP (Autoset T)	29	45.8 (22.6)	-39.8	0.7	-1.26, 2.66	nd	7	B
				autoCPAP (AutoAdjust)	29	45.8 (22.6)	-38.1	2.4	-0.34, 5.14	nd		
				CPAP	29	45.8 (22.6)	-40.5					
Nolan 2007[165] 17326544	15 (8) [≥5)	12.3 (4.0)	2 mo (XO)	autoCPAP	29	14.7 (8)	-12.0	-0.8	-1.89, 0.29**	0.15	15	B
				CPAP	29	14.7 (8)	-11.2					
Galetke 2008[163] 17148931	33 (19) [>10]	10.3 (5.7)	2 mo (XO)	autoCPAP	20	32.9 (19.1)	-27.3	1.0	-0.45, 2.45	nd	0?	C
				CPAP	20	32.9 (19.1)	-28.3					
Hussain 2004[171] 15072173	47 (36) [>15]	11.1 (6.4)	1 mo (XO)	autoCPAP	10	47.2 (35.6)	-34.1	3.5	-1.02, 8.02	nd	0	C
				CPAP	10	47.2 (35.6)	-37.6					
Teschler 2000[179] 10885414	53 (26) [>20]	nd	2 mo (XO)	autoCPAP	10	52.9 (25.6)	-48.9	0.3	-0.29, 0.89	nd	0?	C
				CPAP	10	52.9 (25.6)	-49.2					

* Estimated from reported data
† Directions of changes were not reported in the study
‡ Directions of changes were not reported in the study
§ Actual reported data
** Estimated from reported P value

Table 5.4.4 ESS in randomized controlled trials of autoCPAP vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or diff	95% CI*	P Btw	Dropout, %	Study quality
Damjanovic 2009[161] 19129293	44 (25) [≥15]	8.8 (5.2)	3 mo (PL)	autoCPAP	46	8.5 (5.42)	-2.6	-0.3	-2.32, 1.72	nd	8	B
				CPAP	46	9.3 (4.75)	-2.3					
			9 mo (PL)	autoCPAP	34	8.5 (5.42) ?	-2.6	0.1	-1.92, 2.12	nd	22	
				CPAP	44	9.3 (4.75) ?	-2.7					
Meurice 2007[164] 17638595	55 (10) [nd]	11.8 (4.9)	3 mo (PL)	autoCPAP (AutoSet)	15	12.9 (4.3)	-9.1	-3.3	-6.68, 0.08	NS	15	B
				CPAP	14	10.6 (5.2)	-5.8					
			6 mo (PL)	autoCPAP (AutoSet)	15	12.9 (4.3)	-7.7	-3.0	-6.44, 0.44	NS	15	
				CPAP	14	10.6 (5.2)	-4.7					
Patruno 2007[167] 17494789	46 (14) [>20]	15 (2.7)	3 mo (PL)	autoCPAP	15	15.8 (3.5)	nd	nd	nd	NS	23	C
				CPAP	16	14.1 (1.7)	nd					
Planes 2003[180] 12683473	59 (17) [≥30]	15.1 (3.9)	2 mo (PL)	autoCPAP	16	15.5 (4.7)	-8.0	-0.9	-3.72, 1.92	nd	14	
				CPAP	14	14.7 (3.9)	-7.1					
Series 1997[178] 9341056	44 (20) [nd]	15.5 (4.5)	0.75 mo (PL)	autoCPAP est.	12	17.0 (4.1)	-9.1	-0.8	-4.28, 2.69	nd	0	C
				CPAP	12	16.1 (4.5)	-8.3					
				autoCPAP meas.	12	13.5 (4.7)	-6.5	1.8	-1.78, 5.38	nd		
				CPAP	12	16.1 (4.5)	-8.3					
Fietze 2007[162] 17337881	42 (26) [≥10]	nd	1.5 mo (PL)	autoCPAP	20	nd	nd	nd	nd	NS	0	C
				CPAP	21	nd	nd					
Resta 2004[175] 15679008	47 (11) [>30]	13.9 (3.2)	1 mo (PL)	autoCPAP	10	15.7 (5.1)	-10.5	-2.6	-5.84, 0.64	nd	0	C
				CPAP	10	12.0 (3.2)	-7.9					
Hukins 2004[170] 15683142	56 (nd) [≥5]	12.5 (nd)	1 – 2 mo (XO)	autoCPAP	46	12.5 (nd)	-4.5	-0.2	nd	NS	16	B
				CPAP	46	12.5 (nd)	-4.3					

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or diff	95% CI*	P Btw	Dropout, %	Study quality
Randerath 2001[177] 11254519	35 (26) [≥10]	11.1 (5.1)	1.5 mo (XO)	autoCPAP	52 (46?)	11.1 (5.1)	-3.3	-1	-2.26, 0.26	nd	12	B
				CPAP	52 (46?)	11.1 (5.1)	-2.3					
Massie 2003[173] 12406840	nd [≥15]	nd	1.5 mo (XO)	autoCPAP	44	nd	nd	-1	-2.06, 0.06†	0.065	4	B
				CPAP	44	nd	nd					
To 2008[168] 18197915	54 (nd) [>30]	13.4 (nd)	1 mo (XO)	autoCPAP	41	13.4 (5.76)	-4.9	0.3	-1.46, 2.06	nd	5	B
				CPAP	41	13.4 (5.76)	-5.2					
			2 mo (XO)	autoCPAP	41	13.4 (5.76)	-4.9	0	-1.76, 1.76	nd		
				CPAP	41	13.4 (5.76)	-4.9					
Nussbaumer 2006[166] 16537862	41 (207) [>10]	12.7 (3.29)	1 mo (XO)	autoCPAP	30	12.7 (0.6)	-6.6	0	-1.6, 1.1	nd	12	B
				CPAP	30	12.7 (0.6)	-6.6					
Senn 2003[176] Switzerland 14525804	46 (23) [>10]	14.2 (3.77)	1 mo (XO)	autoCPAP (Autoset T)	29	14.2 (3.77)	-5.2	0.8	-0.49, 2.09	nd	7	B
				autoCPAP (AutoAdjust)	29	14.2 (3.77)	-6.2	-0.2	-1.68, 1.28	nd		
				CPAP	29	14.2 (3.77)	-6.0					
Nolan 2007[165] 17326544	15 (8) [≥5)	12.3 (4.0)	2 mo (XO)	autoCPAP	29	12.3 (4.0)	-3.7	0.9	-0.99, 2.79‡	0.35	15	B
				CPAP	29	12.3 (4.0)	-4.6					
Noseda 2004[174] 15249439	nd [>20]	10.7 (2.4)	2 mo (XO)	autoCPAP	24	10.7 (2.4)	nd	-1	-1.76, -0.24§	<0.01	11	B
				CPAP	24	10.7 (2.4)	nd					
Hudgel 2000[169] 10947032	30 (25) [nd]	16.0 (5.0)	3 mo (XO)	autoCPAP	39	16.0 (5.0)	-7.0	1	-0.96, 2.96	nd	35	C
				CPAP	39	16.0 (5.0)	-8.0					

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or diff	95% CI*	P Btw	Dropout, %	Study quality
Marrone 2004[172] 15165530	68 (12) [30]	16.3 (5.0)	1 mo (XO)	autoCPAP	22	16.3 (5.0)	-12.4	-1	-2.4, 0.4	nd	0	C
				CPAP	22	16.3 (5.0)	-11.4					
Galetke 2008[163] 17148931	33 (19) [>10]	10.3 (5.7)	2 mo (XO)	autoCPAP	20	10.3 (5.7)	-5.4	-1.7	-3.76, 0.36	nd	0	C
				CPAP	20	10.3 (5.7)	-3.7					
Hussain 2004[171] 15072173	47 (36) [>15]	11.1 (6.4)	1 mo (XO)	autoCPAP	10	11.1 (6.4)	-3.1	1.4	-2.2, 5.0	nd	0	C
				CPAP	10	11.1 (6.4)	-4.5					

* Estimated from reported data
† Estimated from reported P value
‡ Estimated from reported P value
§ Estimated from reported P value

Table 5.4.5 Arousal Index (events/hr) in randomized controlled trials of autoCPAP vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or diff	95% CI*	P Btw	Dropout, %	Study quality
Damjanovic 2009[161] 19129293	44 (25) [≥15]	8.8 (5.18)	3 mo (PL)	autoCPAP	46	30.6 (22.4)	-18.3	-0.2	-7.92, 7.52	nd	8	B
				CPAP	46	34.5 (21.0)	-18.1					
				autoCPAP	34	30.6 (22.4)?	-17.7	3.6	-4.09, 11.29	nd	22	
				CPAP	44	34.5 (21.0)?	-21.3					
Planes 2003[180] 12683473	59 (17) [≥30]	15.1 (3.9)	2 mo (PL)	autoCPAP	16	44.4 (19.1)		3.3	-7.14, 12.74	nd	14	C
				CPAP	14	48.5 (14.2)						
Series 1997[178] 9341056	44 (20) [nd]	15.5 (4.5)	0.75 mo (PL)	autoCPAP est.	12	nd	nd†	-	-	NS	0	C
				CPAP	12	nd	nd					
				autoCPAP meas.	12	nd	nd‡	-	-	NS		
				CPAP	12	nd	nd					
Resta 2004[175] 15679008	47 (11) [>30]	13.9 (3.2)	1 mo (PL)	autoCPAP	10	43.1 (11.9)	-35.7	0.1	-8.29, 8.49	nd	0	C
				CPAP	10	43.1 (9.1)	-35.8					
Randerath 2001[177] 11254519	35 (26) [≥10]	11.1 (5.1)	1.5 mo (XO)	autoCPAP	52 (46?)	34 (21.7)	-23.1	-1.7	-3.7, 0.3	nd	12	B
				CPAP	52 (46?)	34 (21.7)	-21.4					
Nolan 2007[165] 17326544	15 (8) [≥5)	12.3 (4)	2 mo (XO)	autoCPAP	29	16.0 (14.0)	-14.0	-3.0	-5.7, -0.29§	0.03	15	B
				CPAP	29	16.0 (14.0)	-11.0					
Galetke 2008[163] 17148931	33 (19) [>10]	10.3 (5.7)	2 mo (XO)	autoCPAP	20	17.6 (9.2)	-4.0	1.0	-2.52, 4.52	nd	0?	C
				CPAP	20	17.6 (9.2)	-5.0					
Hussain 2004[171] 15072173	47 (36) [>15]	11.1 (6.4)	1 mo (XO)	autoCPAP	10	17.3 (17.7)	-11.4	1.0	-2.5, 4.5	nd	0	C
				CPAP	10	17.3 (17.7)	-12.4					

* Estimated from reported data
† Directions of changes were not reported in the study
‡ Directions of changes were not reported in the study
§ Estimated from reported P value

Table 5.4.6 Minimum O_2 saturation (%) in randomized controlled trials of autoPAP vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net Diff or Diff	95% CI*	P Btw	Dropout, %	Study quality
Meurice 2007[164] 17638595	55 (10) [nd]	11.8 (4.9)	6 mo (PL)	AutoCPAP (AutoSet)	15	82.1 (12.8)	0.2	-2.9	-7.1, 7.5	nd	15	B
				CPAP	14	82.3 (9.9)	0.5					
Patruno 2007[167] 17494789	46 (14) [>20]	15 (2.7)	3 mo (PL)	AutoCPAP	15	71.7 (10.6)	16.4	-4.4	-11.8, 3.0	nd	23	C
				CPAP	16	70.0 (11.7)	20.8					
Resta 2004[175] 15679008	47 (11) [>30]	13.9 (3.2)	1 mo (PL)	AutoCPAP	10	72.4 (10.5)	15.9	0.9	-7.4, 9.2	nd	0	C
				CPAP	10	74.1 (10.8)	15.0					
Randerath 2001[177] 11254519	35 (26) [≥10]	11.1 (5.1)	1.5 mo (XO)	AutoCPAP	52 (46?)	81 (8.0)	7.0	-1.0	-2.1, 0.1	nd	12	B
				CPAP	52 (46?)	81 (8.0)	8.0					
Nolan 2007[165] 17326544	15 (8) [≥5)	12.3 (4)	2 mo (XO)	AutoCPAP	29	79 (11.5)	8.5	4.8	-7.4, 17.0†	0.44	15	B
				CPAP	29	79 (11.5)	3.7					
Galetke 2008[163] 17148931	33 (19) [>10]	10.3 (5.7)	2 mo (XO)	AutoCPAP	20	77.8 (8.4)	8.7	-1.8	-3.8, 0.2	nd	0?	C
				CPAP	20	77.8 (8.4)	10.5					
Hussain 2004[171] 15072173	47 (36) [>15]	11.1 (6.4)	1 mo (XO)	AutoCPAP	10	67.8 (12.5)	14.0	-3.9	-7.3, -0.5	nd	0	C
				CPAP	10	67.8 (12.5)	17.9					

* Estimated from reported data
† Estimated from reported P value

Table 5.4.7 Sleep efficiency (%) in randomized controlled trials of autoCPAP vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or diff	95% CI	P Btw	Dropout, %	Study quality
Resta 2004[175] 15679008	47 (11) [>30]	13.9 (3.2)	1 mo (PL)	autoCPAP	10	86.9 (8)	-0.5	-2.5	-8.89, 3.89*	nd	0	C
				CPAP	10	84.2 (4.9)	2					
Nolan 2007[165] 17326544	15 (8) [≥5)	12.3 (4)	2 mo (PL)	autoCPAP	29	79 (9)	4	-1	-4.34, 2.34†	0.39	15	B
				CPAP	29	79 (9)	5					

* Estimated from reported data
† Estimated from reported P value

Table 5.4.8 REM sleep (%) in randomized controlled trials of autoCPAP vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or diff	95% CI	P Btw	Dropout, %	Study quality
Meurice 2007[164] 17638595	55 (10) [nd]	11.8 (4.9)	6 mo (PL)	autoCPAP (AutoSet)	15	18.9 (6.6)	-2.4	-2.9	-7.49, 1.69	nd	15	B
				CPAP	14	19.1 (5.9)	0.5					
Planes 2003[180] 12683473	59 (17) [≥30]	15.1 (3.9)	2 mo (PL)	autoCPAP	16	12.4 (7.0)	4.2	0.5	-5.44, 6.44	nd	14	C
				CPAP	14	13.7 (9.3)	3.7					
Series 1997[178] 9341056	44 (20) [nd]	15.5 (4.5)	0.75 mo (PL)	autoCPAP est.	12	nd	nd*	-	-	NS	0	C
				CPAP	12	nd	nd					
				autoCPAP meas.	12	nd	nd†	-	-	NS		
				CPAP	12	nd	nd					
Resta 2004[175] 15679008	47 (11) [>30]	13.9 (3.2)	1 mo (PL)	autoCPAP	10	15.0 (8.1)	6.7	-2	-10.31, 6.31	nd	0	C
				CPAP	10	15.9 (4.2)	8.7					
Randerath 2001[177] 11254519	35 (26) [≥10]	11.1 (5.1)	1.5 mo (XO)	autoCPAP	52 (46?)	11 (8)	6.0	1	-0.63, 2.63	nd	12	B
				CPAP	52 (46?)	11 (8)	5.0					
Nolan 2007[165] 17326544	15 (8) [≥5)	12.3 (4)	2 mo (XO)	autoCPAP	29	17.6 (5.1)	-0.5	-2.5	-5.11, 0.11‡	0.06	15	B
				CPAP	29	17.6 (5.1)	2.0					
Hussain 2004[171] 15072173	47 (36) [>15]	11.1 (6.4)	1 mo (XO)	autoCPAP	10	15 (7.0)	4.0	-1	-4.72, 2.72	nd	0	C
				CPAP	10	15 (7.0)	5.0					

* Directions of changes were not reported in the study
† Directions of changes were not reported in the study
‡ Estimated from reported P value

Table 5.4.9 Stage 3 or 4 sleep (%) in randomized controlled trials of autoCPAP vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or diff	95% CI*	P Btw	Dropout, %	Study quality
Meurice 2007[164] 17638595	55 (10) [nd]	11.8 (4.9)	6 mo (PL)	autoCPAP (AutoSet)	15	25.5 (14.7)	-4.4	-5.2	-13.51, 3.11	nd	15	B
				CPAP	14	17.1 (7)	0.8					
Series 1997[178] 9341056	44 (20) [nd]	15.5 (4.5)	0.75 mo (PL)	autoCPAP est.	12	nd	nd†	-	-	NS	0	C
				CPAP	12	nd	nd					
				autoCPAP meas.	12	nd	nd‡	-	-	NS		
				CPAP	12	nd	nd					
Resta 2004[175] 15679008	47 (11) [>30]	13.9 (3.2)	1 mo (PL)	autoCPAP	10	19.8 (10.9)	14	7.3	-2.35, 16.95	nd	0	C
				CPAP	10	22.8 (12.5)	6.7					
Randerath 2001[177] 11254519	35 (26) [≥10]	11.1 (5.1)	1.5 mo (XO)	autoCPAP	52 (46?)	14 (11)	0	-1	-3.45, 1.45	NS	12	B
				CPAP	52 (46?)	14 (11)	1.0					
Nolan 2007[165] 17326544	15 (8) [≥5)	12.3 (4)	2 mo (XO)	autoCPAP	29	13.7 (7.8)	1.3	0.3	-3.29, 3.89§	0.87	15	B
				CPAP	29	13.7 (7.8)	1.0					
Hussain 2004[171] 15072173	47 (36) [>15]	11.1 (6.4)	1 mo (XO)	autoCPAP	10	14 (25)	-4.0	-8	-18.32, 2.32	nd	0	C
				CPAP	10	14 (25)	4.0					

* Estimated from reported data
† directions of changes were not reported in the study
‡ directions of changes were not reported in the study
§ Estimated from reported P value

Table 5.4.10 Quality of life and functional outcomes in randomized controlled trials of autoCPAP vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Outcome	Favors	If significant difference Net difference	95% CI	Test range "Worst"	"Best"	P Btw	Dropout, %	Study quality
Meurice 2007[164] 17638595	55 (10) [nd]	11.8 (4.9)	3 mo (PL)	autoCPAP (AutoSet)	15	SF-36-M	0						15	B
				CPAP	14									
						SF-36-P	0							
			6 mo (PL)	autoCPAP (AutoSet)	15	SF-36-M	0						15	
				CPAP	14									
						SF-36-P	0							
Hukins 2004[170] 15683142	56 (nd) [≥5]	12.5 (nd)	2 mo (XO)	autoCPAP	46	SF-36-M	0						16	B
				CPAP	46									
						SF-36-P	0							
Massie 2003[173] 12406840	nd [≥15]	nd	1.5 mo (XO)	autoCPAP	44	SF-36 - MH	autoCPAP	5	0.16, 9.8*	0	100	<0.05	4	B
				CPAP	44									
						SF-36 - vitality	autoCPAP	7	0.6, 13.4†	0	100	<0.05		
						SF-36 – remainder	0							
To 2008[168] 18197915	54.3 (nd) [>30]	13.4 (nd)	1 mo (XO)	autoCPAP	41	SAQLI	0						5	B
				CPAP	41									
			2 mo (XO)	autoCPAP	41	SAQLI	0							
				CPAP	41									
Nussbaumer 2006[166] 16537862	41 (20) [>10]	12.7 (3.3)	1 mo (XO)	autoCPAP	30	SF-36 all	0						12	B
				CPAP	30									
Senn 2003[176] 14525804	46 (23) [>10]	14.2 (3.8)	1 mo (XO)	autoCPAP (Autoset T)	29	SF-36 all	0						7	B
				autoCPAP (AutoAdjust)	29									
				CPAP	29									
						Vigilance (OSLER)	0							
Fietze 2007[162] 17337881	42 (26) [≥10]	nd	1.5 mo (XO)	autoCPAP	20	SF-36 all	0						0	C
				CPAP	21									

* Estimated from reported P value
† Estimated from reported P value

Table 5.5.1 Characteristics of randomized controlled trials of bilevel CPAP vs. CPAP or autoCPAP

Study PMID	Interventions	CPAP pressure* (type)	Mean Age, y	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Other quality issues
Piper 2008[183] 18203817	Bilevel CPAP CPAP	manual (nd)	50	64	53	morbidly obese	Australia (nd)	unclear % of central apnea
Reeves-Hoche 1995[184] 7842204	Bilevel CPAP CPAP	manual (separate)	47	73	39.4	-	US (nd)	differential drop out
Gay 2003[181] 14655921	Bilevel CPAP CPAP	manual (split)	44	81	35.2	-	US (nd)	unclear conduct of randomization
Khayat 2008[182] 18641111	Bilevel CPAP CPAP	manual? (separate)	53	nd	33.6	AHA II or III	US (2005-07)	small sample; possible selection bias
Randerath 2003[185] 12942031	Bilevel CPAP AutoCPAP	manual (separate)	57	85	33.5	intolerance to CPAP	Germany (nd)	assumptions on missing pts unclear

* Method for choosing CPAP pressure: Manual (during sleep study); Auto (determined with AutoCPAP); Algorithm (by an algorithm); nd (no data reported); NA (not applicable, eg if AutoCPAP is the intervention). In parentheses: Split (CPAP introduced in a split night study); Separate (CPAP introduced on a separate full night than the diagnostic sleep study).

Table 5.5.2 Compliance (mean hr/night) in randomized controlled trials of bilevel CPAP vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Compliance (hr/night)	Difference	95% CI	P Btw	Dropout, %	Study quality
Piper 2008[183] 18203817	nd	14.5 (IQR 12-19)	3 mo (PL)	Bilevel CPAP	18	6.1	0.33	-1.8, 1.2	NS	0	B
				CPAP	18	5.8					
Reeves-Hoche 1995[184] 7842204	52 (3) [≥10]	nd	12 mo (PL)	Bilevel CPAP	26	4.9	-0.1	-0.52, 0.32*	NS	25	C
				CPAP	36	5.0					
Gay 2003[181] 14655921	44 (24) [>10]	12 (3.4)	1 mo (PL)	Bilevel CPAP	12	5.6	0	nd	NS	0	C
				CPAP	15	5.6					
Khayat 2008[182] 18641111	32 (16) [>10]	12.6 (6.3)	3 mo (PL)	Bilevel CPAP	13	4.5	0.9	-1.6, 3.4	NS	4	C
				CPAP	11	3.6					
Randerath 2003[185] 12942031	49 (27) [≥10]	12.1 (5.1)	1.5 mo (XO)	Bilevel CPAP	27 (?)	94.4% days used	4.8	-3.14, 12.74†	NS	26	C
				AutoCPAP	27 (?)	89.6% days used					

* Estimated from reported data
† Estimated from reported data

Table 5.5.3 ESS in randomized controlled trials of bilevel CPAP vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or diff	95% CI	P Btw	Dropout, %	Study quality
Piper 2008[183] 18203817	nd	14.5 (IQR 12-19)	3 mo (PL)	Bilevel CPAP	18	14 (IQR 12-19)	-9.0	-2.89	-7.56, 1.78	NS	0	B
				CPAP	18	15 (IQR 8-17)	-6.0					
Gay 2003[181] 14655921	44 (24) [>10]	12 (3.4)	1 mo (PL)	Bilevel CPAP	12	14.2 (3.4)	-6.4	-0.9	-3.88, 2.08*	NS	0	C
				CPAP	15	13.5 (3.4)	-5.5					
Khayat 2008[182] 18641111	32 (16) [>10]	12.6 (6.3)	3 mo (PL)	Bilevel CPAP	13	11.8 (SE 1.8)	-2.6	2.1	-2.7, 6.9	NS	4	C
				CPAP	11	13.5 (SE 1.8)	-4.7					
Randerath 2003[185] 12942031	49 (27) [≥10]	12.1 (5.1)	1.5 mo (XO)	Bilevel CPAP	27 (?)	12.1 (5.1)	-3.7	1.2	-0.63, 3.03†	NS	26	C
				AutoCPAP	27 (?)	12.1 (5.1)	-4.9					

* Estimated from reported data
† Estimated from reported data

Table 5.5.4 Quality of life and functional outcomes in randomized controlled trials of bilevel CPAP vs. CPAP

Study PMID	Baseline AHI (SD)	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Outcome measure	Favors	If significant difference Net difference	95% CI	Test Range "Worst"	"Best"	P Btw	Dropout, %	Study quality
Piper 2008[183] 18203817	nd	14.5 (IQR 12-19)	3 mo (PL)	Bilevel CPAP CPAP	18 18	SF-36 Mental	0						0	B
						SF-36 Physical	0							
Piper 2008[183] 18203817	nd	14.5 (IQR 12-19)	3 mo (PL)	Bilevel CPAP CPAP	18 18	mean of slowest 10% reaction	Bilevel CPAP	net diff of median 0.65				0.03	0	B
						Lapses	0							
						Median (ms)	0							
Gay 2003[181] 14655921	44 (24)	12	1 mo (PL)	Bilevel CPAP CPAP	12 15	FOSQ	0						0	C
Khayat 2008[182] 18641111	32 (16)	12.6 (6.3)	3 mo (PL)	Bilevel CPAP CPAP	13 11	MLHFQ	0						4	C

Table 5.7.1 Characteristics of randomized controlled trials of C-Flex™ vs. CPAP

Study PMID	Interventions	CPAP pressure* (type)	Mean age, y	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Other quality issues
Pepin 2009[189] 19567496	C-Flex CPAP	auto/manual (separate)	56	72	31		France (nd)	
Nilius 2006[188] 17035433	C-Flex CPAP	manual (separate)	57	88	32.7		Germany (nd)	Recruitment unclear
Dolan 2009[187] 18551327	C-Flex CPAP	nd (both)	48	75	34.9		US; Germany (nd)	Incomplete reporting
Leidag 2008[190] 19218664	C-Flex CPAP	manual (separate)	55	73	32		Germany	High drop out rate

* Method for choosing CPAP pressure: Manual (during sleep study); Auto (determined with AutoCPAP); Algorithm (by an algorithm); nd (no data reported); NA (not applicable, eg if AutoCPAP is the intervention). In parentheses: Split (CPAP introduced in a split night study); Separate (CPAP introduced on a separate full night than the diagnostic sleep study).

Table 5.7.2 Compliance (mean hr/night) in randomized controlled trials of C-Flex™ vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Compliance (hr/night)	Difference	95% CI*	P Btw	Dropout, %	Study quality
Pepin 2009[189] 19567496	44 (22) [≥15]	11.6 (5.2)	3 mo (PL)	C-Flex	83	4.98	0.07	-0.4, 0.6	NS	24	B
				CPAP	82	4.91					
Nilius 2006[188] 17035433	53 (21) [>20)	10.5 (nd)	1.75 mo (PL)	C-Flex	25	5.3	0.1	-15.5, 15.7†	0.99	2	B
				CPAP	26	5.2					
Dolan 2009[187] 18551327	52 (28) [≥10]	14.9 (3.6)	6 mo (PL)	C-Flex	92	6.23	0.18	-0.03, 0.39	NS	0?	C
				CPAP	92	6.05					
Leidag 2008[190] 19218664	35 (25) [≥5]	nd	1.5 mo (XO)	C-Flex	25	5.78	-0.05	-0.52, 0.42	NS	40	C
				CPAP	23	5.83					

* Estimated from reported data
† Estimated from reported P value

Table 5.7.3 ESS in randomized controlled trials of C-Flex™ vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff	95% CI	P Btw	Dropout, %	Study quality
Pepin 2009[189] 19567496	44 (22) [≥15]	11.6 (5.2)	3 mo (PL)	C-Flex	83	11.7 (5.1)	-3.9	-0.5	-2.1, 1.1*	NS	24	B
				CPAP	82	11.4 (5.2)	-3.4					
Nilius 2006[188] 17035433	53 (21) [>20)	10.5 (nd)	1.75 mo (PL)	C-Flex	25	10.9 (nd)	-5.1	-1.0	-10.1, 8.1†	NS	2	B
				CPAP	26	10.2 (nd)	-4.1					
Dolan 2009[187] 18551327	52 (28) [≥10]	14.9 (3.6)	6 mo (PL)	C-Flex	92	nd	-6.6	-0.2	-0.7, 0.3‡	NS	0?	C
				CPAP	92	nd	-6.4					

* Estimated from reported data
† Estimated from reported P value
‡ Estimated from reported P value

Table 5.8.1 Randomized controlled trials comparing different aspects of humidification with CPAP or autoCPAP: Study characteristics

Study PMID	Interventions	CPAP pressure* (type)	Mean age, yr	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Other quality issues
Ryan 2009[191] 19961025	Heated humidity + CPAP CPAP	nd (nd)	49	94	34.4	-	Ireland (nd)	-
Neill 2003[194] 12952257	Heated humidity + CPAP CPAP	manual (both)	49	89	34.8	-	New Zealand (nd)	-
Massie 1999[195] 10453869	Heated humidity + CPAP Cold passover humidity + CPAP	manual (both)	44	79	37.6	-	New Zealand (nd)	differential dropouts between arms; washout period used as control
Mador 2005[192] 16236868	Heated humidity + CPAP CPAP + heated humidity as needed only	manual (both)	59	97	36	-	US	unclear analysis
Salgado 2008[193] 18982206	Heated humidity + AutoCPAP AutoCPAP	manual (nd)	56	74	nd	-	Portugal	incomplete reporting

* Method for choosing CPAP pressure: Manual (during sleep study); Auto (determined with AutoCPAP); Algorithm (by an algorithm); nd (no data reported); NA (not applicable, eg if AutoCPAP is the intervention). In parentheses: Split (CPAP introduced in a split night study); Separate (CPAP introduced on a separate full night than the diagnostic sleep study).

Table 5.8.2 Compliance (mean hr/night) in randomized controlled trials comparing different aspects of humidification with CPAP or autoCPAP

Study PMID	Baseline AHI (SD) [minimum]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Compliance (hr/night)	Difference	95% CI	P Btw	Dropout, %	Study Quality
Ryan 2009[191] 19961025	36 (22) [≥10]	12.7 (5)	1 mo (PL)	Heated humidity + CPAP	42	5.21	0	nd	NS	10	B
				CPAP	39	5.21					
Neill 2003[194] 12952257	50 (26) [≥9]	12.1 (5.1)	0.75 mo (XO)	Heated humidity + CPAP	37	5.7	0.4	0.05, 0.76	0.03	12	B
				CPAP	37	5.3					
Massie 1999[195] 10453869	54 (38) [≥10]	nd	0.75 mo (XO)	Heated humidity + CPAP	38	5.52	0.37	nd	NS	19	B
				Cold passover humidity + CPAP	38	5.15					
			0.5 mo (washout as control CPAP)	Heated humidity + CPAP	38	5.52	0.59	0.15, 1.03*	0.008		
				CPAP	38	4.93					
			0.5 mo (washout as control CPAP)	Cold passover humidity + CPAP	38	5.15	0.22	nd	NS		
				CPAP	38	4.93					
Mador 2005[192] 16236868	46 (30) [≥10]	13.5 (5.3)	1 mo (PL)	Heated humidity + CPAP	49	4.3	0	nd	NS	21	C
				CPAP + heated humidity as needed only	49	4.3					
			12 mo	Heated humidity + CPAP	nd	4.3	-0.5	nd	NS		
				CPAP + heated humidity as needed only	nd	4.8					

Study PMID	Baseline AHI (SD) [minimum]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Compliance (hr/night)	Difference	95% CI	P Btw	Dropout, %	Study Quality
Salgado 2008[193] 18982206	28 (20) [nd]	11.6 (6.3)	1 mo (PL)	Heated humidity + AutoCPAP	17	5.3	0.1	nd	NS	22	C
				AutoCPAP	22	5.2					

* Estimated from P value

Table 5.8.3 ESS in randomized controlled trials comparing different aspects of humidification with CPAP or autoCPAP

Study PMID	Baseline AHI (SD) [range]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff*	95% CI	P Btw	Dropout, %	Study quality
Ryan 2009[191] 19961025	36 (22) [≥10]	12.7 (5)	1 mo (PL)	Heated humidity + CPAP	42	13 (6)	-5	-2	nd	NS	10	B
				CPAP	39	12 (5)	-3					
Neill 2003[194] 12952257	50 (26) [≥9]	12.1 (5.1)	0.75 mo (XO)	Heated humidity + CPAP	37	12.1 (5.1)	-8	-0.4	-1.28, 0.48†	0.37	12	B
				CPAP	37	12.1 (5.1)	-7.6					
Massie 1999[195] 10453869	54 (38) [≥10]	nd	0.75 mo (XO)	Heated humidity + CPAP	38	nd	6.2	-1	nd	NS	19	B
				Cold passover humidity + CPAP	38	nd	7.2					
			0.5 mo (washout as control CPAP)	Heated humidity + CPAP	38	nd	6.2	-0.5	nd	NS		
				CPAP	38	nd	6.7					
			0.5 mo (washout as control CPAP)	Cold passover humidity + CPAP	38	nd	7.2	0.5	nd	NS		
				CPAP	38	nd	6.7					
Mador 2005[192] 16236868	46 (30) [≥10]	13.5 (5.3)	1 mo (PL)	Heated humidity + CPAP	49	12.9 (5.2)	-2.4	0.6	nd	NS	21	C
				CPAP + heated humidity as needed only	49	14.1 (5.3)	-3					
			12 mo	Heated humidity + CPAP	nd	12.9 (5.2)	-3.9	1.4	nd	NS		
				CPAP + heated humidity as needed only	nd	14.1 (5.3)	-5.3					

Study PMID	Baseline AHI (SD) [range]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff*	95% CI	P Btw	Dropout, %	Study quality
Salgado 2008[193] 18982206	28 (20) [nd]	11.6 (6.3)	1 mo (PL)	Heated humidity + autoCPAP	17	11.2 (5.8)	-4.3	-0.9	nd	NS	22	C
				autoCPAP	22	11.9 (6.3)	-5.2					

* In crossover studies, if only data on the final values and the difference in final values are reported (as opposed to changes from baseline and net change), these data are italicized.
† Estimated from reported P value

Table 5.9.1 Randomized controlled trials of mandibular devices vs. control: Study characteristics

Study PMID	Interventions	Mean age, yr	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Other quality issues
Bloch 2000[196] 10903249	MAD-1 piece or MAD-2 piece	51	nd	27.4		Switzerland	Patient not blinded, selection bias likely, compliance not accounted for, power not reported, no washout
	No treatment						
Barnes 2004[129] 15201136	Mandibular advancement splint	47	80	31.1		Australia (nd)	
	Placebo tablet						
Kato 2000[197] 10767241	Oral appliance 2 mm, oral appliance 4 mm, or oral appliance 6 mm	49	nd	28.7		Japan (nd)	Interventions not adequately described
	No oral appliance						
Lam 2007[119] 17121868	Conservative management plus MAD	47	79	27.3		Hong Kong (nd)	
	Conservative management						
Petri 2008[198] 18482111	Mandibular advancement appliance	50	81	31.1		Denmark (nd)	
	No treatment						

Table 5.9.2 AHI (events/h) in randomized controlled trials of mandibular devices vs. control

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Bloch 2000[196] 10903249	27 (16) [≥5]	11.9 (3.9)	1 wk (XO)	MAD-1 piece	24	26.7 (3.3)	-18.8	-14.7	-20.0, -9.4*	<0.05	0	B
				No treatment	24	26.7 (3.3)	-4.1					
				MAD-2 piece	24	26.7 (3.3)	-18	-13.9	-19.2, -8.6†	<0.05		
				No treatment	24	26.7 (3.3)	-4.1					
Barnes 2004[129] 15201136	21 (13) [nd]	10.7 (4.1)	3 mo (XO)	Mandibular advancement splint	80	21.3 (1.3, SE)	-16.5	-6.3	-10.1, -2.5‡	0.001	14	B
				Placebo tablet	80	21.3 (1.3, SE)	-7.3					
Lam 2007[119] 17121868	19 (11) [5-40]	12 (5.7)	10 wk (PL)	MAD + conservative management	34	20.9 (1.7, SE)	-10.3	-11.5	-17.0, -6.1§	<0.001	13	B
				Conservative management	33	19.3 (1.9, SE)	1.2					
Petri 2008[198] 18482111	34 (26) [>5]	10.7 (4.6)	4 wk (PL)	Mandibular advancement appliance	27	39.1 (23.8)	-14.1	-13.1	-26.6, 0.4**	nd	9	B
				No treatment	29	34.3 (26.3)	-0.9					
Kato 2000[197] 10767241	nd	nd	8 nights (PL)	Oral appliance 2 mm	37	26.0, ODI	17.3††	-8.7	nd	<0.05	13	C
				No oral appliance	37	26.0	26					
				Oral appliance 4 mm	37	26.0	14.7	-11.3	nd	<0.05		
				No oral appliance	37	26.0	26					
				Oral appliance 6 mm	37	26.0	10.8	-15.2	nd	<0.05		
				No oral appliance	37	26.0	26					

* Estimated from reported data.

† Estimated from reported data.
‡ Estimated from reported P value.
§ Estimated from reported data.
** Estimated from reported data.
†† Median

Table 5.9.3 ESS in randomized controlled trials of mandibular devices vs. control

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Bloch 2000[196] 10903249	27 (16) [≥5]	11.9 (3.9)	1 wk (XO)	MAD-1 piece	24	11.9 (0.8)	9 median	-4.5*	nd	<0.001	0	B
				No treatment	24	11.9 (0.8)	13.5 median					
				MAD-2 piece	24	11.9 (0.8)	9 median	-4.5	nd	<0.001		
				No treatment	24	11.9 (0.8)	13.5 median					
Barnes 2004[129] 15201136	21 (13) [nd]	10.7 (4.1)	3 mo (XO)	Mandibular advancement splint	80	10.7 (0.4)	-1.5	-1	-1.6, -0.4†	0.001	14	B
				Placebo tablet	80	10.7 (0.4)	-0.5					
Lam 2007[119] 17121868	19 (11) [5-40]	12 (5.7)	10 wk (PL)	MAD + conservative management	34	12 (1)	-3	-1	-1.5, -0.5‡	<0.05	13	B
				Conservative management	33	12 (1)	-2					
Petri 2008[198] 18482111	34 (26) [>5]	10.7 (4.6)	4 wk (PL)	Mandibular advancement appliance	27	11.7 (4.3)	-3.3	-2.6	-3.3, 0.1§	<0.05	9	B
				No treatment	29	10.7 (4.6)	-0.7					

* Difference of medians
† Estimated from reported P value.
‡ Estimated from reported data.
§ Estimated from reported data.

Table 5.9.4a Minimum oxygen saturation (%) in randomized controlled trials of mandibular devices vs. control

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Kato 2000[197] 10767241	nd	nd	8 nights (PL)	Oral appliance 2 mm	37	87.2	(89.2) medians	2.0*	nd	<0.05	13	C
				No oral appliance	37		(87.2)					
				Oral appliance 4 mm	37		(89.5)	2.3	nd	<0.05		
				No oral appliance	37		(87.2)					
				Oral appliance 6 mm	37		(89.6)	2.4	nd	<0.05		
				No oral appliance	37		(87.2)					
Lam 2007[119] 17121868	19 (11) [5-40]	12 (5.7)	10 wk (PL)	MAD + conservative management	34	73.8 (1.9, SE)	7.2	5.9	0.1, 11.7†	NS	13	B
				Conservative management	33	76.1 (2.6)	1.3					
Barnes 2004[129] 15201136	21 (13) [nd]	10.7 (4.1)	3 mo (XO)	Mandibular advancement splint	80	86.7 (0.6)	1.1	2.4	1.0, 3.8‡	0.001	14	B
				Placebo tablet	80	86.7 (0.6)	-1.3					

* Differences between final median values.
† Estimated from reported data
‡ Estimated from reported P value.

Table 5.9.4b Arousal Index (events/h) in randomized controlled trials of mandibular devices vs. control

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Bloch 2000[196] 10903249	27 (16) [≥5]	11.9 (3.9)	1 wk (XO)	MAD-1 piece	24	36 (4.3)	26.5	-14.5	-22.6, -6.4*	<0.05	0	B
				No treatment	24	36 (4.3)	41					
				MAD-2 piece	24	36 (4.3)	30.9	-10.1	-17.9, -2.3†	NS		
				No treatment	24	36 (4.3)	41					
Barnes 2004[129] 15201136	21 (13) [nd]	10.7 (4.1)	3 mo (XO)	Mandibular advancement splint	80	22.0 (1.2)	1.8	-1.4	-3.6, 0.8‡	NS	14	B
				Placebo tablet	80	22.0 (1.2)	3.2					
Lam 2007[119] 17121868	19 (11) [5-40]	12 (5.7)	10 wk (PL)	MAD + conservative management	34	24.5 (2.2)	-2.9	-8.2	-14.8, -1.6§	<0.05	13	B
				Conservative management	33	23.5 (2.2)	5.3					

* Estimated from reported data.
† Estimated from reported data.
‡ Estimated from reported data.
§ Estimated from reported data.

Table 5.9.4c Sleep Efficiency (%) in randomized controlled trials of mandibular devices vs. control

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Bloch 2000[196] 10903249	27 (16) [≥5]	11.9 (3.9)	1 wk (XO)	MAD-1 piece	24	85 (2)	3	-1	-4.9, 2.9*	NS	0	B
				MAD-2 piece	24	85 (2)	4	0	-3.4, 3.4†	NS		
				No treatment	24	85 (2)	4					
Barnes 2004[129] 15201136	21 (13) [nd]	10.7 (4.1)	3 mo (XO)	Mandibular advancement splint	80	79.5 (1.1)	2.5	1.3	-0.6, 3.2‡	NS	14	B
				Placebo tablet	80	79.5 (1.1)	1.2					

* Estimated from reported data.
† Estimated from reported data.
‡ Estimated from reported data

Table 5.9.4d Slow Wave Sleep (%) in randomized controlled trials of mandibular devices vs. control

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Bloch 2000[196] 10903249	27 (16) [≥5]	11.9 (3.9)	1 wk (XO)	MAD-1 piece	24	nd	18	nd	nd	<0.05	0	B
				MAD-2 piece	24	nd	16	nd	nd	NS		
				No treatment	24	nd	12					
Barnes 2004[129] 15201136	21 (13) [nd]	10.7 (4.1)	3 mo (XO)	Mandibular advancement splint	80	17.9 (1.2)	2.8	0.6	-0.6, 3.8*	NS	14	B
				Placebo tablet	80	17.9 (1.2)	2.2					

* Estimated from reported data

Table 5.5.4e REM sleep (%) in randomized controlled trials of mandibular devices vs. control

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Bloch 2000[196] 10903249	27 (16) [≥5]	11.9 (3.9)	1 wk (XO)	MAD-1 piece	24	13 (1)	2	1	-1.0, 3.0*	NS	0	B
				MAD-2 piece	24	13 (1)	3	2	0.04, 4.0†	NS		
				No treatment	24	13 (1)	1					
Barnes 2004[129] 15201136	21 (13) [nd]	10.7 (4.1)	3 mo (XO)	Mandibular advancement splint	80	18.8 (0.7)	0.1	0.9	-0.3, 2.1‡	NS	14	B
				Placebo tablet	80	18.8 (0.7)	1					
Petri 2008[198] 18482111	34 (26) [>5]	10.7 (4.6)	4 wk (PL)	Mandibular advancement appliance	27	18.4 (5.6)	0.3	-0.7	-2.1, 2.4§	nd	9	B
				No treatment	29	17.5 (6.2)	1					

* Estimated from reported data.
† Estimated from reported data.
‡ Estimated from reported data.
§ Estimated from reported data.

Table 5.9.5 Quality of life outcomes in randomized controlled trials of mandibular devices vs. control

Study PMID	Baseline AHI (SD)	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Outcome	Favors	If Significant Difference Net Diff	95% CI	Test Range "Worst"	"Best"	P Btw	Dropout, %	Study quality
Barnes 2004[129] 15201136	21 (13) [nd]	10.7 (4.1)	3 mo (XO)	Mandibular advancement splint	80	Beck Depression Inventory	0						14	B
				Placebo tablet	80									
						FOSQ social domain outcome	0							
Lam 2007[119] 17121868	19 (11) [5-40]	12 (5.7)	10 wk (PL)	Conservative management plus MAD	34	SAQLI-social interactions, treatment-related symptoms	0						13	B
				Conservative management	33									
						SAQLI score*	Conservative management plus MAD	0.7	0.6, 0.8†	1	7	<0.001		
						SF-36 All	0							

* Domain A-D, not including treatment-related symptoms
† Estimated from reported data

Table 5.10.1 Randomized controlled trials of mandibular advancement devices vs. inactive oral devices: Study characteristics

Study PMID	Interventions	Mean age, yr	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Major quality issues
Hans 1997[199] 9155816	MAD Sham oral appliance	51	83	29	--	US (nd)	Blinding not reported; no power analysis; dropout rate 30%
Johnston 2002[202] 12143089	MAD MAD Placebo	55	81	32	--	Ireland (nd)	
Mehta 2001[204] 11371418	MAD Lower dental plate	48	79	29	--	Australia (nd)	Blinding not reported
Naismith 2005[203] 17564405 Gotsopoulos 2002[200]12204875 Gotsopoulos 2004[201]15453552	MAD Single upper plate	48	81	29	--	Australia (nd)	
Petri 2008[198] 18482111	MAD Non-advancement MAD	50	81	31	--	Denmark (nd)	

Table 5.10.2 AHI (events/hr) in randomized controlled trials of mandibular advancement devices vs. inactive oral devices

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Outcome	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Johnston 2002[202] 12143089	31 (nd) [nd]	30.7 (nd)	4-6 wk (X0)	AHI	MAD	20	31.9 (21.2)	-9.07	-14.8	-26.2, -3.4	0.011	5	B
					MAD Placebo	20	31.9 (21.18)	5.75					
Mehta 2001[204] 11371418	27 (17) [10-68]	nd	1 wk (XO)	AHI	MAD	24	27 (17)	-13	-16	-24.1,-7.9*	<0.0001	14	B
					Lower dental plate	24	27 (17)	3					
Naismith 2005[203] 17564405 Gotsopoulos 2002[200] 12204875 Gotsopoulos 2004[201] 15453552	25 (13) [≥10]	11.0 (5)	4 wk (X0)	AHI	MAD	73	26.9 (15.4)	-14.7	-13.2	-21.1, -5.3†	<0.001	0	B
					Single upper plate	73	26.9 (15.4)	-1.5					
Petri 2008[198] 18482111	35 (nd) [>5]	11.0 (nd)	4 wk (PL)	AHI	MAD	27	39.1 (23.8)	-14.1	-13.1	-26.0, 0.0‡	<0.05	9	B
					Non-advancement MAD	25	32.6 (22)	-0.9					
Hans 1997[199] 9155816	RDI 36 (43) [RDI <30]	12.5 (5.7)	2 wk (X0)	RDI	MAD-A	17	28.4 (21.1)	-14.5	-24.8	-41.9, -7.6§	<0.0045	29	C
					Sham oral	17	43.7 (46.8)	10.3					

* Estimated from reported P value
† Estimated from reported P value
‡ Estimated from reported P value
§ Estimated from reported P value

Table 5.10.3 ESS in randomized controlled trials of mandibular advancement devices vs. inactive oral devices

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Johnston 2002 [202] 12143089	31 (nd) [nd]	30.7 (nd)	4-6 wk (X0)	MAD	18	13.9 (6.39)	-2.29	-0.94	-3.32,1.43	NS	5	B
				MAD Placebo	18	13.9 (6.39)	-1.34					
Naismith 2005[203] 17564405 Gotsopoulos 2002[200] 12204875 Gotsopoulos 2004[201] 15453552	25 (13) [≥10]	11.0 (5.0)	4 wk (X0)	MAD	73	10.9 (4.8)	-3.8	-2	-3.1, -0.8*	<0.001	0	B
				Single upper plate	73	10.9 (4.8)	-1.8					
Petri 2008[198] 18482111	35 (nd) [>5]	11.0 (nd)	4 wk (PL)	MAD	27	11.7 (4.3)	-3.3	-2.1†	-4.4,0.2‡	nd	9	B
				Non advancement MAD	25	10.8 (4.6)	-1.2					
Hans 1997[199] 9155816	RDI 36 (43) [RDI <30]	12.5 (5.7)	2 wk (X0)	MAD-A	17	12.1 (3.9)	-3.8	-3.3	-6.4,-0.2§	NS	29	C
				Sham oral	17	13.0 (4.5)	-0.5					

* Estimated from reported P value
† Estimated from reported P value
‡ Estimated from reported data
§ Estimated from reported P value .our estimates does not match reported NS

Table 5.10.4 Minimum oxygen saturation (%) in randomized controlled trials of mandibular advancement devices vs. inactive oral devices

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Mehta 2001[204] 11371418	27 (17) [10-68]	nd	1 wk (XO)	MAD	24	85 (8)	6	4	1.9, 6.0*	<0.0001	14	B
				Lower dental plate	24	85 (8)	2					
Naismith 2005[203] 17564405	25 (13) [≥10]	11.0 (5.0)	4 wk (X0)	MAD	73	85.7 (5.6)	3	2.3	0.5, 4.0†	<0.01	0	B
Gotsopoulos 2002[200] 12204875 Gotsopoulos 2004[201] 15453552				Single upper plate	73	85.7 (5.6)	0.7					

* Estimated from reported P value
† Estimated from reported P value

Table 5.10.5 Arousal index (events/hr) in randomized controlled trials of mandibular advancement devices vs. inactive oral devices

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Mehta 2001[204] 11371418	27 (17) [10-68]	nd	1 wk (XO)	MAD	24	nd	27	-14	-21.1, -6.6*	<0.0001	14	B
				Lower dental plate	24	nd	41					
Naismith 2005[203] 17564405 Gotsopoulos 2002[200] 12204875 Gotsopoulos 2004[201] 15453552	25 (13) [≥10]	11.0 (5.0)	4 wk (X0)	MAD	73	35 (13.5)	-10	-8.1	-12.4, -3.2†	<0.001	0	B
				Single upper plate	73	35 (13.5)	-1.9					

* Estimated from reported P value
† Estimated from reported P value

Table 5.10.6 Sleep efficiency (%) in randomized controlled trials of mandibular advancement devices vs. inactive oral devices

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Mehta 2001[204] 11371418	27 (17) [10-68]	nd	1 wk (XO)	MAD	24	nd	85	-2	nd	nd	14	B
				Lower dental plate	24	nd	87					
Naismith 2005[203] 17564405 Gotsopoulos 2002[200] 12204875 Gotsopoulos 2004[201] 15453552	25 (13) [≥10]	11.0 (5.0)	4 wk (X0)	MAD	73	80.6 (12)	3	1.8	-2.1, 5.6*	nd	0	B
				Single upper plate	73	80.6 (12)	1.2					

* Estimated from reported data

Table 5.10.7 REM and slow wave sleep (%) in randomized controlled trials of mandibular advancement devices vs. inactive oral devices

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Outcome	Interventions	No. analyzed	Baseline (SD)	Change (Final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Mehta 2001[204] 11371418	27 (17) [10-68]	nd	1 wk (XO)	REM	MAD	24	nd	21	5	1.5, 8.5*	<0.005	14	B
					Lower dental plate	24	nd	16					
Petri 2008[198] 18482111	35 (nd) [>5]	11.0 (nd)	4 wk (PL)	REM	MAD	27	18.4 (5.6)	0.3	-0.4	-3.7, 2.9†	nd	9	B
					Non-advancement MAD	25	16.8 (7.5)	0.7					
				Stage 3	MAD	27	7 (5)	2.1	2.9	0.1, 5.7‡	nd		
					Non-advancement MAD	25	9.9 (5.1)	-0.8					
				Stage 4	MAD	27	10.2 (10.5)	2.2	-1.2	-6.6, 4.2§	nd		
					Non-advancement MAD	25	9.6 (10.3)	3.4					

* Estimated from reported P value
† Estimated from reported data
‡ Estimated from reported P value
§ Estimated from reported data

Table 5.10.8 Other outcomes (see 5th column) in randomized controlled trials of mandibular advancement devices vs. inactive oral devices

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Outcome	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Naismith 2005[203] 17564405 Gotsopoulos 2002[200] 12204875 Gotsopoulos 2004[201] 15453552	25 (13) [≥10]	11.0 (5.0)	4 wk (X0)	MSLT	MAD	73	nd	10.3(0.5)	nd	nd	0.01	0	B
					Single upper plate	73	nd	9.1(0.5)					
				24 hour systolic BP	MAD	61	127.3 (1.3)*	-2.1	-1.5	-3.0, -0.0†	0.05		
					Single upper plate	61	127.3 (1.3)‡	-0.6					
				24 hour diastolic BP	MAD	61	77 (0.9)§	-1.3	-1.6	-2.5, -0.6**	0.001		
					Single upper plate	61	77 (0.9)††	0.3					

* Mean(SE)
† Estimated from reported P value
‡ Mean(SE)
§ Mean(SE)
** Estimated from reported P value
†† Mean(SE)

Table 5.10.9 Functional Outcomes in randomized controlled trials of mandibular advancement devices vs. inactive oral devices

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Outcome	Favors	If Significant Difference Net diff	95% CI	Test Range "Worst"	"Best"	P Btw	Dropout, %	Study quality
Petri 2008[198] 18482111	35 (nd) [>5]	11.0 (nd)	4 wk (PL)	MAD	27	SF-36 Vitality*	MAD	18.7	nd	0	100	0.001	9	B
				Nonadvance-ment MAD	25									
Naismith 2005[203] 17564405 Gotsopoulos 2002[200] 12204875 Gotsopoulos 2004[201] 15453552	25 (13) [≥10]	11.0 (5.0)	4 wk (X0)	MAD	73	Neuro-psychological† (speed/vigilance-Choice reaction time)	MAD	-0.019	nd			0.001	0	B
				Single upper plate	73									
						Beck Depression inventory (somatic items)‡	MAD	-0.6	nd			<0.05		

*P value for all other domains Not Significant
† P value for other Neuropschological tests Not Significant. See appendix
‡ P value for other items on Beck Depression Inventory Not significant

Table 5.11.1 Randomized controlled trials of mandibular advancement devices vs. mandibular advancement devices: Study characteristics

Study PMID	Interventions	Mean age, yr	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Major quality issues
Campbell 2009[214] 18989715	MAD objective* MAD subjective†	47	86	28.0	BMI<35 Kg/m^2	New Zealand (nd)	-
Deane 2009[217] 19480232	MAD TSD	49	59	29.3		Australia (nd)	-
Dort 2008[218] 18461376	Suction TRD Non suction TRD	48	69	29.4		Canada (nd)	-
Vanderveken 2008[216] 17673699	MAD_{cm}‡ MAD_{tp}**	47	84	28.0	SDB, history of surgery§	Belgium (2003-04)	-
Walker Engstrom 2003[215] 14569523	50% MAD†† 75% MAD‡‡	46	100	30.2	--	Sweden 1998-2000)	-

* "objective adjustment" at 3 weeks following PSG-based feedback
† self-adjustment of mandibular advancement device during the entire study duration (6 weeks)
‡ Custom made mandibular advancement device
§ Some patients had refused CPAP treatment and others had a history of unsuccessful UPPP
** Pre- molded thermoplastic mandibular advancement device
†† 50% mandibular advancement (mean mandibular advancement 5.0 mm)
‡‡ 75% of mandibular advancement (mean mandibular advancement 7.2 mm)

Table 5.11.2 AHI (events/hr) in randomized controlled trials of mandibular advancement devices vs. mandibular advancement devices

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95 % CI	P Btw	Dropout, %	Study quality
Campbell 2009[214] 18989715	25 (7) [10-40]	11.6 (4.7)	6 wk (PL)	MAD objective*	12	26.6 (12)	-14.9	-3.8	-11.4, 3.9†	nd	6	B
				MAD subjective‡	16	25.4 (7.4)	-11.1					
Vanderveken 2008[216] 17673699	13 (11) [<40]	8.0 (5.0)	4 mo (XO)	MAD_{cm}§	23	14 (12)	-8	-5	-8.5, -1.5**	nd	8	B
				MAD_{tp}††	23	14 (12)	-3					
Walker Engstrom 2003[215] 14569523	50 (4) [≥20]	11.5 (3.1)	6 mo (PL)	50% MAD‡‡	37	47.0 (5.1)	-29.6	5.2	2.7,7.6§§	NS	8	B
				75% MAD***	40	50.4 (4.7)	-34.8					

* objective adjustment at 3 weeks following PSG-based feedback
† Estimated from reported data
‡ self-adjustment of mandibular advancement device during the entire study duration (6 weeks)
§ Custom made mandibular advancement device
** Estimated from reported data
†† Pre- molded thermoplastic mandibular advancement device
‡‡ 50% mandibular advancement (mean mandibular advancement 5.0 mm)
§§ Estimated from reported data; our estimates do not match with reported NS
*** 75% of mandibular advancement (mean mandibular advancement 7.2 mm)

Table 5.11.3 AHI (events/hr) in randomized controlled trials of mandibular advancement devices vs. mandibular advancement devices

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Outcome	Interventions	n Event	N Total	Outcome Metric	Result*	95% CI	P Btw	Dropout, %	Study Quality
Campbell 2009[214] 18989715	25 (7) [10-40]	11.6 (4.7)	6 wk (PL)	AHI<5	MAD objective†	3.9	12	%	33.0 vs.12.5	nd	NS	6	B
					MAD subjective‡	1.9	16						
				Improvement Percentage§	MAD objective**	5.0	12	%	42.0 vs. 56.2	nd	NS		
					MAD subjective††	8.9	16						
				Failure percentage‡‡	MAD objective§§	3.0	12	%	25.0 vs. 31.2	nd	NS		
					MAD subjective***	4.9	16						

* Top row intervention vs. bottom row intervention.
† objective adjustment at 3 weeks following PSG-based feedback
‡ self-adjustment of mandibular advancement device during the entire study duration (6 weeks)
§ >50% reduction in AHI but still >5/hr
** objective adjustment at 3 weeks following PSG-based feedback
†† self-adjustment of mandibular advancement device during the entire study duration (6 weeks)
‡‡ AHI decreased by <50%
§§ objective adjustment at 3 weeks following PSG-based feedback
*** self-adjustment of mandibular advancement device during the entire study duration (6 weeks)

Table 5.11.4 ESS in randomized controlled trials of mandibular advancement devices vs. mandibular advancement devices

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Campbell 2009[214] 18989715	25 (7) [10-40]	11.6 (4.7)	6 wk (PL)	MAD objective*	12	11.0(5.3)	-1.5	2.3	-1.4, 6.0†	nd	6	B
				MAD subjective‡	16	11.6(4.7)	-3.8					
Vanderveken 2008[216] 17673699	13 (11) [<40]	8 (5)	4mo (XO)	MAD_{cm}§	23	7(5)	-2	0	-1.6, 1.6**	nd	8	B
				MAD_{tp}††	23	7(5)	-2					
Walker Engstrom 2003[215] 14569523	50 (4) [≥20]	11.5 (3.1)	6 mo (PL)	50% MAD‡‡	37	11.7(3.1)	-3.1	0.9	-0.4, 2.2	nd	8	B
				75% MAD§§	40	11.5(3.1)	-4					

* objective adjustment at 3 weeks following PSG-based feedback
† Estimated from reported data
‡ self-adjustment of mandibular advancement device during the entire study duration (6 weeks)
§ Custom made mandibular advancement device
** Estimated from reported data
†† Pre- molded thermoplastic mandibular advancement device
‡‡ 50% mandibular advancement (mean mandibular advancement 5.0 mm)
§§ 75% of mandibular advancement (mean mandibular advancement 7.2 mm)

Table 5.11.5 other outcomes reported in randomized controlled trials of mandibular advancement devices vs. mandibular advancement devices

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Outcome	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Campbell 2009[214] 18989715	25 (7) [10-40]	11.6 (4.7)	6wk (PL)	Arousal index	MAD objective*	12	33.6(10)	-9.4	0.5	-7.3,8.3†	nd	6	B
					MAD subjective‡	16	32.1(13.3)	-9.9					
Vanderveken 2008[216] 17673699	13 (11) [<40]	8 (5)	4 mo (XO)	Minimum oxygen saturation	MAD_{cm}§	23	83 (7)	-1	0	-3.2,3.2**	nd	8	B
					MAD_{tp}††	23	83 (7)	-1					
				Sleep efficiency	MAD_{cm}‡‡	23	78(11)	2	-1	-5.7,3.7§§	nd		
					MAD_{tp}***	23	78(11)	3					

* objective adjustment at 3 weeks following PSG-based feedback
† Estimated from reported data
‡ self-adjustment of mandibular advancement device during the entire study duration (6 weeks)
§ Custom made mandibular advancement device
** Estimated from reported data
†† Pre- molded thermoplastic mandibular advancement device
‡‡ Custom made mandibular advancement device
§§ Estimated from reported data
*** Pre- molded thermoplastic mandibular advancement device

Table 5.11.6 Outcomes randomized controlled trials of mandibular advancement devices vs. tongue retaining devices

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Outcome	Interventions	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff or Diff	95% CI	P Btw	Dropout, %	Study Quality
Deane 2009[217] 19480232	27.0(nd) [>10]	nd	1 wk (XO)	AHI	MAD	22	27 (17)	-15	-1	-9.7, 7.7*	nd	19	B
					TSD	22	27 (17)	-14					
				Minimum O_2 sat	MAD	22	84 (7)	3	-1	-4.7, 2.7†	nd		
					TSD	22	84 (7)	4					
				Arousal index	MAD	22	33 (16)	-12	0	nd	nd		
					TSD	22	33 (16)	-12					
				Sleep efficiency	MAD	22	80 (11)	-2	-1	-8.7, 6.7‡	nd		
					TSD	22	80 (11)	-1					
				REM	MAD	22	nd	18	1	nd	NS		
					TSD	22	nd	17					

* Estimated from reported data
† Estimated from reported data
‡ Estimated from reported data

Table 5.11.7 Outcomes randomized controlled trials of tongue retaining devices vs. tongue retaining devices

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Outcome	Interventions	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff or Diff	95% CI	P Btw	Dropout, %	Study Quality
Dort 2008[218] 18461376	nd [RDI 5-30]	12.4 (nd)	1 wk (XO)	SQALI	Suction TRD	32	3.9 (1.2)	0.3	0.28	-0.93,0.31	NS	nd	C
					Non suction TRD	32	3.9 (1.2)	0					
				AHI	Suction TRD	32	15.5(17.6)	-6.6	-4.9	-8.9,-0.85	0.019		
					Non suction TRD	32	15.5(17.6)	-2.0					
				ESS	Suction TRD	32	12.4(4.5)	-1.5	0.65	-0.47, 1.8	NS		
					Non suction TRD	32	12.4(4.5)	-21					

Table 5.12.1 Randomized controlled trials of mandibular advancement devices vs. CPAP: Study characteristics

Study PMID	Interventions	CPAP pressure* (type)	Mean age, yr	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Major quality issues
Barnes 2004[129] 15201136	MAD (Medical Dental Sleep Appliance) CPAP	nd (nd)	47	80	31.1	Excluded diabetes	Australia (nd)	
Clark 1996[205] 8769497	MAD, custom CPAP	nd (separate)	47	100	28.1	--	Israel (1991-92)	Failed crossover design
Engleman 2002[206] 12231497	MAD, custom CPAP	nd (split)	46	75	nd	--	UK (nd)	
Ferguson 1996[207] 8625679	MAD (Snore-Guard) CPAP	nd (separate)	46	88	30.4	--	Canada (1991-94)	
Gagnadoux 2009[208] 19324954	MAD (AMC) CPAP	manual (split)	50	61	26.7	--	France (nd)	
Hoekema 2007[212] 17081222 Hoekema 2008[211] 18719218	MAD (Thornton Adjustable Positioner) CPAP	nd (separate)	49	89	33.3	--	Netherlands (2002-05)	
Lam 2007[119] 17121868	MAD, custom CPAP	nd (nd)	45	78	27.5	Excluded previous surgery	Hong Kong (nd)	
Randerath 2002[209] 12171833	MAD (Hinz IST) CPAP	manual (nd)	57	80	31.2	--	Germany (1999)	
Skinner 2004[213] 14718430	Cervicomandibular support collar AutoCPAP	auto (nd)	49	80	34.1	--	New Zealand (nd)	Study stopped with ½ sample size due to lack of objective benefit
Tan 2002[210] 12143088	MAD, custom CPAP	manual (nd)	51	83	31.9	Excluded recent CVD	UK (nd)	

* Method for choosing CPAP pressure: Manual (during sleep study); Auto (determined with AutoCPAP); Algorithm (by an algorithm); nd (no data reported); NA (not applicable, eg if AutoCPAP is the intervention). In parentheses: Split (CPAP introduced in a split night study); Separate (CPAP introduced on a separate full night than the diagnostic sleep study).

Table 5.12.2 Treatment response in randomized controlled trials of mandibular advancement devices vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Outcome (subgroup)	Interventions	n Event	N Total	Metric	Result*	95% CI	P Btw	Dropout, %	Study quality
Hoekema 2008[211] 18719218	40 (28) [≥5]	14.2 (5.6)	78 d [IQR 60-88 d] (PL)	Effective Treatment† (Total)	MAD	39	51	RD	-6.2%	-22, 9.4	NS	4	B
					CPAP	43	52						
				(AHI≤30)	MAD	21	25	RD	+4.0%	-18, 25	NS		
					CPAP	20	25						
				(AHI>30)	MAD	18	26	RD	-1.6%	-37, 6.8	NS		
					CPAP	23	27						
				AHI<5 (Total)	MAD	29	51	RD	-20.0%	-37, -1.9	0.02‡		
					CPAP	40	52						
				(AHI≤30)	MAD	21	25	RD	+4.0%	-18, 25	NS		
					CPAP	20	25						
				(AHI>30)	MAD	8	26	RD	-43.3%	-62, -17	<0.001§		
					CPAP	20	27						
				AHI<10** (Total)	MAD	31	44	RD	-4.5%	-23, 14	NS		
					CPAP	33	44						
				(AHI≤30)	MAD	16	18	RD	+18.3%	-8.7, 43	NS		
					CPAP	12	17						
				(AHI>30)	MAD	15	26	RD	-20.1%	-42, 4.9	NS		
					CPAP	21	27						
Gagnadoux 2009[208] 19324954	34 (13) [10-60]	10.6 (4.5)	2 mo (XO)	Complete Response††	MAD	12	28	RD‡‡	-28.6%	-53, -3.8	0.02§§	0	B
					CPAP	20	28						
				Partial*** or Complete Response	MAD	26	28	RD†††	-3.6%	-15, 8.2	NS‡‡‡		
					CPAP	27	28						

* Top row intervention vs. bottom row intervention.
† AHI<5 or >50% reduction to an AHI<20 without symptoms
‡ Estimated from confidence interval
§ Estimated from confidence interval
** Excluding 15 participants who had AHI<10 at baseline.
†† ≥50% reduction in AHI to <5
‡‡ Calculated from reported data
§§ Calculated from reported data
*** ≥50% reduction in AHI to ≥5
††† Calculated from reported data
‡‡‡ Calculated from reported data

Table 5.12.3 AHI (events/hr) in randomized controlled trials of mandibular advancement devices vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Hoekema 2008[211] 18719218	40 (28) [≥5]	14.2 (5.6)	78 d [IQR 60-88 d] (PL)	MAD	51/47*	39.4 (30.8)	2.2 (0, 9.5)†	--	--	0.006‡	4	B
				CPAP	52/47	40.3 (27.6)	0 (0, 3.0)					
Barnes 2004[129] 15201136	21 (12) [nd]	10.7 (3.6)	3 mo (XO)	MAD	80	21.3 (11.6)	14.0 (9.8)	9.2	7.3, 11.1§	<0.05	23	B
				CPAP			4.8 (4.5)					
Lam 2007[119] 17121868	24 (6) [5-40]	12 (6)	10 wk (PL)	MAD	34	20.9 (9.9)	10.6 (9.9)	10.7	6.1, 15.4**	<0.001	0	B
				CPAP	34	23.8 (11.1)	2.8 (6.4)					
Ferguson 1996[207] 8625679	25 (9) [15-50]	nd	4 mo (XO)	MAD	19	19.7 (13.8)	9.7 (7.3)	4.0	-3.7, 11.7††	nd	24	B
				CPAP	20	17.6 (13.2)	3.6 (1.7)					
Gagnadoux 2009[208] 19324954	34 (13) [10-60]	10.6 (4.5)	2 mo (XO)	MAD	28	34.2 (13.0)	6 (nd)	4	1.6, 6.4‡‡	0.001	0	B
				CPAP			2 (nd)					
Tan 2002[210] 12143088	22 (10) [<50]	13.4 (4.6)	2 mo (XO)	MAD	24	22.2 (9.6)	8.0 (10.9)	4.9	1.0, 8.8§§	NS	12	B
				CPAP			3.1 (2.8)					
Randerath 2002[209] 12171833	18 (8) [5-30]	nd	6 wk (XO)	MAD	20	17.5 (7.7)	13.8 (11.1)	10.6	2.5, 18.7***	0.01	0	B
				CPAP			3.2 (2.9)					
Clark 1996[205] 8769497	34 (14) [≥10]	nd	2 wk (XO)	MAD	21	33.86 (14.30)	19.94 (12.75)	8.8	4.0, 13.6†††	nd	4	C
				CPAP			11.15 (3.93)					
Skinner 2004[213] 14718430	29 (13) [10-60]	13.2 (4.9)	1 mo (XO)	CMS collar	10	29.4 (13.4)	26.9 (17.2)	16.9	6.8, 27.0‡‡‡	0.001	0	C
				AutoCPAP			9.9 (8.0)					

* Baseline/Final
† Median (IQR)
‡ Statistical analysis of final values. By Mann-Whitney test. Skewed distribution.
§ Estimated from reported SE's.
** Estimated from reported SE's.

†† Estimated from reported SD's.
‡‡ Estimated from reported P value.
§§ Estimated from reported SD's. Our estimate does not match with reported significance.
*** Estimated from reported P value.
††† Estimated from reported SD's.
‡‡‡ Estimated from reported P value.

Table 5.12.4 ESS in randomized controlled trials of mandibular advancement devices vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Hoekema 2008[211] 18719218	40 (28) [≥5]	14.2 (5.6)	78 d [IQR 60-88 d] (PL)	MAD	51/47*	12.9 (5.6)	6.9 (5.5)	2.3	0.2, 4.4†	0.53‡	4	B
				CPAP	52/47	14.2 (5.6)	5.9 (4.8)					
Barnes 2004[129] 15201136	21 (12) [nd]	10.7 (3.6)	3 mo (XO)	MAD	80	10.7 (3.6)	9.2 (3.6)	0	-0.8, 0.8§	NS	23	B
				CPAP			9.2 (3.6)					
Lam 2007[119] 17121868	24 (5.8) [5-40]	12 (6)	10 wk (PL)	MAD	34	12 (6)	9 (6)	2	-1, 5**	<0.05	0	B
				CPAP	34	12 (6)	7 (6)					
Engleman 2002[206] 12231497	31 (26) [≥5]	14 (4)	8 wk (XO)	MAD	48	13 (4)	12 (5)	6	4.2, 7.8††	<0.001	6	B
				CPAP		15 (3)	8 (5)					
Gagnadoux 2009[208] 19324954	34 (13) [10-60]	10.6 (4.5)	2 mo (XO)	MAD	28	10.6 (4.5)	7.7 (4.0)	-0.5	-2.0, 1.0‡‡	<0.05	0	B
				CPAP			8.2 (3.9)					
Tan 2002[210] 12143088	22 (10) [<50]	13.4 (4.6)	2 mo (XO)	MAD	24	13.4 (4.6)	9.0 (5.1)	0.9	-1.0, 2.8§§	NS	12	B
				CPAP			8.1 (4.1)					
Skinner 2004[213] 14718430	29 (13) [10-60]	13.2 (4.9)	1 mo (XO)	CMS collar	10	13.2 (4.9)	9.4 (5.5)	-1.9	-4.9, 1.1***	0.22	0	C
				AutoCPAP			11.3 (4.6)					

* Baseline/Final
† Estimated from reported SD's.
‡ Statistical analysis of comparison of final values.
§ Estimated from reported SD's.
** Estimated from reported SE's Our estimate does not match with reported significance.
†† Estimated from reported SD's.
‡‡ Estimated from reported SD's.
§§ Estimated from reported SD's.
*** Estimated from reported P value.

Table 5.12.5a AI (events/hr) in randomized controlled trials of mandibular advancement devices vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Barnes 2004[129] 15201136	21 (12) [nd]	10.7 (3.6)	3 mo (XO)	MAD	80	22.0 (10.7)	23.8 (10.7)	5.5	3.4, 7.6*	<0.05	23	B
				CPAP			18.3 (8.0)					
Lam 2007[119] 17121868	24 (5.8) [5-40]	12 (6)	10 wk (PL)	MAD	34	24.5 (12.8)	21.6 (14.6)	2.4	-3.4, 8.2†	NS	0	B
				CPAP	34	21.6 (9.9)	16.3 (10.5)					
Tan 2002[210] 12143088	22 (10) [<50]	13.4 (4.6)	2 mo (XO)	MAD	24	19.3 (9.6)	11.6 (5.6)	1.8	-0.7, 4.3‡	NS	12	B
				CPAP			9.8 (6.6)					
Randerath 2002[209] 12171833	18 (8) [5-30]	nd	6 wk (XO)	MAD	20	21.8 (9.9)	17.0 (5.1)	2.9	0.7, 5.1§	NS	0	B
				CPAP			14.1 (5.1)					
Skinner 2004[213] 14718430	29 (13) [10-60]	13.2 (4.9)	1 mo (XO)	CMS collar	10	27.7 (9.0)	31.7 (22.8)	15.2	-1.4, 31.7**	0.072	0	C
				AutoCPAP			16.5 (5.9)					

* Estimated from reported SE's.
† Estimated from reported SE's.
‡ Estimated from reported SD's.
§ Estimated from reported SD's. Our estimate does not match with reported significance.
** Estimated from reported P value.

Table 5.12.5b Minimum oxygen saturation (%) in randomized controlled trials of mandibular advancement devices vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Hoekema 2008[211] 18719218	40 (28) [≥5]	14.2 (5.6)	78 d [IQR 60-88 d] (PL)	MAD	51/47*	78.0 (8.5)	87.7 (6.3)	-2.1	-5.3, 1.1	NS†	4	B
				CPAP	52/47	77.9 (9.9)	89.7 (5.8)					
Barnes 2004[129] 15201136	21 (12) [nd]	10.7 (3.6)	3 mo (XO)	MAD	80	86.7 (5.4)	87.8 (3.6)	-4.1	-4.9, -3.4‡	<0.05	23	B
				CPAP			91.9 (2.7)					
Lam 2007[119] 17121868	24 (5.8) [5-40]	12 (6)	10 wk (PL)	MAD	34	73.8 (11.1)	81.0 (9.3)	-5.0	-11.0, 1.0§	NS	0	B
				CPAP	34	75.0 (8.2)	87.2 (16.9)					
Ferguson 1996[207] 8625679	25 (9) [15-50]	nd	4 mo (XO)	MAD	19	83.0 (7.4)	83.8 (7.3)	-5.3	-9.3, -1.3**	nd	24	B
				CPAP	20	82.6 (6.0)	88.7 (2.5)					
Randerath 2002[209] 12171833	18 (8) [5-30]	nd	6 wk (XO)	MAD	20	54.5 (25.9)	85.3 (3.1)	-3.7	-5.1, -2.3††	<0.05	0	B
				CPAP			89.0 (3.4)					
Clark 1996[205] 8769497	34 (14) [≥10]	nd	2 wk (XO)	MAD	21	84.3 (6.77)	90.2 (4.36)	-0.9	-3.3, 1.5‡‡	nd	4	C
				CPAP			91.1 (6.40)					
Skinner 2004[213] 14718430	29 (13) [10-60]	13.2 (4.9)	1 mo (XO)	CMS collar	10	84.3 (4.4)	81.0 (12.0)	-9.8	-20.6, 1.0§§	0.076	0	C
				AutoCPAP			90.8 (3.0)					

* Baseline/Final
† Statistical analysis of comparison of final values.
‡ Estimated from reported SE's.
§ Estimated from reported SE's.
** Estimated from reported SD's.
†† Estimated from reported SD's.
‡‡ Estimated from reported SD's.
§§ Estimated from reported P value.

Table 5.12.5c Sleep efficiency (%TST) in randomized controlled trials of mandibular advancement devices vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Hoekema 2008[211] 18719218	40 (28) [≥5]	14.2 (5.6)	78 d [IQR 60-88 d] (PL)	MAD	51/47*	88.3 (9.7)	86.1 (8.1)	-2.9	-7.4, 1.6†	NS‡	4	B
				CPAP	52/47	85.5 (15.5)	86.2 (10.0)					
Barnes 2004[129] 15201136	21 (12) [nd]	10.7 (3.6)	3 mo (XO)	MAD	80	79.5 (9.8)	82.0 (8.9)	-0.1	-1.9, 1.7§	NS	23	B
				CPAP			82.1 (7.2)					
Ferguson 1996[207] 8625679	25 (9) [15-50]	nd	4 mo (XO)	MAD	19	88.0 (5.4)	86.5 (10.6)	-1.8	-7.1, 3.5**	nd	24	B
				CPAP	20	87.8 (7.7)	88.1 (7.3)					
Tan 2002[210] 12143088	22 (10) [<50]	13.4 (4.6)	2 mo (XO)	MAD	24	81.6 (10.4)	83.2 (8.1)	-4	-7.2, 0.8††	NS	12	B
				CPAP			87.2 (8.1)					
Clark 1996[205] 8769497	34 (14) [≥10]	nd	2 wk (XO)	MAD	21	87.1 (10.7)	89.9 (5.5)	0.4	-2.4, 3.2‡‡	NS	4	C
				CPAP			89.5 (7.3)					
Skinner 2004[213] 14718430	29 (13) [10-60]	13.2 (4.9)	1 mo (XO)	CMS collar	10	81.9 (7.9)	78.6 (11.8)	0.2	-7.1, 7.5§§	0.97	0	C
				AutoCPAP			78.4 (11.6)					

* Baseline/Final
† Estimated from reported SD's.
‡ Statistical analysis of comparison of final values.
§ Estimated from reported SE's.
** Estimated from reported SD's.
†† Estimated from reported SD's.
‡‡ Estimated from reported SD's.
§§ Estimated from reported SD's.

Table 5.12.5d Slow wave sleep (% TST) in randomized controlled trials of mandibular advancement devices vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Hoekema 2008[211] 18719218	40 (28) [≥5]	14.2 (5.6)	78 d [IQR 60-88 d] (PL)	MAD	51/47*	13.7 (9.0)	20.4 (7.7)	-2.1	-5.8, 1.6†	NS‡	4	B
				CPAP	52/47	13.0 (11.5)	21.8 (8.0)					
Barnes 2004[129] 15201136	21 (12) [nd]	10.7 (3.6)	3 mo (XO)	MAD	80	17.9 (10.7)	20.1 (9.8)	-0.6	-2.8, 1.6§	NS	23	B
				CPAP			20.7 (9.8)					
Randerath 2002[209] 12171833	18 (8) [5-30]	nd	6 wk (XO)	MAD	20	14.2 (10.6)	14.1 (10.8)	-2.1	-6.5, 2.3**	NS	0	B
				CPAP			16.2 (9.1)					
Clark 1996[205] 8769497	34 (14) [≥10]	nd	2 wk (XO)	MAD	21	12.4 (7.8)	13.4 (8.0)	-1.8	-4.9, 1.2††	nd	4	C
				CPAP			15.2 (5.6)					
Skinner 2004[213] 14718430	29 (13) [10-60]	13.2 (4.9)	1 mo (XO)	CMS collar	10	20.4 (8.2)	20.1 (13.4)	-3.9	-11.2, 3.4‡‡	0.30	0	C
				AutoCPAP			24.0 (8.9)					

* Baseline/Final
† Estimated from reported SD's.
‡ Statistical analysis of comparison of final values.
§ Estimated from reported SE's.
** Estimated from reported SD's.
†† Estimated from reported SD's.
‡‡ Estimated from reported SD's.

Table 5.12.5e REM sleep (% TST) in randomized controlled trials of mandibular advancement devices vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Hoekema 2008[211] 18719218	40 (28) [≥5]	14.2 (5.6)	78 d [IQR 60-88 d] (PL)	MAD	51/47*	21.0 (7.8)	26.5 (6.7)	0.6	-2.2, 3.4†	NS‡	4	B
				CPAP	52/47	19.2 (7.4)	24.1 (5.7)					
Barnes 2004[129] 15201136	21 (12) [nd]	10.7 (3.6)	3 mo (XO)	MAD	80	18.8 (6.3)	19.8 (5.4)	0.9	-0.2, 2.0§	NS	23	B
				CPAP			18.9 (4.5)					
Ferguson 1996[207] 8625679	25 (9) [15-50]	nd	4 mo (XO)	MAD	19	14.3 (6.5)	20.0 (12.3)	6.1	0.3, 11.9**	nd	24	B
				CPAP	20	16.5 (8.2)	16.1 (6.1)					
Tan 2002[210] 12143088	22 (10) [<50]	13.4 (4.6)	2 mo (XO)	MAD	24	12.7 (5.8)	13.8 (5.6)	-4.7	-7.0, -2.4††	NS	12	B
				CPAP			18.5 (6.1)					
Randerath 2002[209] 12171833	18 (8) [5-30]	nd	6 wk (XO)	MAD	20	15.1 (5.9)	14.8 (7.3)	-0.5	-3.6, 2.6‡‡	NS	0	B
				CPAP			15.3 (6.8)					
Clark 1996[205] 8769497	34 (14) [≥10]	nd	2 wk (XO)	MAD	21	5.9 (5.8)	20.9 (7.5)	0.2	-2.9, 3.3§§	NS	4	C
				CPAP			20.7 (6.7)					
Skinner 2004[213] 14718430	29 (13) [10-60]	13.2 (4.9)	1 mo (XO)	CMS collar	10	20.4 (4.6)	19.7 (5.1)	-0.7	-5.0, 3.6***	0.82	0	C
				AutoCPAP			20.4 (8.0)					

* Baseline/Final
† Estimated from reported SD's.
‡ Statistical analysis of comparison of final values.
§ Estimated from reported SE's.
** Estimated from reported SD's.
†† Estimated from reported SD's. Our estimate does not match with reported significance.
‡‡ Estimated from reported SD's.
§§ Estimated from reported SD's.
*** Estimated from reported SD's.

Table 5.12.6 Wakefulness tests in randomized controlled trials of mandibular advancement devices vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. analyzed	Test	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Engleman 2002[206] 12231497	31 (26) [≥5]	14 (4)	8 wk (XO)	MAD	48	MWT (min)	nd	22 (12)	-2	-7.3, 2.7*	0.46	6	B
				CPAP				24 (12)					
Gagnadoux 2009[208] 19324954	34 (13) [10-60]	10.6 (4.5)	2 mo (XO)	MAD	28	OSLER (sec)	2094 (674)	2312 (322)	12	-122, 146†	NS	0	B
				CPAP				2300 (391)					

* Estimated from reported P value.
† Estimated from reported SD's.

Table 5.12.7a FOSQ in randomized controlled trials of mandibular advancement devices vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Final (SD)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Hoekema 2008[211] 18719218	40 (28) [≥5]	14.2 (5.6)	78 d [IQR 60-88 d] (PL)	MAD	51/49*	13.7 (3.1)	16.6 (2.8)	0.1	-1.1, 1.3	NS†	4	B
				CPAP	52/50	13.9 (3.7)	16.7 (3.1)					
Engleman 2002[206] 12231497	31 (26) [≥5]	14 (4)	8 wk (XO)	MAD	48	12 (2)	13 (3)	-3	-4.8, -1.2‡	0.001	6	B
				CPAP		10 (3)	14 (2)					
Skinner 2004[213] 14718430	29 (13) [10-60]	13.2 (4.9)	1 mo (XO)	CMS collar	10	12.2 (3.1)	12.7 (3.1)	-0.1	-1.2, 1.0§	0.85	0	C
				AutoCPAP			12.8 (2.7)					

* Baseline/Final
† Statistical analysis of comparison of final values.
‡ Estimated from reported P value.
§ Estimated from reported P value.

Table 5.12.7b Quality of life in randomized controlled trials of mandibular advancement devices vs. CPAP

Study PMID	Baseline AHI (SD)	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Outcome	Favors	If Significant Difference Net Difference	Estimated 95% CI	Test Range "Worst"	"Best"	P Btw	Dropout, %	Study quality
Hoekema 2008[211] 18719218	40 (28) [≥5]	14.2 (5.6)	78 d [IQR 60-88 d] (PL)	MAD	51/47*	SF-36 (all 8 components)	0						4	B
				CPAP	52/47	Hospital Anxiety Scale	0							
						Hospital Depression Scale	0							
Barnes 2004[129] 15201136	21 (12) [nd]	10.7 (3.6)	3 mo (XO)	MAD	80	SF-36 (mean score)	0						23	B
				CPAP		Beck Depression Index	0							
Lam 2007[119] 17121868	24 (5.8) [5-40]	12 (6)	10 wk (PL)	MAD	34	SF-36 Bodily Pain	CPAP	-16	-17, -14	0	100	<0.05	0	B
						SF-36 (other components)	0							
						SAQLI (A,B,C,D)†	0							
						SAQLI A-D‡	CPAP	-0.3	-0.4, -0.2	1	7	<0.05		
				CPAP	34	SAQLI E§	MAD	-0.8	-0.9, -0.7	7	1	<0.05		
						SAQLI A-E**	0							
Engleman 2002[206] 12231497	31 (26) [≥5]	14 (4)	8 wk (XO)	MAD	48	SF-36 Health transition	CPAP	0.52	nd	Effect size (SD units)		0.001	6	B
						SF-36 PCS	CPAP	0.35	nd			0.02		
						SF-36 MCS	CPAP	0.34	nd			0.008		
				CPAP		Hospital Anxiety Score	0							
						Hospital Depression Score	0							
Gagnadoux 2009[208] 19324954	34 (13) [10-60]	10.6 (4.5)	2 mo (XO)	MAD	28	Nottingham Health Profile (6 components)	0						0	B
				CPAP										
Tan 2002[210] 12143088	22 (10) [<50]	13.4 (4.6)	2 mo (XO)	MAD	24	General Health††	0						12	B
				CPAP										

Study PMID	Baseline AHI (SD)	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Outcome	Favors	If Significant Difference Net Difference	Estimated 95% CI	Test Range "Worst"	"Best"	P Btw	Dropout, %	Study quality
Skinner 2004[213] 14718430	29 (13) [10-60]	13.2 (4.9)	1 mo (XO)	CMS collar	10	SF-36 PCS	0						0	C
				AutoCPAP		SF-36 MCS	0							
						SQ	0							

* Baseline/Final
† A: Daily functioning; B: Social interactions; C: Emotional; D: Symptoms
‡ Summary score for components A-D.
§ E: Treatment-related symptoms
** Summary score for components A-E.
†† Flemons WW, Whitelaw WA, Brant R, Remmers JE. 1994. Likelihood ratios for a sleep apnea clinical prediction rule. Am J Resp Crit Care Med. 150: 1279-1285

Table 5.12.8 Cognitive function tests in randomized controlled trials of mandibular advancement devices vs. CPAP

Study PMID	Baseline AHI (SD)	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Outcome	Favors*	If Significant Difference Net Difference	Estimated 95% CI	Test Range "Worst"	"Best"	P Btw	Dropout, %	Study quality
Engleman 2002[206] 12231497	31 (26) [≥5]	14 (4)	8 wk (XO)	MAD	48	Performance IQ	0						6	B
						Trailmaking B	0							
				CPAP		SteerClear	0							
						PASAT 2s	0							
Gagnadoux 2009[208] 19324954	34 (13) [10-60]	10.6 (4.5)	2 mo (XO)	MAD	28	OSLER Errors	0						0	B
				CPAP		Trailmaking A	0							
						Trailmaking B	0							

* The noted intervention statistically significantly favors the patient (net better score on test). 0 = no difference.

Table 5.16.1 Randomized controlled trials of positional therapy vs. CPAP: Study characteristics

Study PMID	Interventions	CPAP pressure* (Type)	Mean age, yr	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Other quality issues
Jokic 1999[221] 10084491	Positional treatment CPAP	Manual (Split)	51	nd	30	nd	Canada (nd)	No washout
Skinner 2004[219] 15611894	SHEP† CPAP	Auto (Split)	54	85	34	nd	New Zealand	Patient not blinded, multicenter not accounted for in analysis, no power analysis reported
Skinner 2008[220] 18713092	TASB‡ CPAP	Auto (Separate)	56	nd	30.7	Positional OSA	New Zealand	Patient not blinded

* Method for choosing CPAP pressure: Manual (during sleep study); Auto (determined with AutoCPAP); Algorithm (by an algorithm); nd (no data reported); NA (not applicable, eg if AutoCPAP is the intervention). In parentheses: Split (CPAP introduced in a split night study); Separate (CPAP introduced on a separate full night than the diagnostic sleep study).
† Shoulder-head elevation pillow
‡ Thoracic anti-supine band

Table 5.16.2a AHI (events/hr) in randomized controlled trials of positional therapy vs. CPAP

Study PMID	Baseline AHI (SD) [range]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Difference	95% CI	P Btw	Dropout, %	Study quality
Jokic 1999[221] 10084491	18 (nd) [4-33]	13.4 (nd)	2 wk (XO)	Positional therapy	13	17.9 (nd)	-8.4	6.1	2, 10.2	0.007	7	B
				CPAP	13		-14.5					
Skinner 2004[219] 15611894	27 (12) [13-50]	11.9 (4.6)	1 mo (XO)	SHEP	14	27 (12)	-6	16	4.2, 27.8*	0.008	7	B
				nCPAP	13		-22					
Skinner 2008[220] 18713092	23 (12) [6-51]	13.6 (50.5)	1 mo (XO)	TASB	20	22.7	-10.7	7.1	1.1, 13.1†	0.02	0	B
				nCPAP	20		-17.8					

* Estimated from reported P value
† Estimated from reported P value

Table 5.16.2b AHI ≤10 events/hr in randomized controlled trials of positional therapy

Study PMID	Baseline AHI (SD) [range]	Baseline ESS (SD)	Duration (design)	Interventions	n Event	N Total	Outcome Metric	Result*	95% CI	P Btw	Dropout, %	Study quality
Skinner 2008[220] 18713092	23 (12) [6-51]	13.6 (50.5)	1 mo (XO)	TASB	13	18	RR	0.81	0.58, 1.13	0.004†	0	B
				CPAP	16	18						

* Top row intervention vs. bottom row intervention. Estimated based on reported data.
† Per article, by Wilcoxin sign-rank test.

Table 5.16.3 ESS in randomized controlled trials of positional therapy vs. CPAP

Study PMID	Baseline AHI (SD) [range]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Difference	95% CI	P Btw	Dropout, %	Study quality
Jokic 1999[221] 10084491	18 (nd) [4-33]	13.4 (nd)	2 wk (XO)	Positional therapy	13	13.4 (nd)	9.5	1.5*	-2.9, 0.8	0.2	7	B
				CPAP	13		8.75					
Skinner 2004[219] 15611894	27 (12) [13-50]	11.9 (4.6)	1 mo (XO)	SHEP	14	10.2 (5.0)	-1.7	0.7	-2.8, 4.2†	0.69	7	B
				nCPAP	14	9.5 (4.0)	-2.4					
Skinner 2008[220] 18713092	23 (12) [6-51]	13.6 (50.5)	1 mo (XO)	TASB	20	13.6	50.5	1.2		NS	0	B
				nCPAP	20		50.5					

* median
† Estimated from reported P value.

Table 5.16.4 Other sleep study and related outcomes in randomized controlled trials of positional therapy vs. CPAP

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Outcome	Interventions	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff or Diff	95% CI	P Btw	Dropout, %	Study Quality
Jokic 1999[221] 10084491	18 (nd) [4-33]	13.4 (nd)	2 wk (XO)	Arousal index (events/hr)	Positional therapy	13	24.5 (nd)	-5.0	4.5	(-0.7, 9.4)	0.08	7	B
					CPAP	13		-9.5					
				Sleep efficiency (%)	Positional therapy	13	nd	82	-4	nd	0.51		C*
					CPAP	13		84					
				Slow wave sleep (%)	Positional therapy	13	nd	20	-2	nd	0.31		
					CPAP	13		22					
				REM (%)	Positional therapy	13	nd	24	-2	nd	0.71		
					CPAP	13		26					
				MWT (min)	Positional therapy	13	nd	31.2	-1.7	(-1.9, 5.3)	0.32		
					CPAP	13		32.9					

* No baseline data

Table 5.16.5 Quality of life in randomized controlled trials of Positional Therapy vs CPAP

Study PMID	Baseline AHI (SD)	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Outcome	Favors	If Significant Difference Net Difference	95% CI	Test Range "Worst"	"Best"	P Btw	Dropout, %	Study quality
Jokic 1999 10084491	17.9 (nd) [4.4-32.8]	13.4	2 wk (XO)	Positional Therapy	13	General Health Questionnaire	0						7%	B
				CPAP	13									
Skinner 2004[219] 15611894	27 (12) [13-50]	11.9 (4.6)	1 mo (XO)	SHEP	14	SF-36 physical	0							
				TASB	14	SF-36 mental	0							
Skinner 2008[220] 18713092	23 (12) [6-51]	13.6 (50.5)	1 mo (XO)	SHEP	20	SF-36 physical	0							
				TASB	20	SF-36 mental	0							

Table 5.16.6 FOSQ in randomized controlled trials of positional therapy vs. CPAP

Study PMID	Baseline AHI (SD) [Range]	Baseline ESS (SD)	Duration (Design)	Interventions	No. Analyzed	Baseline (SD)	Change (Final)	Difference	95% CI	P Btw	Dropout, %	Study Quality
Skinner 2004[219] 15611894	27 (12) [13-50]	11.9 (4.6)	1 mo (XO)	SHEP*	14	12.1 (1.9)	1.1	-0.3	nd	0.93	7	B
				CPAP	14		1.4					

* Shoulder-head elevation pillow

Table 5.16.7 Neurocognitive tests in randomized controlled trials of positional therapy vs. CPAP

Study PMID	Baseline AHI (SD)	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Outcome	Favors	If Significant Difference Net difference	95% CI	Test Range "Worst"	"Best"	P Btw	Dropout, %	Study quality
Jokic 1999[221] 10084491	17.9 (nd) [4.4-32.8]	13.4	2 wk (XO)	Positional Therapy	13	Wechsler Memory Scale	0						7	B
				CPAP	13									
						Purdue Pegboard	0							
						Trail-Making test	0							
						Symbol Digit Modalities	0							
						Consonant Trigram	0							
						Concentration Endurance Test	0							
						Nottingham Health Profile Energy	CPAP	-1		0	3	0.04		
						Nottingham Health Profile Others	0							
						Hospital Anxiety Scale	0							
						Hospital Depression Scale	0							
						UWIST adjective checklist	0							

Table 5.17.1 Randomized controlled trials of weight loss: Study characteristics

Study PMID	Interventions	Mean age, yr	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Other quality issues
Foster 2009[222] 19786682	Intensive lifestyle intervention Diabetes support and education	61	42	36.7	Diabetics	US (nd)	Unclear if outcome data included all initial participants, and if so, unclear how data were imputed.
Johansson 2009[223] 19959590	Low energy diet Usual diet	50	100	34.8	No	Sweden (2009)	
Tuomilehto 2009[224] 19011153	VLCD with lifestyle changes General counseling	51	74	31.4	Obese	Finland (2004-06)	

Table 5.17.2 Patients with OSA cure in 1 year in randomized controlled trials of weight loss

Author Year PMID	Baseline AHI (SD) [range]	Baseline ESS (SD)	Duration (design)	Interventions	n Event	N Total	Outcome metric	Result*	95% CI†	P Btw	Dropout, %	Study quality
Tuomilehto 2009[224] 19011153	9 (3) [>5]	9.9 (4.8)	1 yr (PL)	VLCD with lifestyle changes	22	35	OR (adjusted)‡	4.17	(1.41, 12.34)	0.011	11	B
				General counseling	13	37						

* Top row intervention vs. bottom row intervention.
† Estimated from reported P value
‡ Adjusted OR for age, sex, BMI and baseline AHI.

Table 5.17.3 AHI (events/hr) in randomized controlled trials of weight loss

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI*	P Btw	Dropout, %	Study quality
Johansson 2009[223] 19959590	37 (14) [≥15]	7.0 (5.0)	9 wk (PL)	Low energy diet	30	37 (17)	-25	-23	-30, -15	<0.001	3	A
				Usual diet	33	37 (14)	-2					
Foster 2009[222] 19786682	24 (15) [nd]	nd	1 yr (PL)	Intensive lifestyle intervention	125	22.9 (18.0)	-5.4	-9.7	-13.6, -5.7	<0.001	17	B
				Diabetes support and education	139	23.5 (15.0)	4.2					
Tuomilehto 2009[224] 19011153	9 (3) [>5]	9.9 (4.8)	1 yr (PL)	VLCD with lifestyle changes	40	11 (3.6)	-4	-4.3	-7.6, -1.0	0.011	11	B
				General counseling	41	9 (2.7)	0.3					

Table 5.17.4 ESS in randomized controlled trials of weight loss

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Johansson 2009[223] 19959590	37 (14) [≥15]	7.0 (5.0)	9 wk (PL)	Low energy diet	30	9 (5)	-3	-4	-6, -2	<0.001	3	A
				Usual diet	33	7 (5)	1					
Tuomilehto 2009[224] 19011153	9 (3) [>5]	9.9 (4.8)	1 yr (PL)	VLCD with lifestyle changes	40	10.1 (5)	-3.1	-1	-2.7, 0.7†	0.25	11%	B
				General counseling	41	9.9 (4.8)	-2.1					

* Estimated from reported data.
† Estimated from reported data.

Table 5.17.5 Minimum oxygen saturation (%) in randomized controlled trials of weight loss

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Johansson 2009[223] 19959590	37 (14) [≥15]	7.0 (5.0)	9 wk (PL)	Low energy diet	30	82 (6)	5	5	2, 7	0.002	3	A
				Usual diet	33	82 (5)	0					

Table 5.17.6 Blood pressure (mm Hg) in randomized controlled trials of weight loss

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI*	P Btw	Dropout, %	Study quality
Systolic blood pressure												
Tuomilehto 2009[224] 19011153	9 (3) [>5]	9.9 (4.8)	1 yr (PL)	VLCD with lifestyle changes	40	131.2 (10.2)	-1.7	-0.6	-8.4, 7.2	0.88	11	B
				General counseling	41	130.0 (12.8)	-1.9					
Diastolic blood pressure												
Tuomilehto 2009[224] 19011153	9 (3) [>5]	9.9 (4.8)	1 yr (PL)	VLCD with lifestyle changes	40	81.8 (8.9)	-1.9	-1.5	-7.4, 4.4	0.62	11	B
				General counseling	41	80.7 (7.8)	-0.4					

Table 5.17.7 Hemoglobin A1c (%) in randomized controlled trials of weight loss

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI†	P Btw	Dropout, %	Study quality
Foster 2009[222] 19786682	24 (15) [nd]	nd	1 yr (PL)	Intensive lifestyle intervention	125	7.1 (0.9)	-0.7	-0.5	-0.8, -0.2	<0.001	17	B
				Diabetes support and education	139	7.3 (1.1)	-0.2					

* Estimated from reported data.
† Estimated from reported data.

Table 5.17.8 Body weight (kg) in randomized controlled trials of weight loss

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI*	P Btw	Dropout, %	Study quality
Johansson 2009[223] 19959590	37 (14) [≥15]	7.0 (5.0)	9 wk (PL)	Low energy diet	30	113.4 (14.8)	-18.7	-19.8	-21.4, -18.2	nd	3	A
				Usual diet	33	111.7 (13.7)	1.1					
Foster 2009[222] 19786682	24 (15) [nd]	nd	1 yr (PL)	Intensive lifestyle intervention	125	102.9 (19.6)	-10.8	-10.2	-12.1, -8.3	<0.001	17	B
				Diabetes support and education	139	102.0 (17.1)	-0.6					
Tuomilehto 2009[224] 19011153	9 (3) [>5]	9.9 (4.8)	1 yr (PL)	VLCD with lifestyle changes	40	101.2 (11.9)	-10.7	-8.3	-11.1, -5.5	<0.001	11	B
				General counseling	41	92.3 (11.3)	-2.4					

* Estimated from reported data.

Table 5.18.1 Randomized controlled trials of oropharyngeal exercises: Study characteristics

Study PMID	Interventions	Mean age, yr	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Other quality issues
Guimaraes 2009[226] 19234106	Oropharyngeal exercise Sham therapy	48	73	31.0	-	Brazil (nd)	
Randerath 2004[227] 15124719	Tongue training Sham training	53	66	28.9	-	Germany (2002)	
Puhan 2005[225] 16377643	Didgeridoo No intervention	49	84	25.8	-	Switzerland (2004-05)	

Table 5.18.2 AHI (events/hr) in randomized controlled trials of oropharyngeal exercises

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Puhan 2005[225] 16377643	20 (5) [≥15]	11.5 (nd)	4 mo (PL)	Didgeridoo	14	22.3 (5.0)	-10.7	-6.2	-12.3, -0.1	0.05	0	A
				No treatment	11	19.9 (4.7)	-4.5					
Guimaraes 2009[226] 19234106	22 (5) [≥15]	14 (7)	3 mo (PL)	Oropharyngeal exercise	16	22.4 (5.4)	-8.7	-12.2	-19, -5*	<0.001	10	B
				Sham therapy	15	22.4 (5.4)	3.5					
Randerath 2004[227] 15124719	28 (6) [10-40]	9.4 (4.7)	8 wk (PL)	Tongue training	33	24.7 (8.6)	0.6	0.4	-5.6, 6.4†	NS	8	A
				Sham training	24	27.7 (6.3)	0.2					

* Estimated from reported P value
† Estimated from reported data

Table 5.18.3 ESS in randomized controlled trials of oropharyngeal exercises

Study PMID	Baseline AHI (SD) [dligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Puhan 2005[225] 16377643	20 (5) [≥15]	11.5 (nd)	4 mo (PL)	Didgeridoo	14	11.8 (3.5)	-4.4	-2.8	-5.7, -0.3	0.04	0	A
				No treatment	11	11.1 (6.4)	-1.4					
Guimaraes 2009[226] 19234106	22 (5) [≥15]	14 (7)	3 mo (PL)	Oropharyngeal exercise	16	14 (5)	-6	-4	-8, -0.02*	<0.05	10	B
				Sham therapy	15	14 (7)	-2					
Randerath 2004[227] 15124719	28 (6) [10-40]	9.4 (4.7)	8 wk (PL)	Tongue training	33	10.2 (4.9)	-1.5	-0.2	-2.6, 2.4†	NS	8	A
				Sham training	24	10.5 (5.1)	-1.3					

* Estimated from reported P value
† Estimated from reported data

Table 5.18.4 Minimum oxygen saturation (%) in randomized controlled trials of oropharyngeal exercises

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Guimaraes 2009[226] 19234106	22 (5) [≥15]	14 (7)	3 mo (PL)	Oropharyngeal exercise	16	83 (6)	85 (7)	4	0.2, 7.8*	NS	10	B
				Sham therapy	15	82 (4)	80 (4)					
Randerath 2004[227] 15124719	28 (6) [10-40]	9.4 (4.7)	8 wk (PL)	Tongue training	33	81.7 (6.8)	-0.3	1.1	-2.4, 4.6†	NS	8	A
				Sham training	24	82.3 (5.8)	-1.4					

* Estimated from reported data
† Estimated from reported data

Table 5.18.5 Sleep Efficiency (%) in randomized controlled trials of oropharyngeal exercises

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Guimaraes 2009[226] 19234106	22 (5) [≥15]	14 (7)	3 mo (PL)	Oropharyngeal exercise	16	87 (8)	-1	-2	-8.8, 4.8*	0.58	10	B
				Sham therapy	15	86 (10)	1					

* Estimated from reported data.

Table 5.18.6 Other sleep study outcomes in randomized controlled trials of positional therapy vs. CPAP

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Outcome	Interventions	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff or Diff	95% CI	P Btw	Dropout, %	Study Quality
Randerath 2004[227] 15124719	28 (6) [10-40]	9.4 (4.7)	8 wk (PL)	Slow wave sleep	Tongue training	33	19.1 (13.6)	6.8	11	-1.3, 21.5*	NS	8	A
					Sham training	24	23.5 (9.8)	-4.2					
				REM sleep	Tongue training	33	11 (4.7)	1.1	-0.3	-3.0, 2.2†	NS		
					Sham training	24	12.9 (5.2)	1.4					
				Arousal index	Tongue training	33	23.7 (9.5)	-0.7	-1.9	-6.9, 3.5‡	NS		
					Sham training	24	23 (9.8)	1.2					

* Estimated from reported data
† Estimated from reported data
‡ Estimated from reported data

Note: There is no Table 15.18.7.

Table 5.18.8 FOSQ in randomized controlled trials of oropharyngeal exercises

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Randerath 2004[227] 15124719	28 (6) [10-40]	9.4 (4.7)	8 wk (PL)	Tongue training	33	84.8 (32.5)	4.2	1.6	-20.4, 13.6*	NS	8	A
				Sham training	24	74.2 (36.9)	2.6					

Table 5.18.9 Quality of life outcomes in randomized controlled trials of oropharyngeal exercises

Study PMID	Baseline AHI (SD)	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Outcome	Favors	If Significant Difference Net Difference	95% CI	Test Range "Worst"	"Best"	P Btw	Dropout, %	Study quality
Puhan 2005[225] 16377643	20 (5) [≥15]	11.5 (nd)	4 mo (PL)	Didgeridoo	14	PQoSI	0						0	A
				No treatment	11									
						SF-36- all domains	0							
Guimaraes 2009[226] 19234106	22 (5) [≥15]	14 (7)	3 mo (PL)	Oropharyngeal exercise	16	Pittsburgh Quality of Sleep Index	Oropharyngeal exercise	-3.4	nd	21	0	<0.01	10	B
				Sham therapy	15									

Table 5.18.10 Neurocognitive tests in randomized controlled trials of oropharyngeal exercises

Study PMID	Baseline AHI (SD)	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Outcome	Favors	If Significant Difference Net Difference	95% CI	Test Range "Worst"	"Best"	P Btw	Dropout, %	Study quality
Randerath 2004[227] 15124719	28 (6) [10-40]	9.4 (4.7)	8 wk (PL)	Tongue training	33	Attention Test	0						0	A
				Sham training	24									

* Estimated from reported data

Table 5.19.1 Randomized controlled trials of palatal implants vs. control: Study characteristics

Study PMID	Interventions	Mean age (yr)	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Other quality issues
Friedman 2008[228] 18241718	Palatal implants Placebo	39 (9)	53	28.7 (2.3)	-	US (2005-06)	-
Steward 2008[229] 18922335	Soft palate implants Sham implants	49 (nd)	79	27.6 (nd)	-	US (nd)	-

Table 5.19.2a. AHI (events/hr) in randomized controlled trials of palatal implant vs. Control

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Friedman 2008[228] 18241718	20 (4) [5-40]	11.7 (2.7)	3 mo (PL)	Palatal implants	29	23.8 (5.5)	-7.1	-8.8	5.3, 12.2	<0.0001	11	A
				Placebo	26	20.1 (4.0)	+0.9					
Steward 2008[229] 18922335	17 (nd) [10-40]	10.6 (nd)	3 mo (PL)	Soft palate implants	47	17.2 (nd)	2.9	-6	0.9, -13	NS	1	B
				Sham implants	50	16.7(nd)	8.9					

Table 5.19.2b. 50% reduction in AHI to ≤ 20 events/hr in randomized controlled trials of palatal implant vs. control

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	n Event	N Total	Outcome Metric	Result*	95% CI	P Btw	Dropout, %	Study Quality
Steward 2008[229] 18922335	16 (nd) [10-40]	10.6(nd)	3 mo (PL)	Soft palate implants	13	50	RR	2.60	1.00, 6.75	0.04[†]	1	B
				Sham implants	5	50						

* Top row intervention vs. bottom row intervention.
[†] Per article, by chi-squared test.

Table 5.19.3 ESS in randomized controlled trials of palatal implant vs. control

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Friedman 2008[228] 18241718	20 (4) [5-40]	11.7 (2.7)	3 mo (PL)	Palatal implants	31	12.7(2.7)	-2.4	-1.9	1.0, 2.9	0.0002	11	A
				Placebo	31	11.7(2.7)	-0.5					
Steward 2008[229] 18922335	17 (nd) [10-40]	10.6 (nd)	3 mo (PL)	Soft palate implants	47	10.6(nd)	-1.8	-0.3	-1.8, 1.1	NS	1	B
				Sham implants	49	10.7(nd)	-1.5					

Table 5.19.4 Minimum oxygen saturation in randomized controlled trials of palatal implant vs. control

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Friedman 2008[228] 18241718	20 (4) [5-40]	11.7 (2.7)	3 mo (PL)	Palatal implants	28	88.3 (3.0)	-1.3	-0.6	-2.2, 1.0	NS	11	A
				Placebo	23	89.6 (2.5)	-0.7					
Steward 2008[229] 18922335	17 (nd) [10-40]	10.6 (nd)	3 mo (PL)	Soft palate implants	46	nd	0.1	-2.9	-0.8, -5.0	0.007	1	B
				Sham implants	48	nd	3					

Table 5.19.5. REM Sleep in randomized controlled trials of palatal implant vs. control

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Friedman 2008[228] 18241718	20 (4) [5-40]	11.7 (2.7)	3 mo (PL)	Palatal implants	29	16.1 (3.3)	-0.8	-2	-4.0, 0.01	NS	11	A
				Placebo	26	12.9 (3.7)	1.2					

Table 5.19.6. FOSQ total in randomized controlled trials of palatal implant vs. control

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Steward 2008[229] 18922335	17 (nd) [10-40]	10.6 (nd)	3 mo (PL)	Soft palate implants	49	15.5(nd)	1.4	0.83	0.0,1.6	NS	1	B
				Sham implants	49	16.1(nd)	0.6					

Table 5.20.1 Studies of surgery vs. control: Study characteristics

Study PMID	Interventions	Mean age, yr	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (Enrollment years)	Major quality issues
Back 2009[230] 19504550	RFA (Soft palate) Sham surgery	30-65 (range)	100	25.6 (median)	BMI ≤35 kg/m^2	Finland (nd)	
Ferguson 2003[231] 12502473	LAUP No treatment	44	78	31.6	-	Canada (nd)	
Guilleminault 2008[234] 19014072	Surgery combo* Cognitive behavioral therapy for insomnia	32	40	23.9	-	US (2002-03)	First phase†
Koutsourelakis 2008[232] 17898015	Surgery‡ Sham surgery	37	59	29.9	Deviated nasal septum	Greece (nd)	
Lojander 1996[114] 8681614 Lojander 1999[115] 10188139	UPPP Conservative treatment	47	97	31.0	BMI ≤40kg/m^2	Finland (1987-92)	
Woodson 2003[233] 12825037	RFA (tongue & palate) Sham RFA RFA (nd where)	46	70	28.5	-	US (nd)	

* combinations of pharyngoplasty, tonsillectomy, adenoidectomy, genioglossal advancement septoplasty and RFA of the inferior nasal turbinates
† Paper was presented as a crossover study between behavioral therapy and surgery. Only the first phase (prior to crossover) evaluated here.
‡ Submucous resection of the deviated septum and bilateral resection of inferior turbinates

Table 5.20.2 AHI or oxygen desaturation index (events/hr) in randomized controlled trials of surgery vs. control

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Outcomes	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Back 2009[230] 19504550	12 (5–8)* [5-15]	8.0 (3.0-16.0)†	4 mo (PL)	AHI	RFA	17	11 (5-15)‡	2	3	-9.1, 15.1§	NS	0	A
					Sham surgery	15	12.0 (5.0-8.0)**	-1					
Woodson 2003[233] 12825037	15 (7) [10-30 or 5-40]††	11.6(3.5)	2 mo (PL)	AHI	RFA	24	21.3 (11.1)	-4.5	-2.7	-9.9,4.5	NS	13	A
					Sham RFA	28	15.4 (7.8)	-1.8					
Koutsourelakis 2008[232] 17898015	31 (14) [≥5]	13.7 (4.4)	4 mo (PL)	AHI	Surgery‡‡	27	31.5 (16.7)	0	-1.5	-10.3, 7.3§§	nd	3	A
					Sham surgery	22	30.6 (13.8)	1.5					
Ferguson 2003[231] 12502473	16 (4) [10-25]	10.0 (5.2)	8 to15 mo (PL)	AHI	LAUP	21	18.6 (4.3)	-3.9	-10.5	-20.5, -0.4***	nd	1	B
					No treatment	23	16.1 (4.0)	6.6					
Lojander, 1996[114] 8681614	nd	(nd)	12 mo (PL)	ODI_4†††	UPPP	16	45	-31	-20	nd	NS	3	C
					Conservative treatment	10	34	-11					
				ODI_{10}‡‡‡	UPPP	16	17	-14	-6	nd	NS		
					Conservative treatment	10	14	-8					
Guilleminault 2008[234] 19014072	10 (6) [nd]	6.6 (1.2)	3 mo (XO first phase)	AHI	Surgery combo§§§	15	9.7 (5.7)	-5.2	-6.2	-9.3,-3.1****	<0.0001	33	C
					Cognitive behavioral therapy	15	9.7 (5.7)	1					

* Median (range)
† Median (range)
‡ Median (range)
§ Estimated from reported P value
** Median (range)
†† Two parts of methods section disagree with each other
‡‡ Patients had submucous resection of the deviated septum and bilateral resection of inferior turbinates
§§ Estimated from reported data
*** Estimated from reported data
††† no. of desaturation of ≥4% per hr in bed
‡‡‡ no. of desaturation of ≥10% per hr in bed
§§§ combinations of pharyngoplasty, tonsillectomy, adenoidectomy, genioglossal advancement septoplasty and RFA of the inferior nasal turbinates
**** Estimated from reported P value

Table 5.20.3 ESS in randomized controlled trials of surgery vs. control

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Back 2009[230] 19504550	12 (5–8)* [5-15]	8.0 (3.0-16.0)†	4 mo (PL)	RFA	17	10 (3-21)‡	-3	0	nd	NS	0	A
				sham surgery	15	8.0 (3.0–16.0)§	-3					
Koutsourelakis 2008[232] 17898015	31 (14) [≥5]	13.7 (4.4)	4 mo (PL)	Surgery**	27	13.4 (2.9)	-1.7	-0.5	-2.5, 1.5††	nd	3	A
				Sham surgery	22	13.7 (4.4)	-1.2					
Woodson 2003[233] 12825037	15 (7) [10-30 or 5-40]‡‡	11.6(3.5)	2 mo (PL)	RFA	26	11.9 (4.6)	-2.1	-1.2	-3.1,0.8	NS	13	A
				Sham RFA	28	11.6 (3.5)	-1.0					
Ferguson 2003[231] 12502473	16 (4) [10-25]	10.0 (5.2)	8 to15 mo (PL)	LAUP	21	10.7 (3.7)	1.4	-2.2	-5.8, 1.4§§	nd	1	B
				No treatment	23	10.0 (5.2)	-0.8					
Guilleminault 2008[234] 19014072	10 (6) [nd]	6.6 (1.2)	3 mo (XO first phase)	Surgery combo***	15	6.6 (1.2)	-1.8	-1.2	-1.8, -0.5†††	0.005	33	C
				Cognitive behavioral therapy	15	6.6 (1.2)	-0.6					

* Median(range)
† Median(range)
‡ Median(range)
§ Median(range)
** Patients had submucous resection of the deviated septum and bilateral resection of inferior turbinates
†† Estimated from reported data
‡‡ two parts of methods section disagree with each other
§§ Estimated from reported data
*** combinations of pharyngoplasty, tonsillectomy, adenoidectomy, genioglossal advancement septoplasty and RFA of the inferior nasal turbinates
††† Estimated from reported P value

Table 5.20.4 Minimum oxygen saturation (%) in randomized controlled trials of surgery vs. control

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Back 2009[230] 19504550	12 (5–8)* [5-15]	8.0 (3.0-16.0)†	4 mo (PL)	RFA	17	82.0 (68.0-88.0)‡	0	0	nd	NS	0	A
				sham surgery	15	83.0 (69.0-88.0)§	0					
Woodson 2003[233] 12825037	15 (7) [10-30 or 5-40]**	11.6(3.5)	2 mo (PL)	RFA	24	86.3 (7.6)	-0.6	-1.2	-3.8, 1.4	NS	13	A
				Sham RFA	28	88.3 (3.9)	0.6					
Guilleminault 2008[234] 19014072	10 (6) [nd]	6.6 (1.2)	3 mo (XO first phase)	Surgery combo††	15	91.3 (1.9)	4.7	4.4	2.1,6.6‡‡	<0.0001	33	C
				Cognitive behavioral therapy	15	91.3 (1.9)	0.3					

* Median(range)
† Median(range)
‡ Median(range)
§ Median(range)
** Two parts of methods section disagree with each other
†† combinations of pharyngoplasty, tonsillectomy, adenoidectomy, genioglossal advancement septoplasty and RFA of the inferior nasal turbinates
‡‡ Estimated from reported P value

Table 5.20.5 Sleep stage changes (%) in randomized controlled trials of surgery vs. control

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Outcome	Interventions	No. analyzed	Baseline (SD)	Change (Final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Guilleminault 2008[234] 19014072	10 (6) [nd]	6.6 (1.2)	3 mo (XO first phase)	REM	Surgery combo*	15	13.1(1.8)	3.7	3.1	1.5, 4.6†	<0.0001	33	C
					Cognitive behavioral therapy	15	13.1(1.8)	0.6					
				Stage 3 and 4	Surgery combo‡	15	11.5(1.5)	4.5	3.5	1.7, 5.3§	<0.0001		
					Cognitive behavioral therapy	15	11.5(1.5)	1					

* combinations of pharyngoplasty, tonsillectomy, adenoidectomy, genioglossal advancement septoplasty and RFA of the inferior nasal turbinates
† Estimated from reported P value
‡ combinations of pharyngoplasty, tonsillectomy, adenoidectomy, genioglossal advancement septoplasty and RFA of the inferior nasal turbinates
§ Estimated from reported P value

Table 5.20.6. FOSQ in randomized controlled trials of surgery vs. control

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff or Diff	95% CI	P Btw	Dropout, %	Study Quality
Woodson 2003[233] 12825037	15 (7) [10-30 or 5-40]*	11.6(3.5)	2 mo (PL)	RFA	24	16.5(2.0)	1.2	0.9	-0.1, 1.9	0.04	13	A
				Sham RFA	27	16.8(2.1)	0.4					

* Two parts of methods section disagree with each other

Table 5.20.7 Functional Outcomes in randomized controlled trials of surgery vs. control

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. Analyzed	Outcome	Favors	If Significant Difference Net Difference	95% CI	Test Range "Worst"	"Best"	P Btw	Dropout, %	Study Quality
Back 2009[230] 19504550	12 (5–8)* [5-15]	8.0 (3.0-16.0)†	4 mo (PL)	RFA	17	SF-36 (all domains)	0						0	A
				sham surgery	15									
Woodson 2003[233] 12825037	15 (7) [10-30 or 5-40]‡	11.6(3.5)	2 mo (PL)	RFA	24	SF-36 (all domains)	0						13	A
				Sham RFA	27									
Ferguson 2003[231] 12502473	16 (4) [10-25]	10.0 (5.2)	8 to15 mo (PL)	LAUP	21	SAQLI	0						1	B
				No treatment	23									
Lojander, 1999[115] 10188139	nd	(nd)	12 mo (PL)	UPPP	10	Wechsler verbal	0						3	C
				Conservative treatment	10									
						Wechsler performance	0							
						Wechsler memory	0							

* Median (range)
† Median (range)
‡ Two parts of methods section disagree with each other

Table 5.21.1 Studies of surgery vs. CPAP: Study characteristics

Study PMID	Interventions	Mean age, yr	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Major quality issues
Anand 1991[239] 1945423	UPPP CPAP	53 (nd)	60	nd	--	US (1983-90)	No eligibility criteria. Retrospective.
Ceylan 2009[238] 19770425	TCRFVTR CPAP	46 (nd)	89	28.8	--	Turkey (2003-06)	Small sample size. Prospective nonrandomized.
Conradt 1998[235] 9785277	MMO CPAP	42 (10)	100	26.7	Craniofacial abnormalities	Germany (1993-96)	No eligibility criteria. Prospective nonrandomized.
Katsantonis 1988[240] 327 8184	UPP Orthognathic device Tracheostomy Medication(TCA) Tongue retaining device CPAP	49 (19-78)*	81	nd	--	US (1982-86)	No eligibility criteria. Retrospective.
Keenan 1994[241] 8275724	UPPP CPAP	52 (12)	79	36.0	--	Canada (1984-90)	Significant difference between followup durations. Retrospective.
Lin 2006[242] 16735919	Extended UPP CPAP	48 (nd)	nd	27.2	--	Taiwan (2000-01)	Significant differences in baseline characteristics. Retrospective.
Robinson 2009[243] 19643262	Stepwise surgery CPAP	56 (nd)	88	31.6		Australia (2003-04)	Incomplete results. Retrospective.
Weaver 2004[244] 15195049	UPPP CPAP	57 (nd)	98	nd	--	US (1997-2001)	No details on OSA severity. Retrospective.
Woodson 2001[236] 11593163	TCRFVTR CPAP	48 (9)	77	31.2	BMI <35 kg/m^2, Anesthesia risk group ASA class I, II, or III	US (nd)	No eligibility criteria. Prospective nonrandomized.
Woodson 2003[233] 12825037	RFA (tongue & palate) CPAP	53 (nd)	60	nd	--	US (nd)	
Zorick 1990[237] 2086548	UPPP CPAP	46 (nd)	89	28.8	--	US (nd)	Dropout rate >20%. No eligibility criteria. Prospective nonrandomized

* Range

Table 5.21.2 Categorical outcomes in studies of surgery vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Outcome	Interventions	n Event	N Total	Outcome Metric	Result*	95% CI	P Btw	Dropout, %	Study quality
Weaver 2004[244] 15195049	nd [nd]	nd	6 y (NRCS, retrospective)	Mortality	UPPP	nd	2072	HR	1.31	1.03, 1.67	0.03	NA	C
					CPAP	nd	20826						
Katsantonis 1988[240] 327 8184	70 UPPP 80 CPAP [nd]	nd	18 mo (retrospective)	50% improvement in AHI and 85% improvement in severity index	UPPP	37	98	%	38 vs. 100	nd	nd	NA	C
					CPAP	53	53						
Keenan 1994[241] 8275724	nd [≥5]	nd	28 to 43 mo (NRCS, retrospective)	Survival	UPPP	6	149	%	4 vs. 2	nd	NS	NA	C
					CPAP	3	126						
Anand 1991[239] 1945423	(nd) [nd]	nd	16 d to 87mo (NRCS, retrospective)	Increased MSLT score ≥3 min	UPPP	13	43	%	30 vs. 41	nd	nd	NA	C
					CPAP	12	29						

* Top row intervention vs. bottom row intervention.

Table 5.21.3 Survival in studies of surgery vs. CPAP

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Outcome	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Keenan 1994[241] 8275724	nd [≥5]	nd	28 to 43 mo (NRCS, retrospective)	Age adjusted 5 y probability of survival	UPPP	149	nd	0.94 (0.02) *	-0.01	nd	NS	NA	C
					CPAP	126	nd	0.95 (0.03) †					
Weaver 2004[244] 15195049	nd [nd]	nd	4 y (NRCS, retrospective)	Survival (years)	UPPP	2072	nd	2.81	0.06	0.0, 0.1‡	0.03	NA	C
					CPAP	20, 826	nd	2.75					

* Mean (SE)
† Mean (SE)
‡ Estimated from reported P value

Table 5.21.4 AHI or RDI in studies of surgery vs. CPAP

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Outcome	Interventions	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff or Diff	95% CI	P Btw	Dropout, %	Study Quality
Ceylan 2009[238] 19770425	28 (6) [5-40]	11.1 (3.1)	12 mo (NRCS, prospective)	AHI	TCRFTVR	26	29.6 (7.8)	-13.5	-0.7	-4.8, 3.4*	NS	0	C
					CPAP	21	28.5 (6.9)	-12.8					
Conradt 1998[235] 9785277	RDI 59 (24) [nd]	nd	3 mo (NRCS, prospective)	RDI	MMA	24	59.4 (24.1)	-53.8	0.3	-11.7, 12.3†	NS	0	C
					CPAP	24	59.4 (24.1)	-54.1					
Katsantonis 1988[240] 327 8184	70 UPPP 80 CPAP [nd]	nd	18 mo (retrospective)	AHI	UPPP	98	~70 (nd)	-20	35	nd	nd	NA	C
					CPAP	53	~80 (nd)	-55					
Lin 2006[242] 16735919	RDI 65 (24) vs. 44 (30) [nd]	14.1 (4.4) vs. 11.8 (5.5)	6 mo (NRCS, retrospective)	RDI	Extended UPP	55	43.6 (29.7)	-31.5	31.1	12.5, 49.6	<0.001	NA	C
					CPAP	54	65.3 (24.7)	-62.6					

* Estimated from reported P value
† Estimated from reported data

Table 5.21.5 ESS in studies of surgery vs. CPAP

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff or Diff	95% CI	P Btw	Dropout, %	Study Quality
Woodson 2003[233] 12825037	15 (7) [10-30 or 5-40]*	11.6 (3.5)	2 mo (PL RCT)	RFA	26	11.9 (4.6)	-2.1	-0.2	-2.4, 2.8	NS	13	A
				CPAP	25	12.6 (5.0)	-2.3					
Ceylan 2009[238] 19770425	28 (6) [5-40	11.1 (3.1)	12 mo (NRCS prospective)	TCRFTVR†	26	10.8 (3.2)	-2.6	+0.1	-0.7, 0.9‡	NS	0	C
				CPAP	21	11.1 (3.1)	-2.7					
Lin 2006[242] 16735919	RDI 65 (24) vs. 44 (30) [nd]	14.1 (4.4) vs. 11.8 (5.5)	6 mo (NRCS, retrospective)	Extended UPP	55	11.1 (3.72)	-3.78	+1.09	nd	NS	NA	C
				CPAP	54	14.1 (4.43)	-4.87					
Robinson 2009[243] 19643262	RDI 45 (nd) [>15]	10.5 (8.75)§	20-46 mo (NRCS, retrospective)	Surgery, stepwise approach	77	9 (7)**	-5	1.5	-8.7, 11.7††	NS‡‡	NA	C
				CPAP	89	10.5 (8.75)§§	-6.5					
Woodson 2001[236] 11593163	40 (21) [15-60]	11.8 (nd)	8-12 wk (NRCS, prospective)	TCRFTVR***	50	11.1 (nd)	-3.7	0.7	nd	nd	15	C
				CPAP	74	11.8 (nd)	-4.4					

* two parts of methods section disagree with each other
† temperature controlled RF tissue volume reduction and septoplasty ± nasal valve suspension (somnoplasty)
‡ Estimated from reported P value
§ Median (IQR)
** Median (IQR)
†† Estimated from reported P value
‡‡ adjusted for age, RDI, Epworth, length of followup
§§ Median (IQR)
*** temperature controlled radiofrequency tissue volume reduction of the soft palate

Table 5.21.6 Other continuous outcomes in studies of surgery vs. CPAP

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Outcome	Interventions	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff or Diff	95% CI	P Btw	Dropout, %	Study Quality
Woodson 2003[233] 12825037	15 (7) [10-30 or 5-40]*	11.6 (3.5)	2 mo (PL RCT)	FOSQ	RFA	26	16.5 (2.0)	1.2	-0.29	-1.35, 0.77	NS	13	A
					CPAP	25	16.0 (2.6)	1.5					
Conradt 1998[235] 9785277	RDI 59 (24)	nd	3 mo (NRCS, prospective)	Sleep efficiency	MMA	24	80.2 (9.91)	4	-1	-6.2, 4.2†	NS	0	C
					CPAP	24	80.2 (9.91)	5					
				Arousal index	MMA	24	54.3 (20.0)	-34.6	0.4	-10.3, 11.1	NS		
					CPAP	24	54.3 (20.0)	-35					
Ceylan 2009[238] 19770425	28 (6) [5-40	11.1 (3.1)	12 mo (NRCS, prospective)	Minimum O_2 saturation	TCRFTVR	26	86.8 (8.9)	7.8	2.7	-4.7, 10.2‡	NS	0	C
					CPAP	21	88.4 (8.5)	5.1					
Woodson 2001[236] 11593163	40 (21) [15-60]	11.8 (nd)	8-12 wk (NRCS, prospective)	FOSQ	TCRFTVR	18	72.3 (13.8)	7.8	-4.4	-10.2, 1.4§	NS	15	C
					CPAP	74	69.9 (19.7)	12.2					
Zorick 1990[237] 2086548	nd [nd]	nd	6 wk (NRCS, prospective)	MSLT	UPPP	46	4.1 (0.9)	1.4	-4.5	-8.9, -0.02**	<0.05	nd	C
					CPAP	46	4.4 (1.1)	5.9					

* Two parts of methods section disagree with each other
† Estimated from reported data
‡ Estimated from reported P value
§ Estimated from reported P value
** Estimated from reported data

Table 5.21.7 Sleep stage in randomized controlled trials of surgery vs. CPAP

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Outcome	Interventions	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff or Diff	95% CI	P Btw	Dropout, %	Study Quality
Conradt 1998[235] 9785277	RDI 59 (24)	nd	3 mo (NRCS, prospective)	REM	MMA	24	19.6 (7.38)	1.7	0.1	-3.7, 3.9*	NS	0	C
					CPAP	24	19.6 (7.38)	1.6					
				Stage 3 and 4	MMA	24	8.0 (6.08)	6.4	-3.8	-8.9,1.3†	NS		
					CPAP	24	8.0 (6.08)	10.2					
Zorick 1990[237] 2086548	nd [nd]	nd	6 wk (NRCS, prospective)	REM	UPPP	46	10 (5)	3	-8	-15.9,-0.03‡	<0.05	nd	C
					CPAP	46	10 (6)	11					
				Stage 3 and 4	UPPP	46	4.0 (6)	1	--7	-13.9, -0.03§	<0.05		
					CPAP	46	1.0 (3)	8					

* Estimated from reported data
† Estimated from reported data
‡ Estimated from reported data
§ Estimated from reported data

Table 5.21.8 Quality of life outcomes in randomized controlled trials of surgery vs. CPAP

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. Analyzed	Outcome	Favors	If Significant Difference Net Difference	95% CI	Test Range "Worst"	"Best"	P Btw	Dropout, %	Study Quality
Woodson 2003[233] 12825037	15 (7) [10-30 or 5-40]*	11.6 (3.5)	2 mo (PL RCT)	RFA (tongue & palate)	24	SF-36 (PCS, MCS)	0						13	A
				CPAP	24									
Lin 2006[242] 16735919	RDI 65 (24) [nd]	14.1 (4.4)	6 mo (NRCS, retrospective)	Extended UPP	55	SF-36 (all domains)	0						NA	C
				CPAP	54									
Woodson 2001[236] 11593163	40 (21) [15-60]	11.8 (nd)	8-12 wk (NRCS, prospective)	TCRFVTR	nd	SF-36 (all domains)	0						NA	C
				nCPAP	nd									

* Two parts of methods section disagree with each other

Table 5.23.1. Randomized controlled trials of drug interventions: Study characteristics

Study PMID	Interventions	Mean Age, yr	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Other quality issues
Carley 2007[248] 17310863	Mirtazapine 4.5 or 15 mg Placebo	41	58	37.8	Most pts with HTN excluded	US (nd)	-
Clarenbach 2008[253] 18710420	Xylometazoline Placebo	49	87	30.7	nd	Switzerland (2004-05)	-
Kiely 2004[249] 14694248	Fluticasone placebo	47	nd	29.8	Snorers	Ireland (nd)	-
Kraiczi 1999[250] 9989366	Paroxetine Placebo	53	100	28.7	No	Sweden (nd)	-
Suurna 2008[252] 18656731	Pantoprazole Placebo	51	42	31	All patients have GERD	US (2004-06)	-
Ryan 2009[191] 19961025	Steroid + CPAP Dry CPAP	48	94	34	nd	Ireland (nd)	-
Whyte 1988[251] 3067313	Acetazolamide or Protriptyline Placebo	nd	80	nd	nd	UK (nd)	No information on exclusion criteria

Table 5.23.2 AHI (events/hr) in randomized controlled trials of drug interventions

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Carley 2007[248] 17310863	23 (17) [nd]	nd	7 d (XO)	Mirtazapine 4.5 mg	12	nd	13.5	-8.8	-14.8, -2.8*	0.004	0	B
				Mirtazapine 15 mg	12	nd	11.4	-10.9	-18.3, -3.5†	0.004		
				Placebo	12	nd	22.3					
Clarenbach 2008[253] 18710420	33 (25) [>10]	11.8 (4.5)	1 wk (XO)	Xylometazoline	12	32.6 (24.5)	29.3 (32.5)	-2.9	-21.4, 15.6‡	NS	0	A
				Placebo	12	32.6 (24.5)	32.2 (32.8)					
Kiely 2004[249] 14694248	26§ (27)**	12 (nd)	4 wk (XO)	Fluticasone	13	26.5 (26.9)††	23.3	-6.5‡‡	-29.5, 1.8	<0.05	0	B
				Placebo	13	26.5 (26.9)	30.3					
				Fluticasone	18§§	nd	17	-5.6***	-22.6, -0.7	0.01		
				Placebo	13†††	nd	24.3					
Kraiczi 1999[250] 9989366	nd	nd	6 wk (XO)	Paroxetine	17	nd	30.2	-6.1	-17.9, 0.6	0.021	15	B
				Placebo	17	nd	36.3					
Whyte 1988[251] 3067313	nd [>15]	nd	2 wk (XO)	Acetazolamide	10	nd	26	-24	nd	nd	0	C
				Protriptyline	10	nd	46	-4	nd	nd		
				Placebo	10	nd	50					

* Estimated from reported P value
† Estimated from reported P value
‡ Estimated from reported data
§ Median
** Quartile range
†† Median (quartile range)
‡‡ Median
§§ Using definition of AHI ≥ 5 instead of AHI ≥10
*** Median
††† Using definition of AHI ≥ 5 instead of AHI ≥10

Table 5.23.3 ESS in randomized controlled trials of drug interventions

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Clarenbach 2008[253] 18710420	33 (24) [>10]	11.8 (4.5)	1 wk (XO)	Xylometazoline	12	nd	10.5 (3.8)	-1.3	-3.6, 1.0*	NS	0	A
				Placebo	12	nd	11.8 (4.4)					
Suurna 2008[252] 18656731	10 (8) [≤30]	14 (3.5)	2 wk (XO)	Pantoprazole	57	14 (3.5)	-1.8	-0.5	-0.98, -0.02†	0.04	16	B
				Placebo	57	14 (3.5)	-1.3					
Ryan 2009[191] 19961025	36 (22) [≥10]	12 (5)	4 wk (PL)	Steroid + CPAP	42	13 (6)	-4	-1	-4.0, 2.0‡	nd	9	B
				Dry CPAP	39	12 (5)	-3					

* Estimated from reported data.
† Estimated from reported P value.
‡ Estimated from reported data.

Table 5.24.4 Arousal index (events/hr) in randomized controlled trials of drug interventions

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Carley 2007[248] 17310863	23 (17) [nd]	nd	7 d (XO)	Mirtazapine 4.5 mg	12	nd	41.9	0.8	nd	NS	0	B
				Mirtazapine 15 mg	12	nd	28.1	-13.0	-24, -2*	0.02		
				Placebo	12	nd	41.1					
Clarenbach 2008[253] 18710420	33 (24) [>10]	11.8 (4.5)	1 wk (XO)	Xylometazoline	12	nd	54	-2	nd	NS	0	A
				Placebo	12	nd	56					
Whyte 1988[251] 3067313	nd [>15]	nd	2 wk (XO)	Acetazolamide	10	nd	16	-10	nd	nd	0	C
				Protriptyline	10	nd	21	-5	nd	nd		
				Placebo	10	nd	26					

* Estimated from reported P value

Table 5.24.5 Sleep efficiency (%) in randomized controlled trials of drug interventions

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Carley 2007[248] 17310863	23 (17) [nd]	nd	7 d (XO)	Mirtazapine 4.5 mg	12	nd	87.7	4.8	nd	NS	0	B
				Mirtazapine 15 mg	12	nd	90.1	8.2	nd	0.05		
				Placebo	12	nd	82.9					
Clarenbach 2008[253] 18710420	33 (24) [>10]	11.8 (4.5)	1 wk (XO)	Xylometazoline	12	nd	86 (12)	-2	nd	NS	0	A
				Placebo	12	nd	88 (6)					
Kraiczi 1999[250] 9989366	nd	nd	6 wk (XO)	Paroxetine	17	nd	77.2	-2.9	-10.6,4.3	0.411	15	B
				Placebo	17	nd	80.3					
Whyte 1988[251] 3067313	nd [>15]	nd	2 wk (XO)	Acetazolamide	10	nd	82*	12	nd	nd	0	C
				Protriptyline	10	nd	78†	8	nd	nd		
				Placebo	10	nd	70‡					

* Estimated from Figure 4 in paper
† Estimated from Figure 4 in paper
‡ Estimated from Figure 4 in paper

Table 5.23.6 Slow wave sleep (%) in randomized controlled trials of drug interventions

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Carley 2007[248] 17310863	23 (17) [nd]	nd	7 d (XO)	Mirtazapine 4.5 mg	12	nd	7.5	2.4	nd	NS	0	B
				Mirtazapine 15 mg	12	nd	7.2	2.1	nd	NS		
				Placebo	12	nd	5.1					
Clarenbach 2008[253] 18710420	33 (24) [>10]	11.8 (4.5)	1 wk (XO)	Xylometazoline	12	nd	9 (8)	-2	nd	NS	0	A
				Placebo	12	nd	7 (6)					
Kraiczi 1999[250] 9989366	nd	nd	6 wk (XO)	Paroxetine	17	nd	12.2	-0.6	-6.4, 4.7	0.411	15	B
				Placebo	17	nd	12.8					
Whyte 1988[251] 3067313	nd [>15]	nd	2 wk (XO)	Acetazolamide	10	nd	14*	-1	nd	nd	0	C
				Protriptyline	10	nd	15†	0	nd	nd		
				Placebo	10	nd	15‡					

* Estimated from Figure 4 in paper
† Estimated from Figure 4 in paper
‡ Estimated from Figure 4 in paper

Table 5.23.7 REM sleep (%) in randomized controlled trials of drug interventions

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Carley 2007[248] 17310863	23 (17) [nd]	nd	7 d (XO)	Mirtazapine 4.5 mg	12	nd	15.6	-6.6	nd	NS	0	B
				Mirtazapine 15 mg	12	nd	16.6	-5.6	nd	0.04		
				Placebo	12	nd	22.2					
Clarenbach 2008[253] 18710420	33 (24) [>10]	11.8 (4.5)	1 wk (XO)	Xylometazoline	12	nd	10 (5)	-1	nd	NS	0	A
				Placebo	12	nd	11 (5)					
Kiely 2004[249] 14694248	26.5* (26.9)†	12 (nd)	4 wk (XO)	Fluticasone	13	nd	10.9	0.4‡	nd	NS	0	B
				Placebo	13	nd	10.5					
Kraiczi 1999[250] 9989366	nd	nd	6 wk (XO)	Paroxetine	17	nd	9.7	nd	-7.4, 1.4	0.191	15	B
				Placebo	17	nd	12.9					
Whyte 1988[251] 3067313	nd [>15]	nd	2 wk (XO)	Acetazolamide	10	nd	23	4	nd	nd	0	C
				Protriptyline	10	nd	18	-1	nd	nd		
				Placebo	10	nd	19					

* Median
† Quartile range
‡ Median

Table 5.23.8 Minimum oxygen saturation (%) in randomized controlled trials of drug interventions

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Interventions	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff or Diff	95% CI	P Btw	Dropout, %	Study Quality
Carley 2007[248] 17310863	23 (17) [nd]	nd	7 d (XO)	Mirtazapine 4.5 mg	12	nd	81.1	-0.6	nd	NS	0	B
				Mirtazapine 15 mg	12	nd	80.8	-0.9	nd	NS		
				Placebo	12	nd	81.7					
Kiely 2004[249] 14694248	26.5* (26.9)†	12 (nd)	4 wk (XO)	Fluticasone	13	nd	2.1	-0.1	nd	NS	0	B
				Placebo	13	nd	2.2					
Whyte 1988[251] 3067313	nd [>15]	nd	2 wk (XO)	Acetazolamide	10	nd	72	2	nd	nd	0	C
				Protriptyline	10	nd	77	7	nd	nd		
				Placebo	10	nd	70					

Table 5.23.9 FOSQ in randomized controlled trials of drug interventions

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Suurna 2008[252] 18656731	10 (8) [≤30]	14 (3.5)	2 wk (XO)	Pantoprazole	57	nd	-8.1	-2.6	-5.3, 0.1‡	0.06	16	B
				Placebo	57	nd	-5.5					

* Median
† Quartile range
‡ Estimated from reported P value.

Table 5.24.1 Randomized controlled trials of atrial overdrive pacing: Study characteristics

Study PMID	Interventions	Mean Age, yr	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Other quality issues
Melzer 2006[255] 17040007	AOP 75 bpm AOP 45 bpm	69	84%	29.5	nd	Germany, Switzerland (nd)	Dropout >20%, patient not blinded.
Simantirakis 2005[256] 16354893	AOP CPAP	60	75%	nd	Bradyarrhythmia (pacer)	Greece	No description of how pressure was titrated.

Table 5.24.2. AHI (events/hr) in randomized controlled trials of atrial overdrive pacing

Study PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Melzer 2006[255] 17040007	27* (nd) [>15]	9.0 (3.9)	1 wk (XO)	AOP 75 bpm	19	nd	23.0	-3.8	-14.6, 7.0†	0.49	5	A
				AOP 45 bpm	19	nd	26.8					
Simantirakis 2005[256] 16354893	49 (19) [nd]	15.7 (nd)	1 mo (XO)	AOP	16	49.0 (19)	0.2	46.5	-9.8, 27.8‡	nd	0	B
				CPAP	16	49.0 (19)	-46.3					

* Estimated from control value
† Estimated from reported P value.
‡ Estimated from reported data.

Table 5.24.3. ESS in randomized Controlled trials of atrial overdrive pacing

Study PMID	Baseline AHI (SD) [range]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Baseline (SD)	Change (final)	Net diff or Diff	95% CI	P Btw	Dropout, %	Study quality
Simantirakis 2005[256] 16354893	**49.0 (nd)**	**15.7 (nd)**	**1 mo (XO)**	AOP	**16**	**15.7 (nd)**	**0.1**	**10.3**	**nd**	**nd**	**0%**	**B**
				CPAP	16	15.7 (nd)	-10.2					

Table 5.24.4. REM and Slow Wave Sleep (%) in randomized controlled trials of atrial overdrive pacing

Author Year PMID	Baseline AHI (SD) [Eligibility]	Baseline ESS (SD)	Duration (Design)	Outcome	Interventions	No. Analyzed	Baseline (SD)	Change (Final)	Net Diff or Diff	95% CI	P Btw	Dropout, %	Study Quality
Melzer 2006[255] 17040007	nd	9.0 (3.9)	1 wk (XO)	REM (%)	AOP 75 bpm	19	nd	0	0	nd	0.93	5%	A
					AOP 45 bpm	19	nd	0					
				Slow wave sleep (%)	AOP 75 bpm	19	nd	14	-3.8	-46.0, 38.4*	0.86		
					AOP 45 bpm	19	nd	13					

* Estimated from reported P value.

Table 5.25.1 Positive airway pressure devices, reported major adverse events*†

Study PMID	Intervention details	Followup duration	No. analyzed	Adverse event	n	%
Robinson, 2009[243] 19643262	CPAP	2-4 mo	73	Claustrophobia	1	1.4%
Hukins, 2004[170] 15683142	CPAP	2 mo	55	Pressure intolerance	5	9.2%
	AutoCPAP				2	3.6%
Salgado, 2008[193] 18982206	AutoCPAP, humidified	4 wk	17	Epistaxis	0	0
	AutoCPAP, nonhumidified		22		2	9.1%
Khanna, 2003[160] 14592306	Nasal CPAP	1 mo	17	Excessive nasal dryness	2	12%
			17	Epistaxis	2	12%
		2 mo	15	Excessive pressure	2	13%
			13	Severe claustrophobia	3	23%
	Oral CPAP	1 mo	21	Excessive oral dryness	11	52%
			21	Severe gum pain	3	14%
			21	Excessive pressure	4	19%
Nussbaumer, 2006[166] 16537862	AutoCPAP	1 mo	34	Claustrophobia	1	2.9%
Anderson, 2003[158] 14572126	Nasal CPAP	1 mo	21	Claustrophobia	1	4.8%
	Oral CPAP	1 mo	21	Dry mouthr/throat (major problem)	3	14%
				Excess salivation (major problem)	1	4.8%
				Sore gums/lips (major problem)	2	9.5%

* Reporting of no events excluded (unless N≥100), except Salgado 2008 because the direct comparison between humidified and nonhumidified CPAP was reported.
† Other adverse events (or side effects or harms) reported by studies included: skin irritation, nasal irritation or obstruction, dry nose or mouth, excess salivation, minor or moderate sore gums or lips, minor aerophagia, abdominal distension, minor chest wall discomfort, pressure discomfort, and transient or minor epistaxis.

Table 5.25.2 Mandibular advancement devices, reported major adverse events*†

Study PMID	Intervention details	Followup duration	No. analyzed	Adverse event	n	%
Engleman, 2002[206] 12231497	Custom-made (80% maximal comfortable mandibular protrusion, 2-4 mm interdental clearance)	8 wk	48	Dental crown damaged	3	6.3%
Walker-Engstrom 2002[246] 11888954	Custom-made (50% maximal mandibular advancement, 5 mm vertical opening)	4 yr	45	Tooth malocclusion and TMJ pain	1	2.2%
				Aphthous ulcer due to acrylic polymer allergy	1	2.2%
Petri, 2008[198] 18482111	Custom-made (maximal comfortable mandibular advancement, 5 mm vertical opening)	4 wk	31	Teeth loosening	1	3.2%
				TMJ pain	1	3.2%
Ferguson 1996[207] 8625679	Snore-Guard (mandible 3 mm posterior to maximal acceptable advance, 7 mm opening)	4 mo	25	Moderate to severe jaw discomfort	1	4.0%
Johnston, 2002[202] 12143089	Custom-made (75% maximal comfortable mandibular protrusion, 4 mm interincisal clearance)	4-6 wk	19	Persistent daytime TMJ discomfort	1	5.2%

* Reporting of no events excluded (unless N≥100).
† Other adverse events (or side effects or harms) reported by studies included: pressure sensation in the mouth, transient morning mouth and TMJ discomfort or sounds, minor sore teeth or jaw, transient mild mucosal erosions, minor excessive salivation, tooth grinding, and sleep disruption.

Table 5.25.3 Surgical intervention (UPPP primarily), reported major adverse events*†

Study PMID	Intervention details	Followup duration	No. analyzed	Adverse event	n	%
Kezirian, 2004[262] 15091217	UPPP ± tonsil, nasal, turbinate surgery	30 days	3130	Death	7	0.2%
				Reintubation	17	0.5%
				Emergency tracheotomy	7	0.2%
				Ventilation >48 hr	6	0.2%
				Pneumonia	11	0.4%
				Cardiovascular complication	8	0.3%
				Hemorrhage	9	0.3%
				Deep vein thrombosis	0	0%
				Kidney failure	0	0%
				Total serious complications (including death)	51	1.6%
Lundkvist 2009[263] 19863325	UPPP (with tonsillectomy)	1 yr	158	Bleeding from tonsillectomy, profuse	2	1.3%
				Laryngeal edema, substantial	2	1.3%
				Long-term sequelae from complications	0	0%
				Death	0	0%
Esclamado 1989[264] 2530406	UPPP ± tonsil, nasal surgery, tracheostomy	24 hr	135	Reintubation (long-term sequelae = 0/135)	7	5.2%
				Death	1	0.7%
				Pulmonary edema	1	0.7%
				Hemorrhage, requiring surgical intervention	3	2.2%
Friedman, 2004[265] 15091218	UPPP	Perioperative	134	Airway complication	0	0%
				Abscess requiring surgical intervention	0	0%
				Rehospitalization	0	0%
Harmon 1989[266] 2916139	UPPP ± nasal, adenoid, tracheostomy	3 mo	126	Oropharyngeal hemorrhage	7	5.5%
				Voice change (rhinolalia)	2	0.6%
				Nasopharyngeal reflux	0	0%
				Pharyngeal infection	0	0%
			132‡	Pneumonia	2	1.5%
				Death	2	1.5%
				Emergency tracheotomy	2	1.5%
				Intubation difficulty and/or pulmonary edema or respiratory arrest	6	4.5%
Haavisto 1994[267] 7923849	UPPP	Postoperative	101	Hemorrhage requiring surgical intervention	5	5.0%
				Tracheostomy	4	4.0%
				Asystole, post-extubation	1	1.0%
				Infection	0	0%
				Arrhythmia	0	0%
		1 yr	91	Nasopharyngeal regurgitation	22	24%
				Difficulty swallowing	9	10%
				Difficulty with speech or change in voice quality	14	15%
				Loss of taste	2	2.2%
				Breathing difficulty	5	5.5%
				Hemorrhage	1	1.1%

Study PMID	Intervention details	Followup duration	No. analyzed	Adverse event	n	%
Anand 1991[239] 1945423	UPPP ± nose, turbinate, tonsil, epiglottis surgery, tracheostomy	16 d – 7.25 yr	66	Velopharyngeal incompetence >1 mo	8	12%
				Voice change, long term	1	1.5%
				Choanal stenosis, unilateral	1	1.5%
				Bleeding, requiring surgical intervention	1	1.5%
				Reintubation	1	1.5%
				Death	1	1.5%
				Nasal synechiae	2	3.0%
				Tracheal stenosis	1	1.5%
Walker-Engstrom 2002[246] 11888954	UPPP	4 yr	40	Nasopharyngeal regurgitation of fluids (pronounced)	3	8%
				Difficulty swallowing (pronounced)	4	10%
Ferguson, 2003[231] 12502473	LAUP	nd	21	Swallowing difficulty, persistent, moderate	1	4.8%
				Bleeding, requiring medical attention	1	4.8%
Lojander, 1996[114] 8681614	UPPP ± osteotomy	12 mo	18	Tracheotomy x 1 mo	1	5.6%
				Infection, requiring surgical intervention	2	11%
				Velopharyngeal incompetence	2	11%

* Reporting of no events excluded (unless N≥100).
† Other adverse events (or side effects or harms) reported by studies included: unplanned medications, mild transient pain and swallowing difficulty, postoperative (minor) hematomas or ulcerations, mild bleeding, mild and transient tongue deviation, transient swelling sensation, pharyngeal dryness, nasal regurgitation (transient), increased mucus secretion, gagging, cough, infection (self-limited), antibiotic-related diarrhea, burning sensation, anosmia, temporary vocal quality change, and difficulty singing, playing saxophone, etc.
‡ Including patients who received tracheostomy, tonsillectomy, and/or septoplasty without UPPP.

Table 5.25.4 Radiofrequency ablation, reported major adverse events*†

Study PMID	Intervention details	Followup duration	No. analyzed	Adverse event	n	%
Stuck 2003‡[268] 12797590	RFVTR, tongue base or soft palate or turbinates or combination ± other oropharyngeal, nasal, hyoid surgery	3-8 days	497	Tongue base ulceration, requiring surgical intervention	3	0.6%
				Soft palate mucosa ulceration, requiring surgical intervention	1	0.2%
				Dysphagia requiring hospitalization	4	0.8%
				Hypoglossal nerve palsy, temporary	1	0.2%
				Tongue base abscess, requiring surgical intervention	1	0.2%
		>8 days	422	Long-term complications	0	0%
Woodson, 2001[236] 11593163	RFVTR, tongue base	6 wk	73	Severe, suppurative tongue base infection (2 required surgical intervention, 2 drained spontaneously)	4	5.5%
				Tongue abscess	1	1.4%
				Infection or cellulitis	7	9.6%

* Reporting of no events excluded (unless N≥100).
† Other adverse events (or side effects or harms) reported by studies included: unplanned medications, mild transient pain and swallowing difficulty, postoperative (minor) hematomas or ulcerations, mild and transient tongue deviation, transient swelling sensation, and asymptomatic fibrotic narrowing.
‡ Complication rate decreased over time, 1999-2002.

Table 5.25.5 Combination or various surgeries, reported major adverse events*†

Study PMID	Intervention details	Followup duration	No. analyzed	Adverse event	n	%
Riley, 1993[269] 8441535	UPPP + MO/GAHM‡	Postoperative	233	Bleeding requiring anesthesia	3	1.3%
		9 mo		Long-term speech or swallowing problem	0	0%
Riley, 1997[270] 9419093	UPPP + GA + HS§ UPPP ± GA ± HS ± MMO	3-7 days	182**	Bleeding (not described)	4	1.9%
				New onset atrial fibrillation	4	1.9%
				New unstable angina	1	0.5%
				Death	0	0%
Friedman, 2004[265] 15091218	UPPP + Tongue RFA	Perioperative	143	Hypoglossal nerve paralysis	1	0.7%
				Nerve paralysis (transient)	2	1.4%
				Airway complication	0	0%
				Abscess requiring surgical intervention	0	0%
				Rehospitalization	0	0%
Friedman, 2007[271] 17713449	3-level: Tongue RF, Pillar implants, partial uvulectomy, nasal, turbinate surgery	nd	122	Major complication	0	0%
				Nasal septum perforation, tongue mucosal ulceration, & hypoglossal nerve weakness <1 month	1	0.8%
				Turbinate bone exposure	2	1.6%
				Pillar extrusion requiring removal and replacement	5	4.1%
Benazzo, 2008[272] 18568505	HS + nasal, turbinate, palate surgery	6 mo	109	"Major complication"	0	0%
Robinson, 2009[243] 19643262	Stepwise UPPP, GA, TAP, HS, Tongue RFA	nd	64	Paresthesia	11	17%
				Dysphagia	7	11%
				Voice change	2	3.1%
				Taste alteration	1	1.6%
				Wound dehiscence	1	1.6%
				Infection	2	3.1%
				Palatal fistula (transient)	1	1.6%

* Reporting of no events excluded (unless N≥100).
† Other adverse events (or side effects or harms) reported by studies included: aspiration, neck seroma, transient dysphagia, transient tongue base ulceration, suture removal for foreign body reaction, and transient facial anesthesia.
‡ Small number with only UPPP or only MO/GAHM.
§ Mostly
** 210 procedures in 182 patients

Table 5.25.6 Surgical implant, reported major adverse events*

Study PMID	Intervention details	Followup duration	No. analyzed	Adverse event	n	%
Steward, 2008[229] 18922335	Pillar implant	1 wk	50	Infection	1	2%
				Extrusion	2	4%

* Reporting of no events excluded (unless N≥100). Other reported adverse events included sore throat and foreign body sensation.

Table 5.25.7 Bariatric surgery, reported major adverse events*

Study PMID	Intervention details	Followup duration	No. analyzed	Adverse event	n	%
Grunstein, 2007[257] 17580591	Vertical banded gastroplasty (72%) Gastric banding (20%) Gastric bypass (8%)	Perioperative	1592	Perioperative mortality	~3	0.21%
				Bleeding, embolus and/or thrombosis, wound complications, deep infections, pulmonary, and other complications	~207	13.0%

* Reporting of no events excluded (unless N≥100).

Table 5.25.8 Weight loss diet, reported major adverse events*

Study PMID	Intervention details	Followup duration	No. analyzed	Adverse event	n	%
Johansson, 2009[223] 19959590	Liquid, very low energy diet	9 wk	30	Elevated alanine aminotransferase concentration (transient)	2	6.7%
				Gout (transient)	1	3.3%

* Reporting of no events excluded (unless N≥100). Other reported adverse events included dizziness, dry lips, and constipation.

Table 5.25.9 Drugs, reported major adverse events*

Study PMID	Intervention details	Followup duration	No. analyzed	Adverse event	n	%
Bradshaw, 2006[273] 17099012	Zolpidem	4 wk	72	Sleep walking	1	1.4%
Kraiczi, 1999[250] 9989366	Paroxetine†	6 wk	20	Ejaculation disturbance	3	15%
				Decreased libido	2	10%
				Headache	1	5%
				Constipation	1	5%
Whyte, 1988[251] 3067313	Protriptyline	2 wk	10	Severe dry mouth requiring discontinuation	2	20%
				Visual upset	1	10%
				Urinary symptoms	1	10%
				Altered sexual potency & testicular discomfort	1	10%
	Acetazolamide	2 wk	10	Paresthesia, intolerable	1	10%
				Paresthesia, any	8	80%

* Reporting of no events excluded (unless N≥100).
† Other reported adverse events included, fatigue, mouth dryness, somnolence, and dizziness (with both paroxetine and placebo); and sweating, nervousness, infectious pneumonia and Lyme disease (during paroxetine treatment).

Table 6.1a Predictors of compliance with CPAP: Study characteristics

Study PMID	Design Country (study years)	Eligibility	N	Factor	Value	Treatment	CPAP pressure [A] (type)	Ancillary care	(Lack of) Compliance definition
McArdle 1999[274] 10194153	Prosp Scotland, UK (1986-97)	Starting CPAP	1103	**Male** **Age** **BMI** **AHI**	86% 50 [C] yr 30 [C] 50 (18-53) [D]	CPAP various	Manual (separate)	2 weeks with nurse specialist [B]	<2 hr/night x 1 mo or voluntarily discontinued
Krieger 1996[275] 9122571	Prosp France (1984-95)	Starting CPAP	608	**Male** **Age** **BMI** **AHI**	nd 54 yr 31.9 70	CPAP	nd (separate)	Questionnaire: If use <3 hr/night then f/up	<1 hr/night
Pepin 2009[189] 19567496	Prosp (RCT) France (nd)	Starting CPAP	218	**Male** **Age** **BMI** **AHI**	72% 56 yr 31 44	C-Flex vs. CPAP	Auto (separate)	nd	"Objective compliance" not defined (measured by CPAP)
Wild 2004[276] 15358707	Prosp Scotland, UK (nd)	Starting CPAP	119	**Male** **Age** **BMI** **AHI**	79% 51 yr 33 45	CPAP	nd (separate)	Pretitration training Support x2 wk	Adherence = >3 hr/night
Hui 2001[277] 11451834	Prosp Hong Kong (1997-98)	Starting CPAP	112	**Male** **Age** **BMI** **AHI**	90% 46 yr 29.3 48	AutoCPAP	Auto (separate)	Initial education, brochure & training session	hr/night (continuous)

[A] Method for choosing CPAP pressure: Manual (during sleep study); Auto (determined with AutoCPAP); Algorithm (by an algorithm); nd (no data reported); NA (not applicable, eg if AutoCPAP is the intervention). In parentheses: Split (CPAP introduced in a split night study); Separate (CPAP introduced on a separate full night than the diagnostic sleep study).
[B] 2 weeks contact with nurse specialist. At reviews, if objective CPAP use <2 h, confronted with usage data to encourage increase use. If still <2 h at 1 month f/up visit, CPAP machine reclaimed.
[C] Median
[D] Median (interquartile range)

Table 6.1b Predictors of compliance with CPAP, multivariable analyses

Study PMID	Outcome	Overall outcome rate	Follow-up	Predictor	Baseline predictor	HR/OR	95% CI	P	Quality
McArdle [A] 1999[274] 10194153	Discontinue CPAP	16%	(12 mo)	ESS ≤10 [B]	40%	1.92	1.41-2.61	<0.001	A
		32%	(4 yr)	AHI <15 [C]	nd	2.48	1.79-3.46	<0.001	
			22 mo, mean	Nonsnorer	2%	2.76	1.29-5.95	0.009	
				CPAP use at 3 mo <2 hr	*nd*	*13.8*	*8.86-21.5*	*<0.001*	
				AHI <30	~50%			NS	
				Arousal Index <32	~50%			NS	
				No witnessed apneas	17%			NS	
				No somnolence	19%			NS	
				No driving problem	64%			NS	
				Coexisting COPD	10%			NS	
				Pressure <8 cm H2O	~50%			NS	
				Female	14%			NS	
				Age ≥50 y	~50%			NS	
				BMI ≤30	~50%			NS	
Krieger [D] 1996[275] 9122571	CPAP withdrawn	14%	3.2 yr	AHI ≤15	5%	nd		<0.05	C
				Age (continuous [E])	50	nd		<0.05	
				MSLT (continuous [E])	16.5 min			NS	
				ESS (continuous [E])	8.8			NS	
				Respiratory symptoms (nd)				NS	
Pepin [F] 2009[189] 19567496	"Objective compliance" [G]	5 hr/night	3 mo	Mean SaO2, per %	93%	1.22	1.03-1.45	0.02	C
				GrenobleSAQOL Sleepiness [H], per scale unit	~15	1.13	1.04-1.24	<0.01	
				Age, per 10 y	56 y	0.9	0.54-1.34	NS	
				GrenobleSAQOL Treatment, efficacy [J] per unit (3 mo)	*nd*	*1.16*	*1.02-1.32*	*0.02*	
				Noise (3 mo, not defined)	*nd*	*0.74*	*0.98-1.02 [K]*	*nd*	
				Feel exhalation resistance (3 mo)	*nd*	*1.02*	*1.00-1.04*	*0.1 [L]*	
Wild [M] 2004[276] 15358707	Adherence [G]	nd	3 mo	AHI (continuous [E])	45	1.02	nd	0.02	B
				CPAP pressure (continuous [E])	9 cm H_2O	0.82	nd	0.05	
				BMI (continuous [E])	33	1.09	nd	0.02	
				ESS (continuous [E])	13	1.09	nd	0.04	
Hui [N] 2001[277] 11451834	hr/night use	5.4 hr/night	1 mo	AHI (continuous [E])	48	nd	nd	0.006	C
				Snoring		nd	nd	NS	
		5.4 hr/night	3 mo	AHI (continuous [E])	48	nd	nd	0.004	
				Snoring		nd	nd	NS	

Predictors measured after baseline are italicized.

[A] Occupation, referral source, collar size, alcohol consumption, smoking status, diagnostic test type, and CPAP titration method were not associated with discontinuing CPAP by univariable analysis.
[B] Also reported that lower ESS (analyzed as a continuous variable) predicted less compliance across the range of ESS.

[C] Also reported that lower AHI (analyzed as a continuous variable) predicted less compliance across the range of AHI.
[D] No data on which tested variables were not associated with CPAP withdrawal by univariable analysis.
[E] Implied.
[F] No data on which tested variables were not associated with “objective compliance” by univariable analysis.
[G] Note that in contrast to most other studies, the outcome is compliance/adherence, not lack of compliance.
[H] Grenoble Sleep Apnea Quality of Life. 25 point scale (implied), with higher scores indicating worse conditions.
[J] This outcome is not defined or included in the list of domains in Grenoble Sleep Apnea Quality of Life. Higher scores indicate worse conditions.
[K] These illogical OR and confidence interval were what was reported. The reported beta and standard error of the beta did not match any of these values.
[L] Although this P value does not match with the reported beta, standard error of the beta, OR, or 95% CI, it is what was reported.
[M] Also analyzed with psychological variables (Multidimensional locus of control scale). Results for AHI, CPAP pressure, BMI, and ESS were similar. Higher health value scale (measure of how much patient values his/her health) was associated with increased compliance (OR=1.40, P=0.02). Other psychological tests were not significantly associated.
Age, alcohol intake, current cigarette use, marital status, and minimum O2 saturation were not associated with adherence by univariable analysis.
[N] Frequent awakenings, witnessed apneas, and other symptoms were not associated with adherence at 1 or 3 months by univariable analyses.

Table 6.2a Mandibular advancement device as predictors of compliance: Study characteristics

Study PMID	Design Country (Study Years)	Eligibility	N	Factor	Value	Treatment	Description	Ancillary Care	(Lack of) Compliance Definition
Izci 2005[278] 15733510	Retro Scotland, UK (nd)	MAD after PSG	144	**Male** **Age** **BMI** **AHI**	79% 51 y nd 23	Individually fitted mandibular repositioning splint	~80 maximal comfortable mandibular protrusion 2-4 mm interdental clearance	Standard education Adjusted until workable	Compliance hr/night and/or nights/wk (unclear)

Table 6.2b. Pre-treatment predictors of compliance with mandibular advancement device, multivariable analyses

Study PMID	Outcome	Overall Outcome Rate	Follow-up	Predictor	Quality
Izci, 2005[278] 15733510	Compliance	nd	31 mo	Not associated with compliance on univariable analysis (nd): Age, Sex, Occupation, “Marital situation”, Snoring, Refreshment after sleep, Daytime somnolence, Driving problems, ESS, AHI, CPAP failure or refusal	C

Table 7.1 Randomized controlled trials of interventions to improve compliance with CPAP use: Study characteristics

Study PMID	Interventions	CPAP pressure* (type)	Mean age, yr	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Major quality issues
Extra Support or Education								
Chervin 1997[279] 9231954	Telephone calls Literature Standard care	nd (nd)	52	64	nd	Either new to CPAP (31%) or continuous CPAP users (69%)	US (1995)	Different follow-up durations between comparative groups.
Damjanovic 2009[161] 19129293	Intensive support Standard support	Auto and manual (separate)	57	78	31	Newly diagnosed OSA	Germany (nd)	Large dropout rate. Assumed non-compliance for dropout patients.
Fletcher, 1991[281] 2024846	Telephone reinforcement about OSA and CPAP use Usual care	Manual (separate)	52	100	Mean IBW = 158%	New CPAP users	US (nd)	Inconsistent reporting; primarily relying on self-reported readings for CPAP use
Hoy 1999[282] 10194151	Intensive educational programs and nursing support Usual care	Manual (separate)	58	98	33	New CPAP users	UK (nd)	
Hui 2000[283] 10807830	Augmented education and support Basic education and support	Auto (separate)	45	90	30	Newly diagnosed OSA	Hong Kong (nd)	More missing data on objective CPAP use in the intervention group than the control group due to technical problems.
Wiese 2005[284] 15716221	Educational videotape No intervention	nd (nd)	48	53	38	Newly diagnosed OSA	US (nd)	More dropouts in the control group than intervention group. Assumed non-compliance for dropout patients.
Lewis 2006[285] 16564210	Extra early support Usual care	Auto (separate?)	51	86	36	New CPAP users	UK (nd)	More dropouts in the control group than intervention group.
Meurice 2007[286] 17157557	RP+RH RP+SH SP+RH SP+SH	Manual (separate)	58	nd	33	New CPAP users	France (nd)	Potential center effects were not controlled fro in the analyses.
Smith 2009[288] 18829212	Habit-promoting experimental audio intervention: CPAP everyday Placebo control audio-based intervention	Auto (nd)	63	58	82% >30	Newly diagnosed OSA and new CPAP users	US (nd)	Assumed non-compliance for dropout patients.

Study PMID	Interventions	CPAP pressure* (type)	Mean age, yr	Male, %	Mean BMI, kg/m^2	Other patient characteristics	Country (enrollment years)	Major quality issues
Telehealth or telemonitoring care								
DeMolles 2004[280] 15258478	Telephone-linked communications for CPAP Usual care	nd (nd)	46	nd	38	New CPAP users	US (nd)	How CPAP use data were collected was not described. "Usual care" was not described.
Stepnowsky 2007[289] 17513285	Wireless telemonitoring clinical care Usual care	Auto (nd)	59	98	32	Newly diagnosed OSA and new CPAP users	US (2004-06)	Small sample size
Taylor 2006[290] 16565867	Telemedicine support Usual care	nd (nd)	45	69	nd	New CPAP users	US (2002-03)	Patients who had difficulties to use telemedicine support were excluded from the analyses.
Behavioral interventions								
Richards 2007[287] 17552379	Cognitive behavioral therapy Usual care	Manual (nd)	56	86	30	nd	Australia (2005)	
Miscellaneous interventions								
Bradshaw 2006[273] 17099012	Oral hypnotic agent (zolpidem), 10 mg Placebo pill Standard care (no zolpidem or placebo pill)	nd (both)	38	100	32	New CPAP users	US (2001-03)	Patients in the standard care had more severe OSA based on AHI; not blinded.
Massie 2003[291] 12684301	Nasal pillows Nasal mask	Manual (both)	49	82	36	New CPAP users	US (nd)	
Different care models								
Antic 2009[292] 19136368	Simplified nurse-led model of care Usual care	Auto and manual (separate) manual (nd)	50	74	35	nd	Australia (2004-06)	Different CPAP titrations between groups by study design
Holmdahl 2009[293] 19179111	Simplified nurse-led model of care Usual care	Manual (nd)	58	85	35	CPAP-treated patients with OSAS in a stable condition	Sweden (nd)	More patients dropped out in the control group. How CPAP use data were collected was not reported.
Palmer 2004[294] 14725828	A home visit from a specialist nurse A visit to a consultant led clinic	nd (nd)	55	86	nd	The mean duration of CPAP therapy = 2.99 yr	UK (2001)	Baseline patient characteristics were unclear. Dropout and unusable CPAP use data were excluded form the analyses.

* Method for choosing CPAP pressure: Manual (during sleep study); Auto (determined with AutoCPAP); Algorithm (by an algorithm); nd (no data reported); NA (not applicable, eg if AutoCPAP is the intervention). In parentheses: Split (CPAP introduced in a split night study); Separate (CPAP introduced on a separate full night than the diagnostic sleep study).

Table 7.2 Compliance (hr/night) in randomized controlled trials of interventions to improve CPAP use

Study PMID	Baseline AHI (SD) [minimum]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Final	SD	Diff	95% CI	P Btw	Dropout, %	Study quality
Extra Support or Education												
Hoy 1999[282] 10194151	58 (33) [>15]	13 (6)	6 mo (PL)	Intensive support	40	5.4	1.9	+1.6	0.62, 2.58*	0.003	0	A
				Usual care	40	3.8	2.5					
Meurice 2007[286] 17157557	58 (24) [>30]	11.3 (5.4)	3 mo (PL)	RP+RH	27	5.6	2.4	+0.9	-0.38, 2.18†	NS	16	B
				RP+SH	30	4.7	2.2	0	-1.20, 1.20‡			
				SP+RH	28	5.1	2.5	+0.4	-0.90, 1.70§			
				SP+SH	27	4.7	2.4					
			12 mo (PL)	RP+RH	23	5.8	2.8	+0.3	-1.16, 1.76	NS	19	
				RP+SH	22	6.3	2.2	+0.8	-0.49, 2.09			
				SP+RH	21	5.7	2.2	+0.2	-1.09, 1.49			
				SP+SH	25	5.5	2.4					
Damjanovic 2009[161] 19129293	44 (25) [≥15]	8.8 (5.2)	3 mo (PL)	Intensive support	50	5.5	1.4	+0.1	-0.61, 0.81 **	NS	0††	B
				Standard support	50	5.4	2.1					
			9 mo (PL)	Intensive support	50	5.7	1.4	+1.1	0.22, 1.98 ‡‡	<0.05		
				Standard support	50	4.6	2.8					
Hui 2000[283] 10807830	48 (24) [≥10]	12.5 (5.1)	3 mo (PL)	Augmented support	45	5.3	0.3	0	-0.7, 0.7§§	NS	10	B
				Basic support	52	5.3	0.2					
Lewis 2006[285] 16564210	42 (27) [nd]	15.7 (4.3)	1 mo (PL)	Extra early support	36	5.2	nd	-0.2	nd	nd	6	C
				Usual care	32	5.4	nd					
			12 mo (PL)	Extra early support	30	4.6	nd	-0.5	nd	nd	17	
				Usual care	30	5.1	nd					
Chervin 1997[279] 9231954	49 (39) [nd]	10.9 (5.1)	1-2.5 mo (PL)	Telephone calls	12	5.7	2.3	+1.3	-1.45, 4.05 ***	0.02	18	C
				Literature	14	7.1	1.8	+2.7	0.35, 5.05 †††			
				Standard care	7	4.4	3.4					
Fletcher, 1991[281] 2024846	49 (26) [nd]	nd	3 mo (XO)	Telephone reinforcement	10	5.95	2.7	-0.05	-1.76, 1.66 ‡‡‡	NS	0	C
				Usual care	10	6.0	2.8					

Study PMID	Baseline AHI (SD) [minimum]	Baseline ESS (SD)	Duration (design)	Interventions	No. analyzed	Final	SD	Diff	95% CI	P Btw	Dropout, %	Study quality
Telehealth or telemonitoring care												
Stepnowsky 2007[289] 17513285	41 (16) [≥15]	12.6 (5.5)	2 mo (PL)	Wireless telemonitoring	20	4.1	1.8	+1.3	-0.05, 2.5 §§§	0.07	12	B
				Usual care	20	2.8	2.2					
Taylor 2006[290] 16565867	41% severe OSA [>4]	14 (4)	30 d (PL)	Telemedicine support	47	4.3	2.2	+0.07	-0.77, 0.91 ****	NS	16	C
				Usual care	49	4.2	2.1					
DeMolles 2004[280] 15258478	42 (38) [nd]	nd	2 mo (PL)	Telephone-linked CPAP communication	15	4.4	3.0	+1.5	-0.53, 3.53 ††††	0.08	0	C
				Usual care	15	2.9	2.4					
Behavioral interventions												
Richards 2007[287] 17552379	26 (22) [>5]	10.5 (5.3)	28 days (PL)	Cognitive behavioral therapy	48	5.4	2.6	+2.8	1.8, 3.9 ‡‡‡‡	<0.0001	4	A
				Usual care	48	2.5	2.7					
Miscellaneous interventions												
Bradshaw 2006[273] 17099012	43 (28) [≥5]	15.4 (3.5)	Days 1-14 (PL)	Zolpidem 10 mg	24	11.1	3.7	+1.6 §§§§	-0.83, 4.03 *****	NS	0	B
				Placebo pill	24	9.5	4.6					
				Standard care†††††	24	12.1	3.2					
			Days 15-28 (PL)	Zolpidem 10 mg	24	9.5	4.6	+1.2 ‡‡‡‡‡	-1.65, 4.05 §§§§§	NS		
				Placebo pill	24	8.3	5.2					
				Standard care******	24	10.8	3.9					
Massie 2003[291] 12684301	47 (35) [≥15]	12.8 (4.9)	3 wk (XO)	Nasal pillows	39	5.6	1.3	+0.2	-3.8, 4.2 ††††††	NS	7	B
				Nasal mask	39	5.4	1.6					
Different care models												
Antic 2009[292] 19136368	68 (27)	13 (3.9)	3 mo	Simplified nurse-led model of care	94	4.1	2.7	-0.45	-1.26, 0.36	NS	10	B
				Usual care	83	4.6	2.7					
Palmer 2004[294] 14725828	nd [nd]	8.5 (5.5)	12 mo	One home visit by special nurse	63	5.9	2.7	+0.21	-0.40, 0.82 ‡‡‡‡‡‡	NS	28	C
				One consultant clinic visit	63	5.6	2.5					

* Estimated from reported SE's
† Estimated from reported SD's
‡ Estimated from reported SD's
§ Estimated from reported SD's
** Estimated from reported SE's
†† Compliance parameters were set to zero when patients did not appear for their follow-up visit (8% and 22% dropout at 3 and 9 mo, respectively)
‡‡ Estimated from reported SE's
§§ Estimated from reported SE's
*** Estimated from reported SD's
††† Estimated from reported SD's
‡‡‡ Estimated from reported SD's
§§§ Estimated from reported SD's
**** Estimated from reported SD's
†††† Estimated from reported SD's
‡‡‡‡ Estimated from reported SD's
§§§§ Compared to placebo
***** Estimated from reported SD's
††††† Patients in the standard care had more severe OSA based on AHI [mean = 54.8 (28 SD), P=0.012 compared to other groups]
‡‡‡‡‡ Compared to placebo
§§§§§ Estimated from reported SD's
****** Patients in the standard care had more severe OSA based on AHI [mean = 54.8 (28 SD), P=0.012 compared to other groups]
†††††† Estimated from reported SD's
‡‡‡‡‡‡ Estimated from reported changes (SD) from baseline

Table 7.3 Non-compliance outcome in randomized controlled trials of interventions to improve CPAP use

Study PMID	Baseline AHI (SD) [minimum]	Baseline ESS (SD)	Duration (design)	Definition of non-compliance	Interventions	n Event	N Total	Outcome metric	Result*	95% CI†	P Btw	Dropout, %	Study quality
Extra Support or Education													
Hui 2000[283] 10807830	48 (24) [≥10]	12.5 (5.1)	3 mo (PL)	Mean CPAP use ≤4 hr and ≤70% of nights	Augmented support	16	54	RD	-0.04	-0.13, 0.21	NS	10	B
					Basic support	14	54						
Smith 2009[288] 18829212	50 (nd) [≥20]	nd	1 mo (PL)	CPAP use <4 hr/night and less than 80% use rate	Habit-promoting experimental audio intervention	6	55	RD	-0.34	-0.52, -0.17	<0.01	0‡	B
					Placebo control audio-intervention	19	42						
			6 mo (PL)	CPAP use <4 hr/night and less than 80% use rate	Habit-promoting experimental audio intervention	14	55	RD	-0.03	-0.21, 0.15	NS		
					Placebo	12	42						
Wiese 2005[284] 15716221	9 (nd) [>4]	13 (6)	1 mo (PL)	Not return to clinic at 4 weeks	Educational videotape	14	51	RD	-0.24	-0.42, -0.05	0.02	39§	C
					No intervention	25	49						
Behavioral interventions													
Richards 2007[287] 17552379	26 (22) [>5]	10.5 (5.3)	28 d (PL)	CPAP use <4 hr/night at 28 days	Cognitive behavioral therapy	9	48	Adjusted OR**	0.14	0.05, 0.36	<0.0001	4	A
					Usual care	33	48						

Study PMID	Baseline AHI (SD) [minimum]	Baseline ESS (SD)	Duration (design)	Definition of non-compliance	Interventions	n Event	N Total	Outcome metric	Result*	95% CI†	P Btw	Dropout, %	Study quality
Miscellaneous interventions													
Bradshaw 2006[273] 17099012	43 (27) [≥5]	15.4 (3.5)	4 wk (PL)	Mean CPAP use ≤4 hr	Zolpidem 10 mg	7	24	RD	-0.17††	-0.44, 0.10	NS	0	B
					Placebo pill	11	24						
					Standard care‡‡	7	24						
			4 wk (PL)	Receiving CPAP ≤70% of nights	Zolpidem 10 mg	8	24	RD	-0.13§§	-0.40, 0.15	NS		
					Placebo pill	11	24						
					Standard care***	4	24						
			4 wk (PL)	Mean CPAP use ≤4 hr and ≤70% of nights	Zolpidem 10 mg	10	24	RD	-0.08†††	-0.36, 0.20	NS		
					Placebo pill	12	24						
					Standard care‡‡‡	9	24						
Different care models													
Holmdahl 2009[293] 19179111	nd [>15]	nd	2 yr (PL)	<6 hr CPAP use per night	Simplified nurse-led model of care	23	95	RD	-0.02	-0.14, 0.11	NS	16	C
					Usual care	23	89						
			2 yr (PL)	<4 hr CPAP use per night	Simplified nurse-led model of care	5	95	RD	-0.02	-0.08, 0.05	NS		
					Usual care	6	89						

* Top row intervention vs. bottom row intervention.
† Estimated from the reported number of events and total number of patients, unless otherwise noted.
‡ ITT analysis: all dropouts due to lost to contact were also counted as non-adherent patients
§ Lost-to follow-up rate were used as measure of non-compliance
** Adjusted for sex
†† Compared to placebo pill
‡‡ Patients in the standard care had more severe OSA based on AHI [mean = 54.8 (28 SD), P=0.012 compared to other groups]
§§ Compared to placebo pill
*** Patients in the standard care had more severe OSA based on AHI [mean = 54.8 (28 SD), P=0.012 compared to other groups]
††† Compared to placebo pill
‡‡‡ Patients in the standard care had more severe OSA based on AHI [mean = 54.8 (28 SD), P=0.012 compared to other groups]

Appendix B. Search strategy

Databases: Ovid MEDLINE, MEDLINE(R) In-Process, Cochrane Controlled Trials Register (CCTR)
Last run 2/17/2010

#	Searches	Results	
1	exp Sleep Apnea Syndromes/ or exp Sleep Apnea, Obstructive/	19267	Sleep Apnea
2	exp Airway Resistance/	13219	
3	exp snoring/	2922	
4	Upper airway resistance syndrome.mp.	229	
5	Respiratory disturbance.mp.	1151	
6	obstructive sleep apn?ea.mp.	11746	
7	or/1-6	35183	
8	randomized controlled trial.pt.	561439	Comparative Studies
9	controlled clinical trial.pt.	161324	
10	randomized controlled trials/	67116	
11	Random Allocation/	88433	
12	Double-blind Method/	194574	
13	Single-Blind Method/	22535	
14	clinical trial.pt.	748992	
15	Clinical Trials.mp. or exp Clinical Trials/	282752	
16	(clinic$ adj25 trial$).tw.	234940	
17	((singl$ or doubl$ or trebl$ or tripl$) adj (mask$ or blind$)).tw.	223366	
18	Placebos/	48648	
19	placebo$.tw.	236373	
20	random$.tw.	781376	
21	trial$.tw.	607720	
22	(randomized control trial or clinical control trial).sd.	227662	
23	(latin adj square).tw.	3635	
24	Comparative Study.tw. or Comparative Study.pt.	1644250	
25	exp Evaluation studies/	149831	
26	Follow-Up Studies/	437652	
27	Prospective Studies/	331595	
28	(control$ or prospectiv$ or volunteer$).tw.	2591469	
29	Cross-Over Studies/	45716	
30	Or/8-29	5078479	
31	exp Positive-Pressure Respiration/ or exp Continuous Positive Airway Pressure/	18518	Treatments
32	exp Intermittent Positive-Pressure Ventilation/ or exp Ventilators, Mechanical/ or exp Masks/	16688	
33	general surgery/ or neurosurgery/ or otolaryngology/ or surgery, plastic/ or thoracic surgery/	80977	
34	Surgical Procedures, Operative/	46806	
35	oral appliances.mp.	286	
36	exp Physical Therapy Modalities/ or exp Exercise Therapy/	107007	
37	positional therapy.mp.	41	
38	exp Weight Loss/	22268	
39	exp Exercise/ or exp Exercise Therapy/	78677	
40	exp Therapeutics/	2836406	
41	exp Anesthesia/ or Pre-operative screening/ or Anesthetic agents/	164281	
42	Sleep Apnea, Obstructive/th	2408	
43	*tonsillectomy/	4707	
44	or/31-43	3119682	

#	Searches	Results	
45	exp Polysomnography/	11867	Sleep Apnea Diagnostic Terms
46	exp Oximetry/	10559	
47	exp Monitoring, Physiologic/	110172	
48	pulse transit time.mp.	246	
49	exp Monitoring, Ambulatory/	18720	
50	peripheral Arterial Tonometry.mp.	62	
51	exp Questionnaires/	224876	
52	exp Diagnostic Tests, Routine/	5348	
53	exp "Laboratory Techniques and Procedures"/	1586381	
54	(Epworth or Stanford or Berlin or Pittsburgh or scale).af.	470093	
55	(friedman or surgical or staging).mp.	887171	
56	STOP-Bang.af.	2	
57	Sleep Apnea, Obstructive/di	2379	
58	or/45-57	3098114	
59	exp "sensitivity and specificity"/	320624	General Diagnostic Tests
60	exp Predictive Value of Tests/	104513	
61	exp ROC CURVE/	17069	
62	exp Mass Screening/	102939	
63	exp diagnosis/	5190511	
64	exp REPRODUCIBILITY OF RESULTS/	203415	
65	exp false negative reactions/ or false positive reactions/	30462	
66	predictive value.tw.	44461	
67	(sensitivity or specificity).tw.	582712	
68	accuracy.tw.	162713	
69	screen$.tw.	350059	
70	diagno$.tw.	1333212	
71	roc.tw.	12925	
72	reproducib$.tw.	90416	
73	(false positive or false negative).tw.	39967	
74	likelihood ratio.tw.	4450	
75	accuracy.tw.	162713	
76	di.fs.	1684695	
77	or/59-76	6907870	
78	7 and 30 and 44	6008	Group 1: Comparative studies OSA &
79	limit 78 to english language [Limit not valid in CCTR; records were retained]	5354	
80	limit 79 to humans [Limit not valid in CCTR; records were retained]	4883	
81	79 and humans.sh.	4876	
82	80 or 81	4883	
83	remove duplicates from 82	**3751**	
84	7 and 44	11488	Group 2: All but comparative studies on OSA & treatment (not some study designs)
85	84 not 83	7737	
86	limit 85 to english language [Limit not valid in CCTR; records were retained]	5933	
87	limit 86 to humans [Limit not valid in CCTR; records were retained]	4943	
88	86 and humans.sh.	4942	
89	87 or 88	4943	
90	remove duplicates from 89	4596	
91	limit 90 to (addresses or bibliography or biography or case reports or comment or congresses or consensus development conference or dictionary or directory or festschrift or in vitro or interactive tutorial or interview or lectures or legal cases or legislation or news or newspaper article or overall or patient education handout or periodical index or portraits or "scientific integrity review" or twin study)	913	
92	90 not 91	**3683**	

#	Searches	Results	
93	7 and 30 and 58	6424	**Group 3: Comparative studies**
94	limit 93 to english language [Limit not valid in CCTR; records were retained]	5775	
95	limit 94 to humans [Limit not valid in CCTR; records were retained]	5492	
96	94 and humans.sh.	5453	
97	95 or 96	5492	
98	remove duplicates from 97	4295	
99	98 not (83 or 92)	**2477**	
100	7 and 58 and 77	11451	**Group 4: Other OSA diagnosis**
101	limit 100 to english language [Limit not valid in CCTR; records were retained]	9709	
102	limit 101 to humans [Limit not valid in CCTR; records were retained]	9209	
103	101 and humans.sh.	9199	
104	102 or 103	9209	
105	104 not (83 or 92 or 99)	3623	
106	remove duplicates from 105	**3296**	
107	limit 7 to (guideline or meta analysis or practice guideline)	151	**Group 5: Systematic Reviews and Practice Guidelines on OSA**
108	7 and Cochrane Database of Systematic Reviews.jn.	25	
109	107 or 108	170	
110	remove duplicates from 109	129	
111	110 not (83 or 92 or 99 or 106)	**41**	
112	83 or 92 or 99 or 106 or 111	***13248 (+188, from 2/17/10, below)***	
113-120 run on 2/17/2010			
113	7 and 30	12165	**Group 6: Cohort studies for KQ 2 & 6**
114	113 not 112	5912	
115	(ep or co or mo).fs.	2293973	
116	(incidence or longitudinal studies or prospective studies or survival analysis or follow-up studies or logistic models or Proportional Hazards Models or Linear Models or Regression Analysis).sh.	967098	
117	exp patient compliance/ or exp medication adherence/ or exp treatment refusal/	47071	
118	or/115-117	2893257	
119	114 and 118	1771	
120	limit 119 to (english language and humans)	**1088**	
121	112 or 120	*14524*	
122	exp Orthodontic Appliances, Removable/	3929	**Group 1a: Additional interventions**
123	Palate, Soft/su or Pharynx/su or Uvula/su or Sleep Apnea Syndromes/su	3669	
124	Sleep Apnea Syndromes/pc	188	
125	or/122-124	7766	
126	7 and 30 and 125	755	
127	126 not (112 or 119)	77	
128	limit 127 to (english language and humans)	**32**	

Appendix C. Excluded Studies

Studies are listed in alphabetical order by author. The reason for rejection for each study is indicated in italic font.

Practice parameters for the indications for polysomnography and related procedures. Polysomnography Task Force, American Sleep Disorders Association Standards of Practice Committee. Sleep. 1997;20:406-422.
PMID 9302725
Systematic review etc published before 2000

Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances. American Sleep Disorders Association. Sleep. 1995;18:511-513.
PMID 7481422
Systematic review etc published before 2000

Practice parameters for the use of portable recording in the assessment of obstructive sleep apnea. Standards of Practice Committee of the American Sleep Disorders Association. Sleep. 1994;17:372-377.
PMID 7973322
Systematic review etc published before 2000

Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The Report of an American Academy of Sleep Medicine Task Force. Sleep. 1999;22:667-689.
PMID 10450601
Systematic review etc published before 2000

Practice parameters for the treatment of obstructive sleep apnea in adults: the efficacy of surgical modifications of the upper airway. Report of the American Sleep Disorders Association. Sleep. 1996;19:152-155.
PMID 8855038
Systematic review etc published before 2000

Aboussouan LS, Golish JA, Wood BG, Mehta AC, Wood DE, Dinner DS. Dynamic pharyngoscopy in predicting outcome of uvulopalatopharyngoplasty for moderate and severe obstructive sleep apnea. Chest. 1995;107:946-951.
PMID 7705159
Surgical cohort <100/intervention

Acebo C, Watson RK, Bakos L, Thoman EB. Sleep and apnea in the elderly: reliability and validity of 24-hour recordings in the home. Sleep. 1991;14:56-64.
PMID 1811321
No intervention of interest

Akkina NC, Kumar S, Fulambaker A, Cohen M, Farooki B, Copur AS. Role of empiric treatment with autotitrating-cpap in patients suspected of having obstructive sleep apnea. Chest. 2007;132:503b-5504.
Cochrane CN-00642825
Not peer reviewed

Al-Jawder S, Bahammam A. Acceptance of C-FLEX therapy in patients with obstructive sleep apnea who refused auto-continuous positive airway pressure. Saudi Medical Journal. 2008;29:144-145.
PMID 18176692
N<10/intervention

Aloia MS, Di DL, Ilniczky N, Perlis ML, Greenblatt DW, Giles DE. Improving compliance with nasal CPAP and vigilance in older adults with OAHS. Sleep & Breathing. 2001;5:13-21.
PMID 11868136
N<10/intervention

Aloia MS, Stanchina M, Arnedt JT, Malhotra A, Millman RP. Treatment adherence and outcomes in flexible vs standard continuous positive airway pressure therapy. Chest. 2005;127:2085-2093.
PMID 15947324
Not randomized

Alonso-Fernandez A, Garcia-Rio F, Arias MA et al. Effects of CPAP on oxidative stress and nitrate efficiency in sleep apnoea: a randomised trial. Thorax. 2009;64:581-586.
PMID 19074930
No outcomes of interest

Alonso-Fernandez A, Garcia-Rio F, Arias MA et al. Obstructive sleep apnoea-hypoapnoea syndrome reversibly depresses cardiac response to exercise. European Heart Journal. 2006;27:207-215.
PMID 16267074
No outcomes of interest

Altman JS, Halpert RD, Mickelson SA, Senior BA. Effect of uvulopalatopharyngoplasty and genial and hyoid advancement on swallowing in patients with obstructive sleep apnea syndrome. Otolaryngology - Head & Neck Surgery. 1999;120:454-457.
PMID 10187932
Surgical cohort <100/intervention

Alvarez D, Hornero R, Abasolo D, del CF, Zamarron C. Nonlinear characteristics of blood oxygen saturation from nocturnal oximetry for obstructive sleep apnoea detection. Physiological Measurement. 2006;27:399-412.
PMID 16537981
In 2007 EPC Report

Alvarez D, Hornero R, Garcia M, del CF, Zamarron C. Improving diagnostic ability of blood oxygen saturation from overnight pulse oximetry in obstructive sleep apnea detection by means of central tendency measure. Artificial Intelligence in Medicine. 2007;41:13-24.
PMID 17643971
Duplicate of previous study (Previous report)

Ancoli-Israel S, Mason W, Coy TV, Stepnowsky C, Clausen JL, Dimsdale J. Evaluation of sleep disordered breathing with unattended recording: the Nightwatch System. Journal of Medical Engineering & Technology. 1997;21:10-14.
PMID 9080356
In 2007 EPC Report

Ancoli-Israel S, Palmer BW, Cooke JR et al. Cognitive effects of treating obstructive sleep apnea in Alzheimer's disease: a randomized controlled study. Journal of the American Geriatrics Society. 2008;56:2076-2081.
PMID 18795985
Population: Alzheimers

Anttalainen U, Saaresranta T, Kalleinen N, Aittokallio J, Vahlberg T, Polo O. CPAP adherence and partial upper airway obstruction during sleep. Sleep & Breathing. 2007;11:171-176.
PMID 17287956
KQ 6 Retrospective

Argekar P, Griffin V, Litaker D, Rahman M. Sleep apnea in hemodialysis patients: risk factors and effect on survival. Hemodialysis International. 2007;11:435-441.
PMID 17922741
N<500 (KQ 2)

Arias MA, Garcia-Rio F, Alonso-Fernandez A et al. CPAP decreases plasma levels of soluble tumour necrosis factor-alpha receptor 1 in obstructive sleep apnoea. European Respiratory Journal. 2008;32:1009-1015.
PMID 18508832
No outcomes of interest

Arias MA, Garcia-Rio F, Alonso-Fernandez A, Martinez I, Villamor J. Pulmonary hypertension in obstructive sleep apnoea: effects of continuous positive airway pressure: a randomized, controlled cross-over study. European Heart Journal. 2006;27:1106-1113.
PMID 16497687
Superceded by other article

Atef A, Mosleh M, Hesham M, Fathi A, Hassan M, Fawzy M. Radiofrequency vs laser in the management of mild to moderate obstructive sleep apnoea: does the number of treatment sessions matter? Journal of Laryngology & Otology. 2005;119:888-893.
PMID 16354341
Surgical cohort <100/intervention

Ayalon L, Ancoli-Israel S, Stepnowsky C et al. Adherence to continuous positive airway pressure treatment in patients with Alzheimer's disease and obstructive sleep apnea. American Journal of Geriatric Psychiatry. 2006;14:176-180.
PMID 16473983
Population: Alzheimers

Ayappa I, Norman RG, Suryadevara M, Rapoport DM. Comparison of limited monitoring using a nasal-cannula flow signal to full polysomnography in sleep-disordered breathing. Sleep. 2004;27:1171-1179.
PMID 15532212
In 2007 EPC Report

Ayas NT, Pittman S, MacDonald M, White DP. Assessment of a wrist-worn device in the detection of obstructive sleep apnea. Sleep Medicine. 2003;4:435-442.
PMID 14592285
In 2007 EPC Report

Bachour A, Virkkala JT, Maasilta PK. AutoCPAP initiation at home: optimal trial duration and cost-effectiveness. Sleep Medicine. 2007;8:704-710.
PMID 17531533
No predictors of compliance

Back L, Palomaki M, Piilonen A, Ylikoski J. Sleep-disordered breathing: radiofrequency thermal ablation is a promising new treatment possibility. Laryngoscope. 2001;111:464-471.
PMID 11224777
Surgical cohort <100/intervention

Back LJ, Liukko T, Rantanen I et al. Hypertonic saline injections to enhance the radiofrequency thermal ablation effect in the treatment of base of tongue in obstructive sleep apnoea patients: a pilot study. Acta Oto-Laryngologica. 2009;129:302-310.
PMID 18615334
Surgical cohort <100/intervention

Bagnato MC, Nery LE, Moura SM, Bittencourt LR, Tufik S. Comparison of AutoSet and polysomnography for the detection of apnea-hypopnea events. Brazilian Journal of Medical & Biological Research. 2000;33:515-519.
PMID 10775882
In 2007 EPC Report

Baisch A, Maurer JT, Hormann K. The effect of hyoid suspension in a multilevel surgery concept for obstructive sleep apnea. Otolaryngology - Head & Neck Surgery. 2006;134:856-861.
PMID 16647548
Surgical cohort <100/intervention

Baldwin CM, Griffith KA, Nieto FJ, O'Connor GT, Walsleben JA, Redline S. The association of sleep-disordered breathing and sleep symptoms with quality of life in the Sleep Heart Health Study. Sleep. 2001;24:96-105.
PMID 11204058
Cross-sectional

Ballester E, Badia JR, Hernandez L et al. Evidence of the effectiveness of continuous positive airway pressure in the treatment of sleep apnea/hypopnea syndrome.[erratum appears in Am J Respir Crit Care Med 1999 May;159(5 Pt 1):1688]. American Journal of Respiratory & Critical Care Medicine. 1999;159:495-501.
PMID 9927363
Systematic review etc published before 2000

Ballester E, Solans M, Vila X et al. Evaluation of a portable respiratory recording device for detecting apnoeas and hypopnoeas in subjects from a general population. European Respiratory Journal. 2000;16:123-127.
PMID 10933097
In 2007 EPC Report

Ballon JS, Feifel D. A systematic review of modafinil: Potential clinical uses and mechanisms of action. Journal of Clinical Psychiatry. 2006;67:554-566.
PMID 16669720
Not drug of interest

Baltzan MA, Elkholi O, Wolkove N. Evidence of interrelated side effects with reduced compliance in patients treated with nasal continuous positive airway pressure. Sleep Medicine. 2009;10:198-205.
PMID 18314388
Not patient level factors (KQ 6)

Baltzan MA, Verschelden P, Al-Jahdali H, Olha AE, Kimoff RJ. Accuracy of oximetry with thermistor (OxiFlow) for diagnosis of obstructive sleep apnea and hypopnea. Sleep. 2000;23:61-69.
PMID 10678466
In 2007 EPC Report

Bao X, Nelesen RA, Loredo JS, Dimsdale JE, Ziegler MG. Blood pressure variability in obstructive sleep apnea: role of sympathetic nervous activity and effect of continuous positive airway pressure. Blood Pressure Monitoring. 2002;7:301-307.
PMID 12488649
No outcomes of interest

Bar A, Pillar G, Dvir I, Sheffy J, Schnall RP, Lavie P. Evaluation of a portable device based on peripheral arterial tone for unattended home sleep studies. Chest. 2003;123:695-703.
PMID 12628865
In 2007 EPC Report

Barakate M, Havas T. Lingual tonsillectomy: a review of 5 years experience and evolution of surgical technique. Otolaryngology - Head & Neck Surgery. 2008;139:222-227.
PMID 18656719
Surgical cohort <100/intervention

Bassiouny A, El SA, Abd El-Tawab M, Atef A. Bipolar radiofrequency treatment for snoring with mild to moderate sleep apnea: a comparative study between the radiofrequency assisted uvulopalatoplasty technique and the channeling technique. European Archives of Oto-Rhino-Laryngology. 2007;264:659-667.
PMID 17294208
Surgical cohort <100/intervention

Behbehani K, Yen FC, Lucas EA, Burk JR. A sleep laboratory evaluation of an automatic positive airway pressure system for treatment of obstructive sleep apnea. Sleep. 1998;21:485-491.
PMID 9703588
In-lab study

Bennett LS, Davies RJ, Stradling JR. Oral appliances for the management of snoring and obstructive sleep apnoea. Thorax. 1998;53:Suppl-64.
PMID 10193350
Superceded by other article

Berger G, Finkelstein Y, Stein G, Ophir D. Laser-assisted uvulopalatoplasty for snoring: medium- to long-term subjective and objective analysis. Archives of Otolaryngology -- Head & Neck Surgery. 2001;127:412-417.
PMID 11296050
Surgical cohort <100/intervention

Berger G, Stein G, Ophir D, Finkelstein Y. Is there a better way to do laser-assisted uvulopalatoplasty? Archives of Otolaryngology -- Head & Neck Surgery. 2003;129:447-453.
PMID 12707193
Surgical cohort <100/intervention

Berry RB, Hill G, Thompson L, McLaurin V. Portable monitoring and autotitration versus polysomnography for the diagnosis and treatment of sleep apnea. Sleep. 2008;31:1423-1431.
PMID 18853940
No analyses of interest

Bettega G, Pepin JL, Veale D, Deschaux C, Raphael B, Levy P. Obstructive sleep apnea syndrome. fifty-one consecutive patients treated by maxillofacial surgery. American Journal of Respiratory & Critical Care Medicine. 2000;162:t-9.
PMID 10934100
Surgical cohort <100/intervention

Bittencourt LR, Lucchesi LM, Rueda AD et al. Placebo and modafinil effect on sleepiness in obstructive sleep apnea. Progress in Neuro-Psychopharmacology & Biological Psychiatry. 2008;32:552-559.
PMID 18053628
Not drug of interest

Black JE, Hirshkowitz M. Modafinil for treatment of residual excessive sleepiness in nasal continuous positive airway pressure-treated obstructive sleep apnea/hypopnea syndrome. Sleep. 2005;28:464-471.
PMID 16171291
Not drug of interest

Blanco J, Zamarron C, Abeleira Pazos MT, Lamela C, Suarez QD. Prospective evaluation of an oral appliance in the treatment of obstructive sleep apnea syndrome. Sleep & Breathing. 2005;9:20-25.
PMID 15785917
N<10/intervention

Blumen MB, Coquille F, Rocchicioli C, Mellot F, Chabolle F. Radiofrequency tongue reduction through a cervical approach: a pilot study. Laryngoscope. 2006;116:1887-1893.
PMID 17003707
Surgical cohort <100/intervention

Blumen MB, Dahan S, Fleury B, Hausser-Hauw C, Chabolle F. Radiofrequency ablation for the treatment of mild to moderate obstructive sleep apnea. Laryngoscope. 2002;112:2086-2092.
PMID 12439186
Surgical cohort <100/intervention

Boland LL, Shahar E, Iber C et al. Measures of cognitive function in persons with varying degrees of sleep-disordered breathing: the Sleep Heart Health Study. Journal of Sleep Research. 2002;11:265-272.
PMID 12220323
<1 y f/up (KQ 2)

Bolitschek J, Rieder A, Broinger G, Rosenberger A, Kunze M, Aigner K. N-CPAP rejecters--a specific group of noncompliant patients with obstructive sleep apnea syndrome. Wiener Klinische Wochenschrift. 2001;113:245-248.
PMID 11383384
Not RCT (CPAP vs control)

Bonsignore G, Marrone O, Macaluso C, Salvaggio A, Stallone A, Bellia V. Validation of oximetry as a screening test for obstructive sleep apnoea syndrome. European Respiratory Journal - Supplement. 1990;11:542s-544s.
PMID 2278624
In 2007 EPC Report

Boot H, Poublon RM, Van WR et al. Uvulopalatopharyngoplasty for the obstructive sleep apnoea syndrome: value of polysomnography, Mueller manoeuvre and cephalometry in predicting surgical outcome. Clinical Otolaryngology & Allied Sciences. 1997;22:504-510.
PMID 9466058
Surgical cohort <100/intervention

Boot H, Van WR, Poublon RM, Bogaard JM, Schmitz PI, Van der Meche FG. Long-term results of uvulopalatopharyngoplasty for obstructive sleep apnea syndrome. Laryngoscope. 2000;110:t-75.
PMID 10718440
Surgical cohort <100/intervention

Borgel J, Sanner BM, Bittlinsky A et al. Obstructive sleep apnoea and its therapy influence high-density lipoprotein cholesterol serum levels. European Respiratory Journal. 2006;27:121-127.
PMID 16387944
No outcomes of interest

Borgel J, Sanner BM, Keskin F et al. Obstructive sleep apnea and blood pressure. Interaction between the blood pressure-lowering effects of positive airway pressure therapy and antihypertensive drugs. American Journal of Hypertension. 2004;17:t-7.
PMID 15607612
N<500 (KQ 2)

Boudewyns A, De CW, Willemen M, Wagemans M, De BW, Van de Heyning PH. Influence of uvulopalatopharyngoplasty on alpha-EEG arousals in nonapnoeic snorers. European Respiratory Journal. 1997;10:129-132.
PMID 9032504
Surgical cohort <100/intervention

Bowden MT, Kezirian EJ, Utley D, Goode RL. Outcomes of hyoid suspension for the treatment of obstructive sleep apnea. Archives of Otolaryngology -- Head & Neck Surgery. 2005;131:440-445.
PMID 15897424
Surgical cohort <100/intervention

Bradley PA, Mortimore IL, Douglas NJ. Comparison of polysomnography with ResCare Autoset in the diagnosis of the sleep apnoea/hypopnoea syndrome. Thorax. 1995;50:1201-1203.
PMID 8553279
In 2007 EPC Report

Brin YS, Reuveni H, Greenberg S, Tal A, Tarasiuk A. Determinants affecting initiation of continuous positive airway pressure treatment. Israel Medical Association Journal: Imaj. 2005;7:13-18.
PMID 15658139
<1 mo (KQ 6)

Brostrom A, Stromberg A, Martensson J, Ulander M, Harder L, Svanborg E. Association of Type D personality to perceived side effects and adherence in CPAP-treated patients with OSAS. Journal of Sleep Research. 2007;16:439-447.
PMID 18036091
KQ 6 Retrospective

Brown DJ, Kerr P, Kryger M. Radiofrequency tissue reduction of the palate in patients with moderate sleep-disordered breathing. Journal of Otolaryngology. 2001;30:193-198.
PMID 11771028
Surgical cohort <100/intervention

Brownell LG, Perez-Padilla R, West P, Kryger MH. The role of protriptyline in obstructive sleep apnea. Bulletin europeen de physiopathologie respiratoire. 1983;19:621-624.
PMID 6360257
N<10/intervention

Brownell LG, West P, Sweatman P, Acres JC, Kryger MH. Protriptyline in obstructive sleep apnea: a double-blind trial. New England Journal of Medicine. 1982;307:1037-1042.
PMID 6750396
N<10/intervention

Buchner NJ, Sanner BM, Borgel J, Rump LC. Continuous positive airway pressure treatment of mild to moderate obstructive sleep apnea reduces cardiovascular risk. American Journal of Respiratory & Critical Care Medicine. 2007;176:1274-1280.
PMID 17673692
Not randomized

Budhiraja R, Parthasarathy S, Drake CL et al. Early CPAP use identifies subsequent adherence to CPAP therapy. Sleep. 2007;30:320-324.
PMID 17425228
Not multivariate (KQ 6, CPAP)

Busaba NY. Same-stage nasal and palatopharyngeal surgery for obstructive sleep apnea: is it safe? Otolaryngology - Head & Neck Surgery. 2002;126:399-403.
PMID 11997780
Surgical cohort <100/intervention

Cahali MB. Lateral pharyngoplasty: a new treatment for obstructive sleep apnea hypopnea syndrome. Laryngoscope. 2003;113:1961-1968.
PMID 14603056
Surgical cohort <100/intervention

Cahali MB, Formigoni GG, Gebrim EM, Miziara ID. Lateral pharyngoplasty versus uvulopalatopharyngoplasty: a clinical, polysomnographic and computed tomography measurement comparison. Sleep. 2004;27:942-950.
PMID 15453553
Surgical cohort <100/intervention

Caldarelli DD, Cartwright R, Lilie JK. Severity of sleep apnea as a predictor of successful treatment by palatopharyngoplasty. Laryngoscope. 1986;96:t-7.
PMID 3747695
Surgical cohort <100/intervention

Caldarelli DD, Cartwright RD, Lilie JK. Obstructive sleep apnea: variations in surgical management. Laryngoscope. 1985;95:t-3.
PMID 4033329
Surgical cohort <100/intervention

Calleja JM, Esnaola S, Rubio R, Duran J. Comparison of a cardiorespiratory device versus polysomnography for diagnosis of sleep apnoea. European Respiratory Journal. 2002;20:1505-1510.
PMID 12503711
In 2007 EPC Report

Canisius S, Kesper K, Jerrentrup L et al. C-Flex technology: effects on breathing parameters and inspiratory flow limitation. Respiration. 2009;78:168-176.
PMID 19122451
In-lab study

Carmona BC, Capote GF, Botebol BG, Garcia LP, Sanchez AA, Castillo GJ. Assessment of excessive day-time sleepiness in professional drivers with suspected obstructive sleep apnea syndrome. Archivos de bronconeumologia. 2000;36:436-440.
Cochrane CN-00361710
No analyses of interest

Carrasco O, Montserrat JM, Lloberes P et al. Visual and different automatic scoring profiles of respiratory variables in the diagnosis of sleep apnoea-hypopnoea syndrome. European Respiratory Journal. 1996;9:125-130.
PMID 8834345
In 2007 EPC Report

Carratu P, Karageorgiou G, Bonfitto P et al. Long-term evaluation of mental fatigue by Maastricht Questionnaire in patients with OSAS treated with CPAP. Monaldi Archives for Chest Disease. 2007;67:6-9.
PMID 17564278
Not RCT (CPAP vs control)

Casale M, Rinaldi V, Bressi F et al. A suitable test for identifying high risk adult patients of moderate-severe obstructive sleep apnea syndrome. European Review for Medical & Pharmacological Sciences. 2008;12:275-280.
PMID 18727462
No validation set analysis

Chabolle F, Wagner I, Blumen MB, Sequert C, Fleury B, De DT. Tongue base reduction with hyoepiglottoplasty: a treatment for severe obstructive sleep apnea. Laryngoscope. 1999;109:1273-1280.
PMID 10443833
Surgical cohort <100/intervention

Chasens ER, Pack AI, Maislin G, Dinges DF, Weaver TE. Claustrophobia and adherence to CPAP treatment. Western Journal of Nursing Research. 2005;27:307-321.
PMID 15781905
Not multivariate (KQ 6, CPAP)

Chervin RD, Murman DL, Malow BA, Totten V. Cost-utility of three approaches to the diagnosis of sleep apnea: polysomnography, home testing, and empirical therapy. Annals of Internal Medicine. 1999;130:496-505.
PMID 10075617
Systematic review etc published before 2000

Chiner E, Signes-Costa J, Arriero JM, Marco J, Fuentes I, Sergado A. Nocturnal oximetry for the diagnosis of the sleep apnoea hypopnoea syndrome: a method to reduce the number of polysomnographies? Thorax. 1999;54:968-971.
PMID 10525553
In 2007 EPC Report

Chisholm E, Kotecha B. Oropharyngeal surgery for obstructive sleep apnoea in CPAP failures. European Archives of Oto-Rhino-Laryngology. 2007;264:51-55.
PMID 16944237
Surgical cohort <100/intervention

Choi S, Bennett LS, Mullins R, Davies RJ, Stradling JR. Which derivative from overnight oximetry best predicts symptomatic response to nasal continuous positive airway pressure in patients with obstructive sleep apnoea? Respiratory Medicine. 2000;94:895-899.
PMID 11001083
Not RCT

Choi S, Mullins R, Crosby JH, Davies RJO, Stradling JR. Is (re)titration of nasal continuous positive airway pressure for obstructive sleep apnoea necessary? Sleep Medicine. 2001;2:431-435.
Cochrane CN-00425066
Superceded by other article

Chong MS, Ayalon L, Marler M et al. Continuous positive airway pressure reduces subjective daytime sleepiness in patients with mild to moderate Alzheimer's disease with sleep disordered breathing. Journal of the American Geriatrics Society. 2006;54:777-781.
PMID 16696743
Population: Alzheimers

Cillo JE, Jr., Finn R, Dasheiff RM. Combined open rhinoplasty with spreader grafts and laser-assisted uvuloplasty for sleep-disordered breathing: long-term subjective outcomes. Journal of Oral & Maxillofacial Surgery. 2006;64:1241-1247.
PMID 16860217
Surgical cohort <100/intervention

Cincik H, Cekin E, Cetin B, Gungor A, Poyrazoglu E. Comparison of uvulopalatopharyngoplasty, laser-assisted uvulopalatoplasty and cautery-assisted uvulopalatoplasty in the treatment of primary snoring. Orl; Journal of Oto-Rhino-Laryngology & its Related Specialties. 2006;68:149-155.
PMID 16462150
Surgical cohort <100/intervention

Cistulli PA, Palmisano RG, Poole MD. Treatment of obstructive sleep apnea syndrome by rapid maxillary expansion. Sleep. 1998;21:831-835.
PMID 9871945
Surgical cohort <100/intervention

Clark GT, Arand D, Chung E, Tong D. Effect of anterior mandibular positioning on obstructive sleep apnea. American Review of Respiratory Disease. 1993;147:624-629.
PMID 8442597
Not comparative

Coleman JA, Jr. Laser-assisted uvulopalatoplasty: long-term results with a treatment for snoring. Ear, Nose, & Throat Journal. 1998;77:22-24.
PMID 9473829
Surgical cohort <100/intervention

Collen J, Lettieri C, Kelly W, Roop S. Clinical and polysomnographic predictors of short-term continuous positive airway pressure compliance. Chest. 2009;135:704-709.
PMID 19017888
KQ 6 Retrospective

Conradt R, Hochban W, Brandenburg U, Heitmann J, Peter JH. Long-term follow-up after surgical treatment of obstructive sleep apnoea by maxillomandibular advancement. European Respiratory Journal. 1997;10:123-128.
PMID 9032503
Surgical cohort <100/intervention

Conway W, Fujita S, Zorick F et al. Uvulopalatopharyngoplasty. One-year followup. Chest. 1985;88:385-387.
PMID 4028849
Surgical cohort <100/intervention

Craig S, Pepperell JC, Kohler M, Crosthwaite N, Davies RJ, Stradling JR. Continuous positive airway pressure treatment for obstructive sleep apnoea reduces resting heart rate but does not affect dysrhythmias: a randomised controlled trial. Journal of Sleep Research. 2009;18:329-336.
PMID 19549077
No outcomes of interest

Croft CB, Golding-Wood DG. Uses and complications of uvulopalatopharyngoplasty. Journal of Laryngology & Otology. 1990;104:871-875.
PMID 2266310
Surgical cohort <100/intervention

Cross MD, Vennelle M, Engleman HM et al. Comparison of CPAP titration at home or the sleep laboratory in the sleep apnea hypopnea syndrome. Sleep. 2006;29:1451-1455.
PMID 17162992
No intervention of interest

Dattilo DJ, Drooger SA. Outcome assessment of patients undergoing maxillofacial procedures for the treatment of sleep apnea: comparison of subjective and objective results. Journal of Oral & Maxillofacial Surgery. 2004;62:164-168.
PMID 14762748
Surgical cohort <100/intervention

Davis JA, Fine ED, Maniglia AJ. Uvulopalatopharyngoplasty for obstructive sleep apnea in adults: clinical correlation with polysomnographic results. Ear, Nose, & Throat Journal. 1993;72:63-66.
PMID 8444131
Surgical cohort <100/intervention

de Almeida FR, Lowe AA, Tsuiki S et al. Long-term compliance and side effects of oral appliances used for the treatment of snoring and obstructive sleep apnea syndrome. Journal of Clinical Sleep Medicine. 2005;1:143-152.
PMID 17561628
KQ 6 Retrospective

Defaye P, Pepin JL, Poezevara Y et al. Automatic recognition of abnormal respiratory events during sleep by a pacemaker transthoracic impedance sensor. Journal of Cardiovascular Electrophysiology. 2004;15:1034-1040.
PMID 15363076
Not diagnostic test of interest

del Campo F, Hornero R, Zamarron C, Abasolo DE, Alvarez D. Oxygen saturation regularity analysis in the diagnosis of obstructive sleep apnea. Artificial Intelligence in Medicine. 2006;37:111-118.
PMID 16386411
In 2007 EPC Report

den Herder C, Kox D, van Tinteren H, de Vries N. Bipolar radiofrequency induced thermotherapy of the tongue base: Its complications, acceptance and effectiveness under local anesthesia. European Archives of Oto-Rhino-Laryngology. 2006;263:1031-1040.
PMID 16862445
Surgical cohort <100/intervention

den Herder C, van Tinteren H, de Vries N. Hyoidthyroidpexia: a surgical treatment for sleep apnea syndrome.[reprint in Ned Tijdschr Geneeskd. 2006 Jan 28;150(4):198-203; PMID: 16471236]. Laryngoscope. 2005;115:740-745.
PMID 15805891
Surgical cohort <100/intervention

Dickson RI, Mintz DR. One-stage laser-assisted uvulopalatoplasty. Journal of Otolaryngology. 1996;25:155-161.
PMID 8783079
Surgical cohort No complication data

Dimsdale JE, Loredo JS, Profant J. Effect of continuous positive airway pressure on blood pressure : a placebo trial. Hypertension. 2000;35:t-7.
PMID 10642289
No outcomes of interest

Ding J, Nieto FJ, Beauchamp NJ, Jr. et al. Sleep-disordered breathing and white matter disease in the brainstem in older adults. Sleep. 2004;27:474-479.
PMID 15164901
No outcomes of interest

Dinges DF, Weaver TE. Effects of modafinil on sustained attention performance and quality of life in OSA patients with residual sleepiness while being treated with nCPAP. Sleep Medicine. 2003;4:393-402.
PMID 14592280
Not drug of interest

Dingli K, Coleman EL, Vennelle M et al. Evaluation of a portable device for diagnosing the sleep apnoea/hypopnoea syndrome. European Respiratory Journal. 2003;21:253-259.
PMID 12608438
In 2007 EPC Report

Djupesland G, Schrader H, Lyberg T, Refsum H, Lilleas F, Godtlibsen OB. Palatopharyngoglossoplasty in the treatment of patients with obstructive sleep apnea syndrome. Acta Oto-Laryngologica Supplement. 1992;492:50-54.
PMID 1632251
Surgical cohort <100/intervention

Dort LC, Hussein J. Snoring and obstructive sleep apnea: compliance with oral appliance therapy. Journal of Otolaryngology. 2004;33:172-176.
PMID 15841995
N<100 (KQ 6)

d'Ortho MP, Grillier-Lanoir V, Levy P et al. Constant vs. automatic continuous positive airway pressure therapy: home evaluation. Chest. 2000;118:1010-1017.
PMID 11035671
Not RCT (CPAP vs CPAP)

Douglas NJ, Thomas S, Jan MA. Clinical value of polysomnography. Lancet. 1992;339:347-350.
PMID 1346422
In 2007 EPC Report

Drigo R, Fontana M, Coin A, Ferraresso A, Enzo E, Zambotto FM. APAP titration in patients with mild to moderate OSAS and periodic limb movement syndrome. Monaldi Archives for Chest Disease. 2006;65:196-203.
PMID 17393664
In-lab study

Dunlevy TM, Karakla DW. Uvulopalatopharyngoplasty: the Naval Medical Center, Portsmouth, experience. American Journal of Otolaryngology. 1998;19:174-177.
PMID 9617929
Surgical cohort <100/intervention

Elasfour A, Miyazaki S, Itasaka Y, Yamakawa K, Ishikawa K, Togawa K. Evaluation of uvulopalatopharyngoplasty in treatment of obstructive sleep apnea syndrome. Acta Oto-Laryngologica Supplement. 1998;537:52-56.
PMID 9870650
Surgical cohort <100/intervention

Elbaz M, Roue GM, Lofaso F, Quera Salva MA. Utility of actigraphy in the diagnosis of obstructive sleep apnea. Sleep. 2002;25:527-531.
PMID 12150319
Not diagnostic test of interest

Elshaug AG, Moss JR, Southcott AM, Hiller JE. An analysis of the evidence-practice continuum: is surgery for obstructive sleep apnoea contraindicated? Journal of Evaluation in Clinical Practice. 2007;13:3-9.
PMID 17286716
Surgical cohort <100/intervention

el-Solh AA, Mador MJ, Ten-Brock E, Shucard DW, Abul-Khoudoud M, Grant BJ. Validity of neural network in sleep apnea. Sleep. 1999;22:105-111.
PMID 9989371
No validation set analysis

Emsellem HA, Corson WA, Rappaport BA, Hackett S, Smith LG, Hausfeld JN. Verification of sleep apnea using a portable sleep apnea screening device. Southern Medical Journal. 1990;83:748-752.
PMID 2371595
In 2007 EPC Report

Engelke WG, Mendoza M, Repetto G. Preliminary radiographic observations of the tongue-repositioning manoeuvre. European Journal of Orthodontics. 2006;28:618-623.
PMID 17101703
Surgical cohort <100/intervention

Engleman HM, Asgari-Jirhandeh N, McLeod AL, Ramsay CF, Deary IJ, Douglas NJ. Self-reported use of CPAP and benefits of CPAP therapy: a patient survey. Chest. 1996;109:1470-1476.
PMID 8769496
No predictors of compliance

Engleman HM, Cheshire KE, Deary IJ, Douglas NJ. Daytime sleepiness, cognitive performance and mood after continuous positive airway pressure for the sleep apnoea/hypopnoea syndrome. Thorax. 1993;48:911-914.
PMID 8236074
Not randomized

Epstein LJ, Dorlac GR. Cost-effectiveness analysis of nocturnal oximetry as a method of screening for sleep apnea-hypopnea syndrome. Chest. 1998;113:97-103.
PMID 9440575
In 2007 EPC Report

Esnaola S, Duran J, Infante-Rivard C, Rubio R, Fernandez A. Diagnostic accuracy of a portable recording device (MESAM IV) in suspected obstructive sleep apnoea. European Respiratory Journal. 1996;9:2597-2605.
PMID 8980975
In 2007 EPC Report

Eun YG, Kim SW, Kwon KH, Byun JY, Lee KH. Single-session radiofrequency tongue base reduction combined with uvulopalatopharyngoplasty for obstructive sleep apnea syndrome. European Archives of Oto-Rhino-Laryngology. 2008;265:1495-1500.
PMID 18443811
Surgical cohort <100/intervention

Eun YG, Kwon KH, Shin SY, Lee KH, Byun JY, Kim SW. Multilevel surgery in patients with rapid eye movement-related obstructive sleep apnea. Otolaryngology - Head & Neck Surgery. 2009;140:536-541.
PMID 19328343
Surgical cohort <100/intervention

Eveloff SE, Rosenberg CL, Carlisle CC, Millman RP. Efficacy of a Herbst mandibular advancement device in obstructive sleep apnea. American Journal of Respiratory & Critical Care Medicine. 1994;149:t-9.
PMID 8143054
Not comparative

Faber CE, Hilberg O, Grymer L. Flextube reflectometry for level diagnosis in patients with obstructive sleep apnoea and snoring. Rhinology. 2002;40:122-128.
PMID 12357711
No reference standard (overnight PSG)

Farney RJ, Walker LE, Jensen RL, Walker JM. Ear oximetry to detect apnea and differentiate rapid eye movement (REM) and non-REM (NREM) sleep. Screening for the sleep apnea syndrome. Chest. 1986;89:533-539.
PMID 3956278
In 2007 EPC Report

Ferguson KA, Ono T, Lowe AA, al-Majed S, Love LL, Fleetham JA. A short-term controlled trial of an adjustable oral appliance for the treatment of mild to moderate obstructive sleep apnoea. Thorax. 1997;52:362-368.
PMID 9196520
Superceded by other article

Ferland A, Poirier P, Series F. Sibutramine versus continuous positive airway pressure in obese obstructive sleep apnoea patients. European Respiratory Journal. 2009;34:694-701.
PMID 19357147
Not randomized

Fernandez-Julian E, Munoz N, Achiques MT, Garcia-Perez MA, Orts M, Marco J. Randomized study comparing two tongue base surgeries for moderate to severe obstructive sleep apnea syndrome. Otolaryngology - Head & Neck Surgery. 2009;140:917-923.
PMID 19467415
Surgical cohort <100/intervention

Fibbi A, Ameli F, Brocchetti F, Mignosi S, Cabano ME, Semino L. Tongue base suspension and radiofrequency volume reduction: a comparison between 2 techniques for the treatment of sleep-disordered breathing. American Journal of Otolaryngology. 2009;30:401-406.
PMID 19880029
Surgical cohort <100/intervention

Ficker JH, Clarenbach CF, Neukirchner C et al. Auto-CPAP therapy based on the forced oscillation technique. Biomedizinische Technik. 2003;48:68-72.
PMID 12701337
In-lab study

Ficker JH, Fuchs FS, Wiest GH, Asshoff G, Schmelzer AH, Hahn EG. An auto-continuous positive airway pressure device controlled exclusively by the forced oscillation technique. European Respiratory Journal. 2000;16:914-920.
PMID 11153592
In-lab study

Ficker JH, Wiest GH, Lehnert G, Wiest B, Hahn EG. Evaluation of an auto-CPAP device for treatment of obstructive sleep apnoea. Thorax. 1998;53:643-648.
PMID 9828849
In-lab study

Ficker JH, Wiest GH, Wilpert J, Fuchs FS, Hahn EG. Evaluation of a portable recording device (Somnocheck) for use in patients with suspected obstructive sleep apnoea. Respiration. 2001;68:307-312.
PMID 11416253
In 2007 EPC Report

Fietze I, Glos M, Rottig J, Witt C. Automated analysis of data is inferior to visual analysis of ambulatory sleep apnea monitoring. Respiration. 2002;69:235-241.
PMID 12097767
In 2007 EPC Report

Fietze I, Quispe-Bravo S, Hansch T, Rottig J, Baumann G, Witt C. Arousals and sleep stages in patients with obstructive sleep apnoea syndrome: Changes under nCPAP treatment. Journal of Sleep Research. 1997;6:128-133.
PMID 9377532
In-lab study

Findley L, Smith C, Hooper J, Dineen M, Suratt PM. Treatment with nasal CPAP decreases automobile accidents in patients with sleep apnea. American Journal of Respiratory & Critical Care Medicine. 2000;161:t-9.
PMID 10712333
Not RCT (CPAP vs control)

Finkelstein Y, Shapiro-Feinberg M, Stein G, Ophir D. Uvulopalatopharyngoplasty vs laser-assisted uvulopalatoplasty. Anatomical considerations. Archives of Otolaryngology -- Head & Neck Surgery. 1997;123:265-276.
PMID 9076231
Surgical cohort No complication data

Finkelstein Y, Stein G, Ophir D, Berger R, Berger G. Laser-assisted uvulopalatoplasty for the management of obstructive sleep apnea: myths and facts. Archives of Otolaryngology -- Head & Neck Surgery. 2002;128:429-434.
PMID 11926920
Surgical cohort <100/intervention

Fischer Y, Khan M, Mann WJ. Multilevel temperature-controlled radiofrequency therapy of soft palate, base of tongue, and tonsils in adults with obstructive sleep apnea. Laryngoscope. 2003;113:1786-1791.
PMID 14520107
Surgical cohort <100/intervention

Fitzpatrick MF, Alloway CE, Wakeford TM, MacLean AW, Munt PW, Day AG. Can patients with obstructive sleep apnea titrate their own continuous positive airway pressure? American Journal of Respiratory & Critical Care Medicine. 2003;167:716-722.
PMID 12598214
Not comparison of different PAP types

Flemons WW, Whitelaw WA, Brant R, Remmers JE. Likelihood ratios for a sleep apnea clinical prediction rule. American Journal of Respiratory & Critical Care Medicine. 1994;150:t-85.
PMID 7952553
No validation set analysis

Fleury B, Rakotonanahary D, Hausser-Hauw C, Lebeau B, Guilleminault C. A laboratory validation study of the diagnostic mode of the Autoset system for sleep-related respiratory disorders.[erratum appears in Sleep 1996 Sep;19(7):601]. Sleep. 1996;19:502-505.
PMID 8865509
In 2007 EPC Report

Foltan R, Hoffmannova J, Pretl M, Donev F, Vlk M. Genioglossus advancement and hyoid myotomy in treating obstructive sleep apnoea syndrome - A follow-up study. Journal of Cranio-Maxillo-Facial Surgery. 2007;35:246-251.
PMID 17761431
Surgical cohort <100/intervention

Fong SY, Ho CK, Wing YK. Comparing MSLT and ESS in the measurement of excessive daytime sleepiness in obstructive sleep apnoea syndrome. Journal of Psychosomatic Research. 2005;58:55-60.
PMID 15771871
No analyses of interest

Fransson AM, Isacsson G, Leissner LC, Nasman AB, Alton MK. Treatment of snoring and obstructive sleep apnea with a mandibular protruding device: an open-label study. Sleep & Breathing. 2001;5:23-33.
PMID 11868137
Not RCT (Oral vs Cx)

Freedman RR, Roehrs TA. Sleep disturbance in menopause. Menopause. 2007;14:826-829.
PMID 17486023
Not diagnostic test

Friedman M, Duggal P, Joseph NJ. Revision uvulopalatoplasty by Z-palatoplasty. Otolaryngology - Head & Neck Surgery. 2007;136:638-643.
PMID 17418265
Surgical cohort <100/intervention

Friedman M, Ibrahim H, Bass L. Clinical staging for sleep-disordered breathing. Otolaryngology - Head & Neck Surgery. 2002;127:13-21.
PMID 12161725
Surgical cohort No complication data

Friedman M, Ibrahim H, Joseph NJ. Staging of obstructive sleep apnea/hypopnea syndrome: a guide to appropriate treatment. Laryngoscope. 2004;114:454-459.
PMID 15091218
Superceded by other article

Friedman M, Ibrahim H, Lowenthal S, Ramakrishnan V, Joseph NJ. Uvulopalatoplasty (UP2): a modified technique for selected patients. Laryngoscope. 2004;114:441-449.
PMID 15091216
Surgical cohort <100/intervention

Friedman M, Ibrahim HZ, Vidyasagar R, Pomeranz J, Joseph NJ. Z-palatoplasty (ZPP): a technique for patients without tonsils. Otolaryngology - Head & Neck Surgery. 2004;131:89-100.
PMID 15243563
Surgical cohort <100/intervention

Friedman M, Schalch P, Joseph NJ. Palatal stiffening after failed uvulopalatopharyngoplasty with the Pillar Implant System. Laryngoscope. 2006;116:1956-1961.
PMID 17075397
Surgical cohort <100/intervention

Friedman M, Soans R, Gurpinar B, Lin HC, Joseph N. Evaluation of submucosal minimally invasive lingual excision technique for treatment of obstructive sleep apnea/hypopnea syndrome. Otolaryngology - Head & Neck Surgery. 2008;139:378-384.
PMID 18722216
Surgical cohort <100/intervention

Friedman M, Soans R, Joseph N, Kakodkar S, Friedman J. The effect of multilevel upper airway surgery on continuous positive airway pressure therapy in obstructive sleep apnea/hypopnea syndrome. Laryngoscope. 2009;119:193-196.
PMID 19117285
Surgical cohort <100/intervention

Friedman M, Tanyeri H, La RM et al. Clinical predictors of obstructive sleep apnea. Laryngoscope. 1999;109:1901-1907.
PMID 10591345
No validation set analysis

Friedman M, Vidyasagar R, Bliznikas D, Joseph N. Does severity of obstructive sleep apnea/hypopnea syndrome predict uvulopalatopharyngoplasty outcome? Laryngoscope. 2005;115:2109-2113.
PMID 16369152
Superceded by other article

Friedman M, Vidyasagar R, Bliznikas D, Joseph NJ. Patient selection and efficacy of pillar implant technique for treatment of snoring and obstructive sleep apnea/hypopnea syndrome. Otolaryngology - Head & Neck Surgery. 2006;134:187-196.
PMID 16455363
Surgical cohort <100/intervention

Fry JM, DiPhillipo MA, Curran K, Goldberg R, Baran AS. Full polysomnography in the home. Sleep. 1998;21:635-642.
PMID 9779523
In 2007 EPC Report

Fujita S, Conway W, Zorick F, Roth T. Surgical correction of anatomic azbnormalities in obstructive sleep apnea syndrome: uvulopalatopharyngoplasty. Otolaryngology - Head & Neck Surgery. 1981;89:923-934.
PMID 6801592
Surgical cohort <100/intervention

Fujita S, Conway WA, Zorick FJ et al. Evaluation of the effectiveness of uvulopalatopharyngoplasty. Laryngoscope. 1985;95:70-74.
PMID 3965833
Surgical cohort <100/intervention

Fujita S, Woodson BT, Clark JL, Wittig R. Laser midline glossectomy as a treatment for obstructive sleep apnea. Laryngoscope. 1991;101:805-809.
PMID 1865726
Surgical cohort <100/intervention

Furuta H, Kaneda R, Kosaka K, Arai H, Sano J, Koshino Y. Epworth Sleepiness Scale and sleep studies in patients with obstructive sleep apnea syndrome. Psychiatry & Clinical Neurosciences. 1999;53:301-302.
PMID 10459718
No analyses of interest

Gagnadoux F, Pelletier-Fleury N, Philippe C, Rakotonanahary D, Fleury B. Home unattended vs hospital telemonitored polysomnography in suspected obstructive sleep apnea syndrome: a randomized crossover trial. Chest. 2002;121:753-758.
PMID 11888956
In 2007 EPC Report

Galetke W, Randerath WJ, Stieglitz S et al. Comparison of manual titration and automatic titration based on forced oscillation technique, flow and snoring in obstructive sleep apnea. Sleep Medicine. 2009;10:337-343.
PMID 18650127
Not comparison of different PAP types

Gali B, Whalen FX, Schroeder DR, Gay PC, Plevak DJ. Identification of patients at risk for postoperative respiratory complications using a preoperative obstructive sleep apnea screening tool and postanesthesia care assessment. Anesthesiology. 2009;110:869-877.
PMID 19293694
No analyses of interest

Gauthier L, Laberge L, Beaudry M, Laforte M, Rompre PH, Lavigne GJ. Efficacy of two mandibular advancement appliances in the management of snoring and mild-moderate sleep apnea: a cross-over randomized study. Sleep Medicine. 2009;10:329-336.
PMID 18583187
Not comparison of different MAD types

Ghazal A, Sorichter S, Jonas I, Rose EC. A randomized prospective long-term study of two oral appliances for sleep apnoea treatment. Journal of Sleep Research. 2009;18:321-328.
PMID 19493297
Not comparison of different MAD types

Gilman MP, Floras JS, Usui K, Kaneko Y, Leung RS, Bradley TD. Continuous positive airway pressure increases heart rate variability in heart failure patients with obstructive sleep apnoea. Clinical Science. 2008;114:243-249.
PMID 17824846
N<10/intervention

Gislason T, Lindholm CE, Almqvist M et al. Uvulopalatopharyngoplasty in the sleep apnea syndrome. Predictors of results. Archives of Otolaryngology -- Head & Neck Surgery. 1988;114:45-51.
PMID 3334818
Surgical cohort <100/intervention

Gislason T, Tammivaara R. Airway obstruction, obesity and CO2 ventilatory responsiveness in the sleep apnea syndrome. Upsala Journal of Medical Sciences. 1992;97:141-148.
PMID 1471313
Surgical cohort <100/intervention

Goessler UR, Hein G, Verse T, Stuck BA, Hormann K, Maurer JT. Soft palate implants as a minimally invasive treatment for mild to moderate obstructive sleep apnea. Acta Oto-Laryngologica. 2007;127:527-531.
PMID 17453480
Surgical cohort <100/intervention

Goh YH, Lim KA. Modified maxillomandibular advancement for the treatment of obstructive sleep apnea: a preliminary report. Laryngoscope. 2003;113:1577-1582.
PMID 12972937
Surgical cohort <100/intervention

Goh YH, Mark I, Fee WE, Jr. Quality of life 17 to 20 years after uvulopalatopharyngoplasty. Laryngoscope. 2007;117:503-506.
PMID 17334312
Surgical cohort <100/intervention

Golpe R, Jimenez A, Carpizo R. Home sleep studies in the assessment of sleep apnea/hypopnea syndrome. Chest. 2002;122:1156-1161.
PMID 12377836
In 2007 EPC Report

Golpe R, Jimenez A, Carpizo R, Cifrian JM. Utility of home oximetry as a screening test for patients with moderate to severe symptoms of obstructive sleep apnea. Sleep. 1999;22:932-937.
PMID 10566911
In 2007 EPC Report

Grontved AM, Karup P. Complaints and satisfaction after uvulopalatopharyngoplasty. Acta Oto-Laryngologica Supplement. 2000;543:190-192.
PMID 10909017
Surgical cohort <100/intervention

Gugger M. Comparison of ResMed AutoSet (version 3.03) with polysomnography in the diagnosis of the sleep apnoea/hypopnoea syndrome. European Respiratory Journal. 1997;10:587-591.
PMID 9072989
In 2007 EPC Report

Gugger M, Mathis J, Bassetti C. Accuracy of an intelligent CPAP machine with in-built diagnostic abilities in detecting apnoeas: a comparison with polysomnography. Thorax. 1995;50:1199-1201.
PMID 8553278
In 2007 EPC Report

Guilleminault C, Hayes B. Naloxone, theophylline, bromocriptine, and obstructive sleep apnea. Negative results. Bulletin europeen de physiopathologie respiratoire. 1983;19:632-634.
PMID 6360259
Not drug of interest

Guilleminault C, Hayes B, Smith L, Simmons FB. Palatopharyngoplasty and obstructive sleep apnea syndrome. Bulletin europeen de physiopathologie respiratoire. 1983;19:595-599.
PMID 6652266
Surgical cohort <100/intervention

Gyulay S, Gould D, Sawyer B, Pond D, Mant A, Saunders N. Evaluation of a microprocessor-based portable home monitoring system to measure breathing during sleep. Sleep. 1987;10:130-142.
PMID 3589326
In 2007 EPC Report

Gyulay S, Olson LG, Hensley MJ, King MT, Allen KM, Saunders NA. A comparison of clinical assessment and home oximetry in the diagnosis of obstructive sleep apnea. American Review of Respiratory Disease. 1993;147:50-53.
PMID 8420431
In 2007 EPC Report

Hagert B, Wahren LK, Wikblad K, Odkvist L. Patients' and cohabitants' reports on snoring and daytime sleepiness, 1-8 years after surgical treatment of snoring. Orl; Journal of Oto-Rhino-Laryngology & its Related Specialties. 1999;61:19-24.
PMID 9892865
Surgical cohort No complication data

Han F, Song W, Li J, Zhang L, Dong X, He Q. Influence of UPPP surgery on tolerance to subsequent continuous positive airway pressure in patients with OSAHS. Sleep & Breathing. 2006;10:37-42.
PMID 16432757
Surgical cohort <100/intervention

Hanada T, Furuta S, Tateyama T, Uchizono A, Seki D, Ohyama M. Laser-assisted uvulopalatoplasty with Nd:YAG laser for sleep disorders. Laryngoscope. 1996;106:t-3.
PMID 8948617
Surgical cohort <100/intervention

Haraldsson PO, Bredbacka S. Laser-uvulopalatoplasty (LUPP) under local anesthesia: effective, safe and comfortable. Orl; Journal of Oto-Rhino-Laryngology & its Related Specialties. 1996;58:99-104.
PMID 8736055
Surgical cohort <100/intervention

Haraldsson PO, Carenfelt C, Knutsson E, Persson HE, Rinder J. Preliminary report: validity of symptom analysis and daytime polysomnography in diagnosis of sleep apnea. Sleep. 1992;15:261-263.
PMID 1621028
Not diagnostic test of interest

Haraldsson PO, Carenfelt C, Lysdahl M, Tornros J. Long-term effect of uvulopalatopharyngoplasty on driving performance. Archives of Otolaryngology -- Head & Neck Surgery. 1995;121:90-94.
PMID 7803027
Surgical cohort <100/intervention

Hattori C, Nishimura T, Kawakatsu K, Hayakawa M, Suzuki K. Comparison of surgery and nasal continuous positive airway pressure treatment for obstructive sleep apnea syndrome. Acta Oto-Laryngologica Supplement (550):46-50, 2003. 2003;46-50.
PMID 12737342
Surgical cohort <100/intervention

Hayakawa M, Nishimura T, Suzuki K et al. Comparison of the state of sleep in patients with sleep-disordered breathing before and after surgical treatment. Acta Oto-Laryngologica Supplement (550):51-5, 2003. 2003;51-55.
PMID 12737343
Surgical cohort <100/intervention

He J, Kryger MH, Zorick FJ, Conway W, Roth T. Mortality and apnea index in obstructive sleep apnea. Experience in 385 male patients. Chest. 1988;94:9-14.
PMID 3289839
N<500 (KQ 2)

Hedner J, Kraiczi H, Peker Y, Murphy P. Reduction of sleep-disordered breathing after physostigmine. American Journal of Respiratory & Critical Care Medicine. 2003;168:1246-1251.
PMID 12958052
In-lab study

Hedner J, Pillar G, Pittman SD, Zou D, Grote L, White DP. A novel adaptive wrist actigraphy algorithm for sleep-wake assessment in sleep apnea patients. Sleep. 2004;27:1560-1566.
PMID 15683148
In 2007 EPC Report

Hendler BH, Costello BJ, Silverstein K, Yen D, Goldberg A. A protocol for uvulopalatopharyngoplasty, mortised genioplasty, and maxillomandibular advancement in patients with obstructive sleep apnea: an analysis of 40 cases. Journal of Oral & Maxillofacial Surgery. 2001;59:892-897.
PMID 11474445
Surgical cohort <100/intervention

Herer B, Roche N, Carton M, Roig C, Poujol V, Huchon G. Value of clinical, functional, and oximetric data for the prediction of obstructive sleep apnea in obese patients. Chest. 1999;116:1537-1544.
PMID 10593773
In 2007 EPC Report

Herford AS, Finn R. Single-stage CO2 laser assisted uvuloplasty for treatment of snoring and mild obstructive sleep apnoea. Journal of Cranio-Maxillo-Facial Surgery. 2000;28:213-216.
PMID 11110152
Surgical cohort <100/intervention

Hermida RC, Zamarron C, Ayala DE, Calvo C. Effect of continuous positive airway pressure on ambulatory blood pressure in patients with obstructive sleep apnoea. Blood Pressure Monitoring. 2004;9:193-202.
PMID 15311146
Not RCT (CPAP vs control)

Hertegonne KB, Rombaut B, Houtmeyers P, Van MG, Pevernagie DA. Titration efficacy of two auto-adjustable continuous positive airway pressure devices using different flow limitation-based algorithms. Respiration. 2008;75:48-54.
PMID 17541262
Not comparison of different PAP types

Hertegonne KB, Volna J, Portier S, De PR, Van MG, Pevernagie DA. Titration procedures for nasal CPAP: automatic CPAP or prediction formula? Sleep Medicine. 2008;9:732-738.
PMID 17921064
In-lab study

Hessel NS, de VN. Results of uvulopalatopharyngoplasty after diagnostic workup with polysomnography and sleep endoscopy: a report of 136 snoring patients. European Archives of Oto-Rhino-Laryngology. 2003;260:91-95.
PMID 12582786
Surgical cohort <100/intervention

Hessel NS, Vries N. Increase of the apnoea-hypopnoea index after uvulopalatopharyngoplasty: analysis of failure. Clinical Otolaryngology & Allied Sciences. 2004;29:682-685.
PMID 15533159
Surgical cohort <100/intervention

Hester TO, Phillips B, Archer SM. Surgery for obstructive sleep apnea: effects on sleep, breathing, and oxygenation. Southern Medical Journal. 1995;88:907-910.
PMID 7660205
Surgical cohort <100/intervention

Hira HS. Obstructive sleep apnea syndrome: evaluation of subcritical continuous positive airway pressure. Journal of the Association of Physicians of India. 1998;46:796-797.
PMID 11229251
Not RCT (CPAP vs control)

Hirshkowitz M, Black JE, Wesnes K, Niebler G, Arora S, Roth T. Adjunct armodafinil improves wakefulness and memory in obstructive sleep apnea/hypopnea syndrome. Respiratory Medicine. 2007;101:616-627.
PMID 16908126
Not drug of interest

Hla KM, Young T, Finn L, Peppard PE, Szklo-Coxe M, Stubbs M. Longitudinal association of sleep-disordered breathing and nondipping of nocturnal blood pressure in the Wisconsin Sleep Cohort Study. Sleep. 2008;31:795-800.
PMID 18548823
N<500 (KQ 2)

Hochban W, Brandenburg U, Peter JH. Surgical treatment of obstructive sleep apnea by maxillomandibular advancement. Sleep. 1994;17:624-629.
PMID 7846461
Surgical cohort <100/intervention

Hochban W, Conradt R, Brandenburg U, Heitmann J, Peter JH. Surgical maxillofacial treatment of obstructive sleep apnea. Plastic & Reconstructive Surgery. 627;99:619-626.
PMID 9047179
Surgical cohort <100/intervention

Hoekema A. Efficacy and comorbidity of oral appliances in the treatment of obstructive sleep apnea-hypopnea: a systematic review and preliminary results of a randomized trial. Sleep & Breathing. 2006;10:102-103.
PMID 16408240
Short communication

Hoekema A, Stegenga B, Bakker M et al. Simulated driving in obstructive sleep apnoea-hypopnoea; effects of oral appliances and continuous positive airway pressure. Sleep & Breathing. 2007;11:129-138.
PMID 17245607
N<10/intervention

Hoekema A, Voors AA, Wijkstra PJ et al. Effects of oral appliances and CPAP on the left ventricle and natriuretic peptides. International Journal of Cardiology. 2008;128:232-239.
PMID 17727981
Duplicate of previous study

Hofer SO, Dhar BK, Robinson PH, Goorhuis-Brouwer SM, Nicolai JP. A 10-year review of perioperative complications in pharyngeal flap surgery. Plastic & Reconstructive Surgery. 1398;110:1393-1397.
PMID 12409754
Not OSA

Hoffstein V, Szalai JP. Predictive value of clinical features in diagnosing obstructive sleep apnea. Sleep. 1993;16:118-122.
PMID 8446830
No validation set analysis

Hoffstein V, Viner S, Mateika S, Conway J. Treatment of obstructive sleep apnea with nasal continuous positive airway pressure. Patient compliance, perception of benefits, and side effects. American Review of Respiratory Disease. 1992;145:t-5.
PMID 1554212
N<100 (KQ 6)

Hollandt JH, Mahlerwein M. Nasal breathing and continuous positive airway pressure (CPAP) in patients with obstructive sleep apnea (OSA). Sleep & Breathing. 2003;7:87-94.
PMID 12861488
Not multivariate (KQ 6, CPAP)

Hsiao HR, Wang PC, Cheng WN et al. Survey of short-term patient satisfaction after surgery for obstructive sleep apnea. Chang Gung Medical Journal. 2009;32:212-219.
PMID 19403012
Surgical cohort <100/intervention

Hsu CY, Vennelle M, Li HY, Engleman HM, Dennis MS, Douglas NJ. Sleep-disordered breathing after stroke: a randomised controlled trial of continuous positive airway pressure. Journal of Neurology, Neurosurgery & Psychiatry. 2006;77:1143-1149.
PMID 16772358
Population: stroke

Huang TW, Cheng PW. Microdebrider-assisted extended uvulopalatoplasty: an effective and safe technique for selected patients with obstructive sleep apnea syndrome. Archives of Otolaryngology -- Head & Neck Surgery. 2008;134:141-145.
PMID 18283155
Surgical cohort <100/intervention

Hultcrantz E, Johansson K, Bengtson H. The effect of uvulopalatopharyngoplasty without tonsillectomy using local anaesthesia: a prospective long-term follow-up. Journal of Laryngology & Otology. 1999;113:542-547.
PMID 10605585
Surgical cohort <100/intervention

Iber C, Redline S, Kaplan Gilpin AM et al. Polysomnography performed in the unattended home versus the attended laboratory setting--Sleep Heart Health Study methodology. Sleep. 2004;27:536-540.
PMID 15164911
In 2007 EPC Report

Insalaco G, Romano S, Marrone O, Salvaggio A, Bonsignore G. A new method of negative expiratory pressure test analysis detecting upper airway flow limitation to reveal obstructive sleep apnea. Chest. 2005;128:2159-2165.
PMID 16236869
No analyses of interest

Ip MS, Lam B, Ng MM, Lam WK, Tsang KW, Lam KS. Obstructive sleep apnea is independently associated with insulin resistance. American Journal of Respiratory & Critical Care Medicine. 2002;165:670-676.
PMID 11874812
N<500 (KQ 2)

Issa FG, Morrison D, Hadjuk E, Iyer A, Feroah T, Remmers JE. Digital monitoring of sleep-disordered breathing using snoring sound and arterial oxygen saturation. American Review of Respiratory Disease. 1993;148:t-9.
PMID 8214920
In 2007 EPC Report

Itasaka Y, Miyazaki S, Tanaka T, Ishikawa K. Uvulopalatopharyngoplasty for obstructive sleep-related breathing disorders: one-year follow up. Psychiatry & Clinical Neurosciences. 2001;55:261-262.
PMID 11422867
Surgical cohort <100/intervention

Jacobowitz O. Palatal and tongue base surgery for surgical treatment of obstructive sleep apnea: a prospective study. Otolaryngology - Head & Neck Surgery. 2006;135:258-264.
PMID 16890079
Surgical cohort <100/intervention

Janson C, Gislason T, Bengtsson H et al. Long-term follow-up of patients with obstructive sleep apnea treated with uvulopalatopharyngoplasty. Archives of Otolaryngology -- Head & Neck Surgery. 1997;123:257-262.
PMID 9076230
Surgical cohort <100/intervention

Jenkinson C, Davies RJ, Mullins R, Stradling JR. Long-term benefits in self-reported health status of nasal continuous positive airway pressure therapy for obstructive sleep apnoea. Qjm. 2001;94:95-99.
PMID 11181985
Not RCT

Jenkinson C, Stradling J, Petersen S. How should we evaluate health status? A comparison of three methods in patients presenting with obstructive sleep apnoea. Quality of Life Research. 1998;7:95-100.
PMID 9523490
Systematic review etc published before 2000

Jobin V, Mayer P, Bellemare F. Predictive value of automated oxygen saturation analysis for the diagnosis and treatment of obstructive sleep apnoea in a home-based setting. Thorax. 2007;62:422-427.
PMID 17251319
No reference standard (overnight PSG)

Johal A. Health-related quality of life in patients with sleep-disordered breathing: effect of mandibular advancement appliances. Journal of Prosthetic Dentistry. 2006;96:298-302.
PMID 17052475
Not RCT (Oral vs Cx)

Kamami YV. Outpatient treatment of sleep apnea syndrome with CO2 laser: laser-assisted UPPP. Journal of Otolaryngology. 1994;23:395-398.
PMID 7897767
Surgical cohort <100/intervention

Kao YH, Shnayder Y, Lee KC. The efficacy of anatomically based multilevel surgery for obstructive sleep apnea. Otolaryngology - Head & Neck Surgery. 2003;129:327-335.
PMID 14574285
Surgical cohort <100/intervention

Karason K, Lindroos AK, Stenlof K, Sjostrom L. Relief of cardiorespiratory symptoms and increased physical activity after surgically induced weight loss: results from the Swedish Obese Subjects study. Archives of Internal Medicine. 2000;160:1797-1802.
PMID 10871973
Superceded by later article

Katz I, Zamel N, Slutsky AS, Rebuck AS, Hoffstein V. An evaluation of flow-volume curves as a screening test for obstructive sleep apnea. Chest. 1990;98:337-340.
PMID 2198137
In 2007 EPC Report

Kawakatsu K, Nishimura T. Long-term surgical follow-up of sleep apnea syndrome. Acta Oto-Laryngologica Supplement (550):11-21, 2003. 2003;11-21.
PMID 12737335
Surgical cohort No complication data

Keenan SP, Anderson B, Wiggs B, Ryan CF, Fleetham JA. The predictive accuracy of home oximetry in patients with suspected obstructive sleep apnea. Sleep. 1993;16:Suppl-4.
PMID 8178005
No validation set analysis

Kern RC, Kutler DI, Reid KJ, Conley DB, Herzon GD, Zee P. Laser-assisted uvulopalatoplasty and tonsillectomy for the management of obstructive sleep apnea syndrome. Laryngoscope. 2003;113:1175-1181.
PMID 12838016
Surgical cohort <100/intervention

Khan A, Ramar K, Maddirala S, Friedman O, Pallanch JF, Olson EJ. Uvulopalatopharyngoplasty in the management of obstructive sleep apnea: the mayo clinic experience. Mayo Clinic Proceedings. 2009;84:795-800.
PMID 19720777
Surgical cohort <100/intervention

Khan W, Gleason R, Strome M, Regestein Q. Clinical features as diagnostic guides in obstructive sleep apnea. Comprehensive Psychiatry. 1995;36:46-52.
PMID 7705087
Retrospective

Khayat RN, Abraham WT, Patt B, Pu M, Jarjoura D. In-hospital treatment of obstructive sleep apnea during decompensation of heart failure. Chest. 2009;136:991-997.
PMID 19567491
No outcomes of interest

Kiely JL, Delahunty C, Matthews S, McNicholas WT. Comparison of a limited computerized diagnostic system (ResCare Autoset) with polysomnography in the diagnosis of obstructive sleep apnoea syndrome. European Respiratory Journal. 1996;9:2360-2364.
PMID 8947086
In 2007 EPC Report

Kiely JL, Murphy M, McNicholas WT. Subjective efficacy of nasal CPAP therapy in obstructive sleep apnoea syndrome: a prospective controlled study. European Respiratory Journal. 1999;13:1086-1090.
PMID 10414408
Not RCT (CPAP vs control)

Kim JA, Lee JJ, Jung HH. Predictive factors of immediate postoperative complications after uvulopalatopharyngoplasty. Laryngoscope. 2005;115:1837-1840.
PMID 16222206
Surgical cohort <100/intervention

Kim ST, Choi JH, Jeon HG, Cha HE, Kim DY, Chung YS. Polysomnographic effects of nasal surgery for snoring and obstructive sleep apnea. Acta Oto-Laryngologica. 2004;124:297-300.
PMID 15141758
Surgical cohort <100/intervention

Kingshott RN, Douglas NJ. The effect of in-laboratory polysomnography on sleep and objective daytime sleepiness. Sleep. 2000;23:1109-1113.
PMID 11145325
Not diagnostic test

Kingshott RN, Vennelle M, Coleman EL, Engleman HM, Mackay TW, Douglas NJ. Randomized, double-blind, placebo-controlled crossover trial of modafinil in the treatment of residual excessive daytime sleepiness in the sleep apnea/hypopnea syndrome. American Journal of Respiratory & Critical Care Medicine. 2001;163:918-923.
PMID 11282766
Not drug of interest

Kita H, Ohi M, Chin K et al. Effects of nasal continuous positive airway pressure therapy on respiratory parameters of upper airway patency in patients with obstructive sleep apnea syndrome. Chest. 1998;114:691-696.
PMID 9743152
In-lab study

Kohler M, Pepperell JC, Casadei B et al. CPAP and measures of cardiovascular risk in males with OSAS. European Respiratory Journal. 2008;32:1488-1496.
PMID 18653654
Superceded by other article

Konermann M, Sanner BM, Vyleta M et al. Use of conventional and self-adjusting nasal continuous positive airway pressure for treatment of severe obstructive sleep apnea syndrome: a comparative study. Chest. 1998;113:714-718.
PMID 9515848
Not RCT (CPAP vs CPAP)

Koziej M, Cieslicki JK, Gorzelak K, Sliwinski P, Zielinski J. Hand-scoring of MESAM 4 recordings is more accurate than automatic analysis in screening for obstructive sleep apnoea. European Respiratory Journal. 1994;7:1771-1775.
PMID 7828683
In 2007 EPC Report

Krahn AD, Yee R, Erickson MK et al. Physiologic pacing in patients with obstructive sleep apnea: a prospective, randomized crossover trial. Journal of the American College of Cardiology. 2006;47:379-383.
PMID 16412864
In-lab study

Krakow B, Melendrez D, Ferreira E et al. Prevalence of insomnia symptoms in patients with sleep-disordered breathing. Chest. 2001;120:1923-1929.
PMID 11742923
N<500 (KQ 2)

Krekmanov L, Andersson L, Ringqvist M et al. Anterior-inferior mandibular osteotomy in treatment of obstructive sleep apnea syndrome. International Journal of Adult Orthodontics & Orthognathic Surgery. 1998;13:289-298.
PMID 10196816
Surgical cohort <100/intervention

Krieger J. Long-term compliance with nasal continuous positive airway pressure (CPAP) in obstructive sleep apnea patients and nonapneic snorers. Sleep. 1992;15:Suppl-6.
PMID 1470808
Not multivariate (KQ 6, CPAP)

Krieger J, Meslier N, Lebrun T et al. Accidents in obstructive sleep apnea patients treated with nasal continuous positive airway pressure: a prospective study. The Working Group ANTADIR, Paris and CRESGE, Lille, France. Association Nationale de Traitement a Domicile des Insuffisants Respiratoires. Chest. 1997;112:1561-1566.
PMID 9404754
Not multivariate (with AHI, KQ 2)

Kryger MH, Roos L, Delaive K, Walld R, Horrocks J. Utilization of health care services in patients with severe obstructive sleep apnea. Sleep. 1996;19:Suppl-6.
PMID 9122567
Systematic review etc published before 2000

Kuhnel TS, Schurr C, Wagner B, Geisler P. Morphological changes of the posterior airway space after tongue base suspension. Laryngoscope. 2005;115:475-480.
PMID 15744161
Surgical cohort <100/intervention

Kushida CA, Nichols DA, Quan SF et al. The Apnea Positive Pressure Long-term Efficacy Study (APPLES): rationale, design, methods, and procedures. Journal of Clinical Sleep Medicine. 2006;2:288-300.
PMID 17561541
Not RCT

Langin T, Pepin JL, Pendlebury S et al. Upper airway changes in snorers and mild sleep apnea sufferers after uvulopalatopharyngoplasty (UPPP). Chest. 1998;113:1595-1603.
PMID 9631799
Surgical cohort <100/intervention

Larsson H, Carlsson-Nordlander B, Svanborg E. Long-time follow-up after UPPP for obstructive sleep apnea syndrome. Results of sleep apnea recordings and subjective evaluation 6 months and 2 years after surgery. Acta Oto-Laryngologica. 1991;111:582-590.
PMID 1887784
Surgical cohort <100/intervention

Larsson LH, Carlsson-Nordlander B, Svanborg E. Four-year follow-up after uvulopalatopharyngoplasty in 50 unselected patients with obstructive sleep apnea syndrome. Laryngoscope. 1994;104:t-8.
PMID 7968165
Surgical cohort <100/intervention

Lauretano AM, Khosla RK, Richardson G et al. Efficacy of laser-assisted uvulopalatoplasty. Lasers in Surgery & Medicine. 1997;21:109-116.
PMID 9261787
Surgical cohort No complication data

Lawton HM, Battagel JM, Kotecha B. A comparison of the Twin Block and Herbst mandibular advancement splints in the treatment of patients with obstructive sleep apnoea: a prospective study. European Journal of Orthodontics. 2005;27:82-90.
PMID 15743867
Not comparison of different MAD types

Lee CH, Shin HW, Han DH et al. The implication of sleep position in the evaluation of surgical outcomes in obstructive sleep apnea. Otolaryngology - Head & Neck Surgery. 2009;140:531-535.
PMID 19328342
Surgical cohort <100/intervention

Lee NR, Givens CD, Jr., Wilson J, Robins RB. Staged surgical treatment of obstructive sleep apnea syndrome: a review of 35 patients. Journal of Oral & Maxillofacial Surgery. 1999;57:382-385.
PMID 10199488
Surgical cohort <100/intervention

Leng PH, Mosharraf-Hossain AK, Chan YH, Tan WC. The clinical predictors of hypertension and sleepiness in an Asian population with sleep-disordered breathing. Annals of the Academy of Medicine, Singapore. 2006;35:6-10.
PMID 16470267
N<500 (KQ 2)

Levy P, Pepin JL, Deschaux-Blanc C, Paramelle B, Brambilla C. Accuracy of oximetry for detection of respiratory disturbances in sleep apnea syndrome. Chest. 1996;109:395-399.
PMID 8620711
In 2007 EPC Report

Lewis MR, Ducic Y. Genioglossus muscle advancement with the genioglossus bone advancement technique for base of tongue obstruction. Journal of Otolaryngology. 2003;32:168-173.
PMID 12921135
Surgical cohort <100/intervention

Li HY, Chen NH, Lee LA, Shu YH, Fang TJ, Wang PC. Use of morphological indicators to predict outcomes of palatopharyngeal surgery in patients with obstructive sleep apnea. Orl; Journal of Oto-Rhino-Laryngology & its Related Specialties. 2004;66:119-123.
PMID 15316231
Surgical cohort No complication data

Li HY, Chen NH, Shu YH, Wang PC. Changes in quality of life and respiratory disturbance after extended uvulopalatal flap surgery in patients with obstructive sleep apnea. Archives of Otolaryngology -- Head & Neck Surgery. 2004;130:195-200.
PMID 14967750
Surgical cohort <100/intervention

Li HY, Huang YS, Chen NH, Fang TJ, Liu CY, Wang PC. Mood improvement after surgery for obstructive sleep apnea. Laryngoscope. 2004;114:1098-1102.
PMID 15179220
Surgical cohort <100/intervention

Li HY, Lee LA. Relocation pharyngoplasty for obstructive sleep apnea. Laryngoscope. 2009;119:2472-2477.
PMID 19688851
Surgical cohort <100/intervention

Li HY, Li KK, Chen NH, Wang CJ, Liao YF, Wang PC. Three-dimensional computed tomography and polysomnography findings after extended uvulopalatal flap surgery for obstructive sleep apnea. American Journal of Otolaryngology. 2005;26:7-11.
PMID 15635574
Surgical cohort <100/intervention

Li HY, Li KK, Chen NH, Wang PC. Modified uvulopalatopharyngoplasty: The extended uvulopalatal flap. American Journal of Otolaryngology. 2003;24:311-316.
PMID 13130443
Surgical cohort <100/intervention

Li HY, Lin Y, Chen NH, Lee LA, Fang TJ, Wang PC. Improvement in quality of life after nasal surgery alone for patients with obstructive sleep apnea and nasal obstruction. Archives of Otolaryngology -- Head & Neck Surgery. 2008;134:429-433.
PMID 18427011
Surgical cohort <100/intervention

Li HY, Wang PC, Hsu CY, Chen NH, Lee LA, Fang TJ. Same-stage palatopharyngeal and hypopharyngeal surgery for severe obstructive sleep apnea. Acta Oto-Laryngologica. 2004;124:820-826.
PMID 15370567
Surgical cohort <100/intervention

Li HY, Wang PC, Hsu CY, Lee SW, Chen NH, Liu SA. Combined nasal-palatopharyngeal surgery for obstructive sleep apnea: simultaneous or staged? Acta Oto-Laryngologica. 2005;125:298-303.
PMID 15966701
Surgical cohort <100/intervention

Li HY, Wang PC, Lee LA, Chen NH, Fang TJ. Prediction of uvulopalatopharyngoplasty outcome: anatomy-based staging system versus severity-based staging system. Sleep. 2006;29:1537-1541.
PMID 17252884
Surgical cohort No complication data

Li KK, Guilleminault C, Riley RW, Powell NB. Obstructive sleep apnea and maxillomandibular advancement: an assessment of airway changes using radiographic and nasopharyngoscopic examinations. Journal of Oral & Maxillofacial Surgery. 2002;60:526-530.
PMID 11988930
Surgical cohort <100/intervention

Li KK, Powell NB, Riley RW, Guilleminault C. Temperature-controlled radiofrequency tongue base reduction for sleep-disordered breathing: Long-term outcomes. Otolaryngology - Head & Neck Surgery. 2002;127:230-234.
PMID 12297815
Surgical cohort <100/intervention

Li KK, Powell NB, Riley RW, Zonato A, Gervacio L, Guilleminault C. Morbidly obese patients with severe obstructive sleep apnea: is airway reconstructive surgery a viable treatment option? Laryngoscope. 2000;110:982-987.
PMID 10852518
Surgical cohort <100/intervention

Li KK, Riley RW, Powell NB, Gervacio L, Troell RJ, Guilleminault C. Obstructive sleep apnea surgery: patient perspective and polysomnographic results. Otolaryngology - Head & Neck Surgery. 2000;123:572-575.
PMID 11077343
Surgical cohort <100/intervention

Li KK, Riley RW, Powell NB, Guilleminault C. Maxillomandibular advancement for persistent obstructive sleep apnea after phase I surgery in patients without maxillomandibular deficiency. Laryngoscope. 2000;110:t-8.
PMID 11037825
Surgical cohort <100/intervention

Li KK, Riley RW, Powell NB, Troell RJ. Obstructive sleep apnea surgery: genioglossus advancement revisited. Journal of Oral & Maxillofacial Surgery. 2001;59:1181-1184.
PMID 11573177
Surgical cohort <100/intervention

Liesching TN, Carlisle C, Marte A, Bonitati A, Millman RP. Evaluation of the accuracy of SNAP technology sleep sonography in detecting obstructive sleep apnea in adults compared to standard polysomnography. Chest. 2004;125:886-891.
PMID 15006946
Retrospective

Lin CC, Chang KC, Lee KS. Effects of treatment by laser-assisted uvuloplasty on sleep energy expenditure in obstructive sleep apnea patients. Metabolism: Clinical & Experimental. 2002;51:622-627.
PMID 11979396
Surgical cohort <100/intervention

Lin CC, Chang KC, Lee KS, Wu KM, Chou CS, Lin CK. Effect of treatment by laser-assisted uvulopalatoplasty on cardiopulmonary exercise test in obstructive sleep apnea syndrome. Otolaryngology - Head & Neck Surgery. 2005;133:55-61.
PMID 16025053
Surgical cohort <100/intervention

Lin CC, Lee KS, Chang KC, Wu KM, Chou CS. Effect of laser-assisted uvulopalatoplasty on oral airway resistance during wakefulness in obstructive sleep apnea syndrome. European Archives of Oto-Rhino-Laryngology. 2006;263:241-247.
PMID 16163511
Surgical cohort <100/intervention

Lin CC, Lee KS, Wang YP et al. Effect of uvulopalatopharyngoplasty on work of breathing during wakefulness in obstructive sleep apnea syndrome. Annals of Otology, Rhinology & Laryngology. 2007;116:271-277.
PMID 17491526
Surgical cohort <100/intervention

Lin CL, Yeh C, Yen CW, Hsu WH, Hang LW. Comparison of the indices of oxyhemoglobin saturation by pulse oximetry in obstructive sleep apnea hypopnea syndrome. Chest. 2009;135:86-93.
PMID 18689584
Not Dx'ic study (already diagnosed w/OSA)

Liu SA, Li HY, Tsai WC, Chang KM. Associated factors to predict outcomes of uvulopharyngopalatoplasty plus genioglossal advancement for obstructive sleep apnea. Laryngoscope. 2005;115:2046-2050.
PMID 16319622
Surgical cohort <100/intervention

Lloberes P, Marti S, Sampol G et al. Predictive factors of quality-of-life improvement and continuous positive airway pressure use in patients with sleep apnea-hypopnea syndrome: study at 1 year. Chest. 2004;126:1241-1247.
PMID 15486388
Not multivariate (KQ 6, CPAP)

Lloberes P, Montserrat JM, Ascaso A et al. Comparison of partially attended night time respiratory recordings and full polysomnography in patients with suspected sleep apnoea/hypopnoea syndrome. Thorax. 1996;51:1043-1047.
PMID 8977607
In 2007 EPC Report

Lloberes P, Sampol G, Levy G et al. Influence of setting on unattended respiratory monitoring in the sleep apnoea/hypopnoea syndrome. European Respiratory Journal. 2001;18:530-534.
PMID 11589351
In 2007 EPC Report

Lu SJ, Chang SY, Shiao GM. Comparison between short-term and long-term post-operative evaluation of sleep apnoea after uvulopalatopharyngoplasty. Journal of Laryngology & Otology. 1995;109:308-312.
PMID 7782686
Surgical cohort <100/intervention

Ludwig A. Results of electromyostimulation therapy in obstructive sleep apnea. Artificial Organs. 2008;32:655-658.
PMID 18782139
No outcomes of interest

Lye KW, Waite PD, Meara D, Wang D. Quality of life evaluation of maxillomandibular advancement surgery for treatment of obstructive sleep apnea. Journal of Oral & Maxillofacial Surgery. 2008;66:968-972.
PMID 18423288
Surgical cohort <100/intervention

Lysdahl M, Haraldsson PO. Uvulopalatopharyngoplasty versus laser uvulopalatoplasty: prospective long-term follow-up of self-reported symptoms. Acta Oto-Laryngologica. 2002;122:752-757.
PMID 12484653
Surgical cohort <100/intervention

Macaluso RA, Reams C, Gibson WS, Vrabec DP, Matragrano A. Uvulopalatopharyngoplasty: postoperative management and evaluation of results. Annals of Otology, Rhinology & Laryngology. 1989;98:t-7.
PMID 2751209
Surgical cohort <100/intervention

Magalang UJ, Dmochowski J, Veeramachaneni S et al. Prediction of the apnea-hypopnea index from overnight pulse oximetry. Chest. 2003;124:1694-1701.
PMID 14605037
In 2007 EPC Report

Magnan A, Philip-Joet F, Rey M, Reynaud M, Porri F, Arnaud A. End-tidal CO2 analysis in sleep apnea syndrome. Conditions for use. Chest. 1993;103:129-131.
PMID 8417866
Not diagnostic test of interest

Maisel RH, Antonelli PJ, Iber C et al. Uvulopalatopharyngoplasty for obstructive sleep apnea: a community's experience. Laryngoscope. 1992;102:604-607.
PMID 1602908
Surgical cohort <100/intervention

Maislin G, Pack AI, Kribbs NB et al. A survey screen for prediction of apnea. Sleep. 1995;18:158-166.
PMID 7610311
No validation set analysis

Malow BA, Foldvary-Schaefer N, Vaughn BV et al. Treating obstructive sleep apnea in adults with epilepsy: a randomized pilot trial. Neurology. 2008;71:572-577.
PMID 18711110
Population: Epilepsy

Man GC, Kang BV. Validation of a portable sleep apnea monitoring device. Chest. 1995;108:388-393.
PMID 7634872
In 2007 EPC Report

Marcos JV, Hornero R, Alvarez D, del CF, Lopez M. Applying neural network classifiers in the diagnosis of the obstructive sleep apnea syndrome from nocturnal pulse oximetric recordings. Conference Proceedings: Annual International Conference of the IEEE Engineering in Medicine & Biology Society. 2007;2007:5174-5177.
PMID 18003173
Duplicate of previous study

Marklund M. Predictors of long-term orthodontic side effects from mandibular advancement devices in patients with snoring and obstructive sleep apnea. American Journal of Orthodontics & Dentofacial Orthopedics. 2006;129:214-221.
PMID 16473713
KQ 6 Retrospective

Marklund M, Franklin KA. Long-term effects of mandibular repositioning appliances on symptoms of sleep apnoea. Journal of Sleep Research. 2007;16:414-420.
PMID 18036087
No predictors of compliance

Marklund M, Stenlund H, Franklin KA. Mandibular advancement devices in 630 men and women with obstructive sleep apnea and snoring: tolerability and predictors of treatment success. Chest. 2004;125:1270-1278.
PMID 15078734
No predictors of compliance

Marrone O, Salvaggio A, Insalaco G, Bonsignore MR, Bonsignore G. Evaluation of the POLYMESAM system in the diagnosis of obstructive sleep apnea syndrome. Monaldi Archives for Chest Disease. 2001;56:486-490.
PMID 11980277
In 2007 EPC Report

Marshall NS, Neill AM, Campbell AJ. Randomised trial of compliance with flexible (C-Flex) and standard continuous positive airway pressure for severe obstructive sleep apnea. Sleep & Breathing. 2008;12:393-396.
PMID 18516638
N<10/intervention

Martinho FL, Tangerina RP, Moura SM, Gregorio LC, Tufik S, Bittencourt LR. Systematic head and neck physical examination as a predictor of obstructive sleep apnea in class III obese patients. Brazilian Journal of Medical & Biological Research. 2008;41:1093-1097.
PMID 19148371
No analyses of interest

Mayer P, Meurice JC, Philip-Joet F et al. Simultaneous laboratory-based comparison of ResMed Autoset with polysomnography in the diagnosis of sleep apnoea/hypopnoea syndrome. European Respiratory Journal. 1998;12:770-775.
PMID 9817143
In 2007 EPC Report

McArdle N, Kingshott R, Engleman HM, Mackay TW, Douglas NJ. Partners of patients with sleep apnoea/hypopnoea syndrome: effect of CPAP treatment on sleep quality and quality of life. Thorax. 2001;56:513-518.
PMID 11413348
No outcomes of interest

McFadyen TA, Espie CA, McArdle N, Douglas NJ, Engleman HM. Controlled, prospective trial of psychosocial function before and after continuous positive airway pressure therapy. European Respiratory Journal. 2001;18:996-1002.
PMID 11829108
Not randomized

McGuirt WF, Jr., Johnson JT, Sanders MH. Previous tonsillectomy as prognostic indicator for success of uvulopalatopharyngoplasty. Laryngoscope. 1995;105:1253-1255.
PMID 7475885
Surgical cohort <100/intervention

McLean HA, Urton AM, Driver HS et al. Effect of treating severe nasal obstruction on the severity of obstructive sleep apnoea. European Respiratory Journal. 2005;25:521-527.
PMID 15738298
In-lab study

Mehra R, Principe-Rodriguez K, Kirchner HL, Strohl KP. Sleep apnea in acute coronary syndrome: high prevalence but low impact on 6-month outcome. Sleep Medicine. 2006;7:521-528.
PMID 16931151
No predictors of compliance

Meston N, Davies RJ, Mullins R, Jenkinson C, Wass JA, Stradling JR. Endocrine effects of nasal continuous positive airway pressure in male patients with obstructive sleep apnoea. Journal of Internal Medicine. 2003;254:447-454.
PMID 14535966
No outcomes of interest

Meurice JC, Marc I, Series F. Efficacy of auto-CPAP in the treatment of obstructive sleep apnea/hypopnea syndrome. American Journal of Respiratory & Critical Care Medicine. 1996;153:794-798.
PMID 8564134
N<10/intervention

Michaelson PG, Allan P, Chaney J, Mair EA. Validations of a portable home sleep study with twelve-lead polysomnography: comparisons and insights into a variable gold standard. Annals of Otology, Rhinology & Laryngology. 2006;115:802-809.
PMID 17165661
In 2007 EPC Report

Mickelson SA, Rosenthal L. Midline glossectomy and epiglottidectomy for obstructive sleep apnea syndrome. Laryngoscope. 1997;107:614-619.
PMID 8544614
Surgical cohort <100/intervention

Mickelson SA, Ahuja A. Short-term objective and long-term subjective results of laser-assisted uvulopalatoplasty for obstructive sleep apnea. Laryngoscope. 1999;109:362-367.
PMID 10089958
Surgical cohort <100/intervention

Miles PG, Nimkarn Y. Maxillomandibular advancement surgery in patients with obstructive sleep apnea: mandibular morphology and stability. International Journal of Adult Orthodontics & Orthognathic Surgery. 1995;10:193-200.
PMID 9082007
Surgical cohort <100/intervention

Miljeteig H, Tvinnereim M. Uvulopalatopharyngoglossoplasty (UPPGP) in the treatment of the obstructive sleep apnea syndrome. Acta Oto-Laryngologica Supplement. 1992;492:86-89.
PMID 1632261
Surgical cohort <100/intervention

Milleron O, Pilliere R, Foucher A et al. Benefits of obstructive sleep apnoea treatment in coronary artery disease: a long-term follow-up study. European Heart Journal. 2004;25:728-734.
PMID 15120882
No specific treatment

Millman RP, Carlisle CC, Rosenberg C, Kahn D, McRae R, Kramer NR. Simple predictors of uvulopalatopharyngoplasty outcome in the treatment of obstructive sleep apnea. Chest. 2000;118:1025-1030.
PMID 11035673
Surgical cohort <100/intervention

Millman RP, Kipp GJ, Beadles SC, Braman SS. A home monitoring system for nasal CPAP. Chest. 1988;93:730-733.
PMID 3280258
Not Dx'ic study (already on CPAP)

Millman RP, Rosenberg CL, Carlisle CC, Kramer NR, Kahn DM, Bonitati AE. The efficacy of oral appliances in the treatment of persistent sleep apnea after uvulopalatopharyngoplasty. Chest. 1998;113:992-996.
PMID 9554637
Not comparative

Miyata S, Noda A, Nakata S et al. Daytime polysomnography for early diagnosis and treatment of patients with suspected sleep-disordered breathing. Sleep & Breathing. 2007;11:109-115.
PMID 17221275
Not diagnostic test of interest

Miyazaki S, Tanaka T, Itasaka Y, Ishikawa K. A trial study of RhinoSleep for the diagnosis of sleep apnea. Psychiatry & Clinical Neurosciences. 2001;55:249-250.
PMID 11422861
No reference standard (overnight PSG)

Mizuma H, Sonnenschein W, Meier-Ewert K. Diagnostic use of daytime polysomnography versus nocturnal polysomnography in sleep apnea syndrome. Psychiatry & Clinical Neurosciences. 1996;50:211-216.
PMID 9201778
Not diagnostic test of interest

Mooe T, Franklin KA, Holmstrom K, Rabben T, Wiklund U. Sleep-disordered breathing and coronary artery disease: long-term prognosis. American Journal of Respiratory & Critical Care Medicine. 2001;164:t-3.
PMID 11734445
N<500 (KQ 2)

Moraes W, Poyares D, Sukys-Claudino L, Guilleminault C, Tufik S. Donepezil improves obstructive sleep apnea in Alzheimer disease: a double-blind, placebo-controlled study. Chest. 2008;133:677-683.
PMID 18198262
Not drug of interest

Morales Divo C, Selivanova O, Mewes T, Gosepath J, Lippold R, Mann WJ. Polysomnography and ApneaGraph in patients with sleep-related breathing disorders. Orl; Journal of Oto-Rhino-Laryngology & its Related Specialties. 2009;71:27-31.
PMID 18953186
No analyses of interest

Morinaga M, Nakata S, Yasuma F et al. Pharyngeal morphology: a determinant of successful nasal surgery for sleep apnea. Laryngoscope. 2009;119:1011-1016.
PMID 19301414
Surgical cohort <100/intervention

Morris LG, Kleinberger A, Lee KC, Liberatore LA, Burschtin O. Rapid risk stratification for obstructive sleep apnea, based on snoring severity and body mass index. Otolaryngology - Head & Neck Surgery. 2008;139:615-618.
PMID 18984252
No validation set analysis

Morrish E, Shneerson JM, Smith IE. Why does gender influence survival in obstructive sleep apnoea? Respiratory Medicine. 2008;102:1231-1236.
PMID 18617382
N<500 (KQ 2)

Mueller A, Fietze I, Voelker R et al. Screening for sleep-related breathing disorders by transthoracic impedance recording integrated into a Holter ECG system. Journal of Sleep Research. 2006;15:455-462.
PMID 17118103
Not diagnostic test of interest

Mulgrew AT, Fox N, Ayas NT, Ryan CF. Diagnosis and initial management of obstructive sleep apnea without polysomnography: a randomized validation study. Annals of Internal Medicine. 2007;146:157-166.
PMID 17283346
In 2007 EPC Report

Munoz R, Duran-Cantolla J, Martinez-Vila E et al. Severe sleep apnea and risk of ischemic stroke in the elderly. Stroke. 2006;37:2317-2321.
PMID 16888274
N<500 (KQ 2)

Myatt HM, Croft CB, Kotecha BT, Ruddock J, Mackay IS, Simonds AK. A three-centre prospective pilot study to elucidate the effect of uvulopalatopharyngoplasty on patients with mild obstructive sleep apnoea due to velopharyngeal obstruction. Clinical Otolaryngology & Allied Sciences. 1999;24:95-103.
PMID 10225152
Surgical cohort <100/intervention

Nader NZ, Steinel JA, Auckley DH. Newly identified obstructive sleep apnea in hospitalized patients: analysis of an evaluation and treatment strategy. Journal of Clinical Sleep Medicine. 2006;2:431-437.
PMID 17557473
Not RCT (CPAP vs control)

Nakano H, Hayashi M, Ohshima E, Nishikata N, Shinohara T. Validation of a new system of tracheal sound analysis for the diagnosis of sleep apnea-hypopnea syndrome. Sleep. 2004;27:951-957.
PMID 15453554
In 2007 EPC Report

Nakano H, Ikeda T, Hayashi M et al. Effect of body mass index on overnight oximetry for the diagnosis of sleep apnea. Respiratory Medicine. 2004;98:421-427.
PMID 15139571
In 2007 EPC Report

Nakata S, Miyazaki S, Ohki M et al. Reduced nasal resistance after simple tonsillectomy in patients with obstructive sleep apnea. American Journal of Rhinology. 2007;21:192-195.
PMID 17424878
Surgical cohort <100/intervention

Nakata S, Noda A, Yagi H et al. Nasal resistance for determinant factor of nasal surgery in CPAP failure patients with obstructive sleep apnea syndrome. Rhinology. 2005;43:296-299.
PMID 16405275
Surgical cohort <100/intervention

Nakata S, Noda A, Yanagi E, Suzuki K, Yamamoto H, Nakashima T. Tonsil size and body mass index are important factors for efficacy of simple tonsillectomy in obstructive sleep apnoea syndrome. Clinical Otolaryngology. 2006;31:41-45.
PMID 16441801
Surgical cohort <100/intervention

Nakata S, Noda A, Yasuma F et al. Effects of nasal surgery on sleep quality in obstructive sleep apnea syndrome with nasal obstruction. American Journal of Rhinology. 2008;22:59-63.
PMID 18284861
Surgical cohort <100/intervention

Nelson LM. Combined temperature-controlled radiofrequency tongue reduction and UPPP in apnea surgery. Ear, Nose, & Throat Journal. 2001;80:640-644.
PMID 11579850
Surgical cohort <100/intervention

Neruntarat C. Genioglossus advancement and hyoid myotomy under local anesthesia. Otolaryngology - Head & Neck Surgery. 2003;129:85-91.
PMID 12869922
Surgical cohort <100/intervention

Neruntarat C. Genioglossus advancement and hyoid myotomy: short-term and long-term results. Journal of Laryngology & Otology. 2003;117:482-486.
PMID 12818058
Surgical cohort <100/intervention

Neruntarat C. Hyoid myotomy with suspension under local anesthesia for obstructive sleep apnea syndrome. European Archives of Oto-Rhino-Laryngology. 2003;260:286-290.
PMID 12750922
Surgical cohort <100/intervention

Neruntarat C, Chantapant S. Radiofrequency surgery for the treatment of obstructive sleep apnea: short-term and long-term results. Otolaryngology - Head & Neck Surgery. 2009;141:722-726.
PMID 19932844
Surgical cohort <100/intervention

Nilius G, Domanski U, Franke KJ, Ruhle KH. Impact of a controlled heated breathing tube humidifier on sleep quality during CPAP therapy in a cool sleeping environment. European Respiratory Journal. 2008;31:830-836.
PMID 18184678
Not comparison of different PAP types

Nimkarn Y, Miles PG, Waite PD. Maxillomandibular advancement surgery in obstructive sleep apnea syndrome patients: long-term surgical stability. Journal of Oral & Maxillofacial Surgery. 1995;53:1414-1418.
PMID 7490651
Surgical cohort <100/intervention

Nino-Murcia G, McCann CC, Bliwise DL, Guilleminault C, Dement WC. Compliance and side effects in sleep apnea patients treated with nasal continuous positive airway pressure. Western Journal of Medicine. 1989;150:165-169.
PMID 2658326
Not multivariate (KQ 6, CPAP)

Nordgard S, Hein G, Stene BK, Skjostad KW, Maurer JT. One-year results: palatal implants for the treatment of obstructive sleep apnea. Otolaryngology - Head & Neck Surgery. 2007;136:818-822.
PMID 17478222
Surgical cohort <100/intervention

Nordgard S, Stene BK, Skjostad KW. Soft palate implants for the treatment of mild to moderate obstructive sleep apnea. Otolaryngology - Head & Neck Surgery. 2006;134:565-570.
PMID 16564373
Surgical cohort <100/intervention

Noseda A, Jann E, Hoffmann G, Linkowski P, Kerkhofs M. Compliance with nasal continuous positive airway pressure assessed with a pressure monitor: pattern of use and influence of sleep habits. Respiratory Medicine. 2000;94:76-81.
PMID 10714483
Not multivariate (KQ 6, CPAP)

Noseda A, Nouvelle M, Lanquart JR et al. High leg motor activity in sleep apnea hypopnea patients: efficacy of clonazepam combined with nasal CPAP on polysomnographic variables. Respiratory Medicine. 2002;96:693-699.
PMID 12243315
In-lab study

Ohayon MM, Guilleminault C, Zulley J, Palombini L, Raab H. Validation of the sleep-EVAL system against clinical assessments of sleep disorders and polysomnographic data. Sleep. 1999;22:925-930.
PMID 10566910
No analyses of interest

Okabayashi K, Kasahara E, Uchiyama H et al. Obstructive sleep apnea-hypopnea syndrome patients with overweight and hypertension in a Japanese workplace. Journal of Occupational Health. 2007;49:117-124.
PMID 17429169
No analyses of interest

Olson LG, Ambrogetti A, Gyulay SG. Prediction of sleep-disordered breathing by unattended overnight oximetry. Journal of Sleep Research. 1999;8:51-55.
PMID 10188136
In 2007 EPC Report

Omur M, Ozturan D, Elez F, Unver C, Derman S. Tongue base suspension combined with UPPP in severe OSA patients. Otolaryngology - Head & Neck Surgery. 2005;133:218-223.
PMID 16087018
Surgical cohort <100/intervention

Orr WC, Eiken T, Pegram V, Jones R, Rundell OH. A laboratory validation study of a portable system for remote recording of sleep-related respiratory disorders. Chest. 1994;105:160-162.
PMID 8275725
In 2007 EPC Report

Osman EZ, Osborne J, Hill PD, Lee BW. The Epworth Sleepiness Scale: can it be used for sleep apnoea screening among snorers? Clinical Otolaryngology & Allied Sciences. 1999;24:239-241.
PMID 10384854
No analyses of interest

Osnes T, Rollheim J, Hartmann E. Effect of UPPP with respect to site of pharyngeal obstruction in sleep apnoea: follow-up at 18 months by overnight recording of airway pressure and flow. Clinical Otolaryngology & Allied Sciences. 2002;27:38-43.
PMID 11903370
Surgical cohort <100/intervention

Overland B, Bruskeland G, Akre H, Skatvedt O. Evaluation of a portable recording device (Reggie) with actimeter and nasopharyngeal/esophagus catheter incorporated. Respiration. 2005;72:600-605.
PMID 15988172
In 2007 EPC Report

Ozegowski S, Wilczynska E, Piorunek T, Szymanowska K, Paluszkiewicz L. Usefulness of ambulatory ECG in the diagnosis of sleep-related breathing disorders. Kardiologia Polska. 2007;65:1321-1328.
PMID 18058583
Non-English

Pack AI, Black JE, Schwartz JR, Matheson JK. Modafinil as adjunct therapy for daytime sleepiness in obstructive sleep apnea. American Journal of Respiratory & Critical Care Medicine. 2001;164:1675-1681.
PMID 11719309
Not drug of interest

Pang KP. One-stage nasal and multi-level pharyngeal surgery for obstructive sleep apnoea: safety and efficacy. Journal of Laryngology & Otology. 2005;119:272-276.
PMID 15949079
Surgical cohort <100/intervention

Pang KP, Dillard TA, Blanchard AR, Gourin CG, Podolsky R, Terris DJ. A comparison of polysomnography and the SleepStrip in the diagnosis of OSA. Otolaryngology - Head & Neck Surgery. 2006;135:265-268.
PMID 16890080
In 2007 EPC Report

Pang KP, Terris DJ. Modified cautery-assisted palatal stiffening operation: new method for treating snoring and mild obstructive sleep apnea. Otolaryngology - Head & Neck Surgery. 2007;136:823-826.
PMID 17478223
Surgical cohort <100/intervention

Pang KP, Woodson BT. Expansion sphincter pharyngoplasty: a new technique for the treatment of obstructive sleep apnea. Otolaryngology - Head & Neck Surgery. 2007;137:110-114.
PMID 17599576
Surgical cohort <100/intervention

Parra O, Garcia-Esclasans N, Montserrat JM et al. Should patients with sleep apnoea/hypopnoea syndrome be diagnosed and managed on the basis of home sleep studies? European Respiratory Journal. 1997;10:1720-1724.
PMID 9272909
In 2007 EPC Report

Partinen M, Guilleminault C. Daytime sleepiness and vascular morbidity at seven-year follow-up in obstructive sleep apnea patients. Chest. 1990;97:27-32.
PMID 2295260
Not randomized

Penzel T, Fricke R, Jerrentrup A, Peter JH, Vogelmeier C. Peripheral arterial tonometry for the diagnosis of obstructive sleep apnea. Biomedizinische Technik. 2002;47:Suppl-7.
PMID 12451851
Not diagnostic test of interest

Penzel T, Kesper K, Pinnow I, Becker HF, Vogelmeier C. Peripheral arterial tonometry, oximetry and actigraphy for ambulatory recording of sleep apnea. Physiological Measurement. 2004;25:1025-1036.
PMID 15382839
In 2007 EPC Report

Pepin JL, Veale D, Mayer P, Bettega G, Wuyam B, Levy P. Critical analysis of the results of surgery in the treatment of snoring, upper airway resistance syndrome (UARS), and obstructive sleep apnea (OSA). Sleep. 1996;19:Suppl-100.
PMID 9122580
Systematic review etc published before 2000

Pepin JL, Viot-Blanc V, Escourrou P et al. Prevalence of residual excessive sleepiness in CPAP-treated sleep apnoea patients: the French multicentre study. European Respiratory Journal. 2009;33:1062-1067.
PMID 19407048
Cross-sectional

Peppard PE, Szklo-Coxe M, Hla KM, Young T. Longitudinal association of sleep-related breathing disorder and depression. Archives of Internal Medicine. 2006;166:1709-1715.
PMID 16983048
Cross-sectional

Pepperell JC, Ramdassingh-Dow S, Crosthwaite N et al. Ambulatory blood pressure after therapeutic and subtherapeutic nasal continuous positive airway pressure for obstructive sleep apnoea: a randomised parallel trial. Lancet. 2002;359:204-210.
PMID 11812555
No outcomes of interest

Perez de Llano LA, Golpe R, Piquer MO et al. Clinical heterogeneity among patients with obesity hypoventilation syndrome: therapeutic implications. Respiration. 2008;75:34-39.
PMID 17622772
Not RCT (CPAP vs NIPPV)

Persson HE, Svanborg E. Sleep deprivation worsens obstructive sleep apnea. Comparison between diurnal and nocturnal polysomnography. Chest. 1996;109:645-650.
PMID 8617071
Not diagnostic test of interest

Petri N, Suadicani P, Wildschiodtz G, Bjorn-Jorgensen J. Predictive value of Muller maneuver, cephalometry and clinical features for the outcome of uvulopalatopharyngoplasty. Evaluation of predictive factors using discriminant analysis in 30 sleep apnea patients. Acta Oto-Laryngologica. 1994;114:565-571.
PMID 7825443
Surgical cohort <100/intervention

Phillips BA, Schmitt FA, Berry DT, Lamb DG, Amin M, Cook YR. Treatment of obstructive sleep apnea. A preliminary report comparing nasal CPAP to nasal oxygen in patients with mild OSA. Chest. 1990;98:325-330.
PMID 2198135
N<10/intervention

Piccirillo JF, Gates GA, White DL, Schectman KB. Obstructive sleep apnea treatment outcomes pilot study. Otolaryngology - Head & Neck Surgery. 1998;118:833-844.
PMID 9627245
No treatment comparison

Pieters T, Collard P, Aubert G, Dury M, Delguste P, Rodenstein DO. Acceptance and long-term compliance with nCPAP in patients with obstructive sleep apnoea syndrome. European Respiratory Journal. 1996;9:939-944.
PMID 8793455
N<100 (KQ 6)

Pillar G, Bar A, Betito M et al. An automatic ambulatory device for detection of AASM defined arousals from sleep: the WP100. Sleep Medicine. 2003;4:207-212.
PMID 14592323
In 2007 EPC Report

Pillar G, Bar A, Shlitner A, Schnall R, Shefy J, Lavie P. Autonomic arousal index: an automated detection based on peripheral arterial tonometry. Sleep. 2002;25:543-549.
PMID 12150321
In 2007 EPC Report

Piper AJ, Laks L, Sullivan CE. Effectiveness of short-term NIPPV in the management of patients with severe OSA and REM hypoventilation. Sleep.16:Suppl-6.
PMID 8177997
Not randomized

Pitsis AJ, Darendeliler MA, Gotsopoulos H, Petocz P, Cistulli PA. Effect of vertical dimension on efficacy of oral appliance therapy in obstructive sleep apnea. American Journal of Respiratory & Critical Care Medicine. 2002;166:860-864.
PMID 12231498
Not comparison of different MAD types

Pittman SD, Ayas NT, MacDonald MM, Malhotra A, Fogel RB, White DP. Using a wrist-worn device based on peripheral arterial tonometry to diagnose obstructive sleep apnea: in-laboratory and ambulatory validation. Sleep. 2004;27:923-933.
PMID 15453551
In 2007 EPC Report

Pittman SD, Pillar G, Berry RB, Malhotra A, MacDonald MM, White DP. Follow-up assessment of CPAP efficacy in patients with obstructive sleep apnea using an ambulatory device based on peripheral arterial tonometry. Sleep & Breathing. 2006;10:123-131.
PMID 16586136
Not Dx'ic study (already on CPAP)

Platt AB, Field SH, Asch DA et al. Neighborhood of residence is associated with daily adherence to CPAP therapy. Sleep. 2009;32:799-806.
PMID 19544757
KQ 6 Retrospective

Platt AB, Kuna ST, Field SH et al. Adherence to sleep apnea therapy and use of lipid-lowering drugs: a study of the healthy-user effect. Chest. 2010;137:102-108.
PMID 19820075
KQ 6 Retrospective

Polo O, Brissaud L, Fraga J, Dejean Y, Billiard M. Partial upper airway obstruction in sleep after uvulopalatopharyngoplasty. Archives of Otolaryngology -- Head & Neck Surgery. 1989;115:1350-1354.
PMID 2803716
Surgical cohort <100/intervention

Popescu G, Latham M, Allgar V, Elliott MW. Continuous positive airway pressure for sleep apnoea/hypopnoea syndrome: usefulness of a 2 week trial to identify factors associated with long term use. Thorax. 2001;56:727-733.
PMID 11514695
Multivariate analysis not adequately reported

Portier F, Portmann A, Czernichow P et al. Evaluation of home versus laboratory polysomnography in the diagnosis of sleep apnea syndrome. American Journal of Respiratory & Critical Care Medicine. 2000;162:t-8.
PMID 10988088
In 2007 EPC Report

Powell N, Riley R, Guilleminault C, Troell R. A reversible uvulopalatal flap for snoring and sleep apnea syndrome. Sleep. 1996;19:593-599.
PMID 8899940
Surgical cohort <100/intervention

Powell NB, Riley RW, Guilleminault C. Radiofrequency tongue base reduction in sleep-disordered breathing: A pilot study. Otolaryngology - Head & Neck Surgery. 1999;120:656-664.
PMID 10229589
Surgical cohort <100/intervention

Powell NB, Riley RW, Troell RJ, Li K, Blumen MB, Guilleminault C. Radiofrequency volumetric tissue reduction of the palate in subjects with sleep-disordered breathing. Chest. 1998;113:1163-1174.
PMID 9596289
Surgical cohort <100/intervention

Powell NB, Zonato AI, Weaver EM et al. Radiofrequency treatment of turbinate hypertrophy in subjects using continuous positive airway pressure: a randomized, double-blind, placebo-controlled clinical pilot trial. Laryngoscope. 2001;111:1783-1790.
PMID 11801946
N<10/intervention

Pradhan PS, Gliklich RE, Winkelman J. Screening for obstructive sleep apnea in patients presenting for snoring surgery.[erratum appears in Laryngoscope 1997 Jan;107(1):149]. Laryngoscope. 1996;106:1393-1397.
PMID 8914907
No validation set analysis

Pribitkin EA, Schutte SL, Keane WM et al. Efficacy of laser-assisted uvulopalatoplasty in obstructive sleep apnea. Otolaryngology - Head & Neck Surgery. 1998;119:643-647.
PMID 9852540
Surgical cohort <100/intervention

Prinsell JR. Maxillomandibular advancement surgery in a site-specific treatment approach for obstructive sleep apnea in 50 consecutive patients. Chest. 1999;116:1519-1529.
PMID 10593771
Surgical cohort <100/intervention

Proctor A, Billings C, Billings C, Moloney ED. Improvement in energy and vitality over a short-term CPAP trial predicts long-term compliance in patients with obstructive sleep apnea. Journal of Sleep Research. 2007;16:448-449.
PMID 18036092
Letter

Punjabi NM, Shahar E, Redline S et al. Sleep-disordered breathing, glucose intolerance, and insulin resistance: the Sleep Heart Health Study. American Journal of Epidemiology. 2004;160:521-530.
PMID 15353412
Cross-sectional

Quintana-Gallego E, Villa-Gil M, Carmona-Bernal C et al. Home respiratory polygraphy for diagnosis of sleep-disordered breathing in heart failure. European Respiratory Journal. 2004;24:443-448.
PMID 15358704
In 2007 EPC Report

Ramirez SG, Loube DI. Inferior sagittal osteotomy with hyoid bone suspension for obese patients with sleep apnea. Archives of Otolaryngology -- Head & Neck Surgery. 1996;122:953-957.
PMID 8797559
Surgical cohort <100/intervention

Randerath W, Parys K, Lehmann D, Sanner B, Feldmeyer F, Ruhle KH. Self-adjusting continuous positive airway pressure therapy based on the measurement of impedance. A comparison of free pressure variation and individually fixed higher minimum pressure. Respiration. 2000;67:272-279.
PMID 10867595
In-lab study

Randerath WJ, Parys K, Feldmeyer F, Sanner B, Ruhle KH. Self-adjusting nasal continuous positive airway pressure therapy based on measurement of impedance: A comparison of two different maximum pressure levels. Chest. 1999;116:991-999.
PMID 10531164
Not comparison of different PAP types

Rauscher H, Formanek D, Popp W, Zwick H. Nasal CPAP and weight loss in hypertensive patients with obstructive sleep apnoea. Thorax. 1993;48:529-533.
PMID 8322241
Not RCT (CPAP vs control)

Rauscher H, Popp W, Zwick H. Quantification of sleep disordered breathing by computerized analysis of oximetry, heart rate and snoring. European Respiratory Journal. 1991;4:655-659.
PMID 1889491
In 2007 EPC Report

Redline S, Tosteson T, Boucher MA, Millman RP. Measurement of sleep-related breathing disturbances in epidemiologic studies. Assessment of the validity and reproducibility of a portable monitoring device. Chest. 1991;100:1281-1286.
PMID 1935282
In 2007 EPC Report

Rees K, Wraith PK, Berthon-Jones M, Douglas NJ. Detection of apnoeas, hypopnoeas and arousals by the AutoSet in the sleep apnoea/hypopnoea syndrome. European Respiratory Journal. 1998;12:764-769.
PMID 9817142
In 2007 EPC Report

Reichert JA, Bloch DA, Cundiff E, Votteri BA. Comparison of the NovaSom QSG, a new sleep apnea home-diagnostic system, and polysomnography. Sleep Medicine. 2003;4:213-218.
PMID 14592324
In 2007 EPC Report

Reimao R, Lemmi H, Akiskal H, Cocke E. Obstructive sleep apnea treated with uvulopalatopharyngoplasty: a systematic follow-up study. Southern Medical Journal. 1986;79:1064-1066.
PMID 3749988
Surgical cohort <100/intervention

Ribeiro Franco CM, Cestaro BJ, Jaguaribe AM, Ataide L, Jr. Study into the use of continuous positive airway pressure in obstructive sleep apnoea-hypopnoea syndrome patients with daytime drowsiness. Revista Portuguesa de Pneumologia. 2009;15:215-226.
PMID 19280070
Not RCT (CPAP vs control)

Richard W, Kox D, den HC, van TH, de VN. One stage multilevel surgery (uvulopalatopharyngoplasty, hyoid suspension, radiofrequent ablation of the tongue base with/without genioglossus advancement), in obstructive sleep apnea syndrome. European Archives of Oto-Rhino-Laryngology. 2007;264:439-444.
PMID 17063353
Surgical cohort <100/intervention

Riley RW, Powell NB, Guilleminault C. Maxillofacial surgery and nasal CPAP. A comparison of treatment for obstructive sleep apnea syndrome. Chest. 1990;98:1421-1425.
PMID 2245683
Not comparative

Riley RW, Powell NB, Guilleminault C. Maxillary, mandibular, and hyoid advancement for treatment of obstructive sleep apnea: a review of 40 patients. Journal of Oral & Maxillofacial Surgery. 1990;48:20-26.
PMID 2294208
Surgical cohort <100/intervention

Riley RW, Powell NB, Guilleminault C. Obstructive sleep apnea and the hyoid: a revised surgical procedure. Otolaryngology - Head & Neck Surgery. 1994;111:717-721.
PMID 7991249
Surgical cohort <100/intervention

Riley RW, Powell NB, Guilleminault C. Maxillofacial surgery and obstructive sleep apnea: a review of 80 patients. Otolaryngology - Head & Neck Surgery. 1989;101:353-361.
PMID 2508006
Surgical cohort <100/intervention

Riley RW, Powell NB, Guilleminault C. Obstructive sleep apnea syndrome: a surgical protocol for dynamic upper airway reconstruction. Journal of Oral & Maxillofacial Surgery. 1993;51:742-747.
PMID 8509912
Surgical cohort No complication data

Riley RW, Powell NB, Li KK, Troell RJ, Guilleminault C. Surgery and obstructive sleep apnea: long-term clinical outcomes. Otolaryngology - Head & Neck Surgery. 2000;122:415-421.
PMID 10699820
Surgical cohort <100/intervention

Riley RW, Powell NB, Li KK, Weaver EM, Guilleminault C. An adjunctive method of radiofrequency volumetric tissue reduction of the tongue for OSAS. Otolaryngology - Head & Neck Surgery. 2003;129:37-42.
PMID 12869914
Surgical cohort <100/intervention

Ringqvist M, Walker-Engstrom ML, Tegelberg A, Ringqvist I. Dental and skeletal changes after 4 years of obstructive sleep apnea treatment with a mandibular advancement device: a prospective, randomized study. American Journal of Orthodontics & Dentofacial Orthopedics. 2003;124:53-60.
PMID 12867898
No outcomes of interest

Robbins J, Redline S, Ervin A, Walsleben JA, Ding J, Nieto FJ. Associations of sleep-disordered breathing and cerebral changes on MRI. Journal of Clinical Sleep Medicine. 2005;1:159-165.
PMID 17561631
No outcomes of interest

Robinson GV, Pepperell JC, Segal HC, Davies RJ, Stradling JR. Circulating cardiovascular risk factors in obstructive sleep apnoea: data from randomised controlled trials. Thorax. 2004;59:777-782.
PMID 15333855
No outcomes of interest

Robinson S, Lewis R, Norton A, McPeake S. Ultrasound-guided radiofrequency submucosal tongue-base excision for sleep apnoea: a preliminary report. Clinical Otolaryngology & Allied Sciences. 2003;28:341-345.
PMID 12871249
Surgical cohort <100/intervention

Roche N, Herer B, Roig C, Huchon G. Prospective testing of two models based on clinical and oximetric variables for prediction of obstructive sleep apnea. Chest. 2002;121:747-752.
PMID 11888955
In 2007 EPC Report

Rolfe I, Olson LG, Saunders NA. Long-term acceptance of continuous positive airway pressure in obstructive sleep apnea. American Review of Respiratory Disease. 1991;144:1130-1133.
PMID 1952444
Not multivariate (KQ 6, CPAP)

Roosli C, Schneider S, Hausler R. Long-term results and complications following uvulopalatopharyngoplasty in 116 consecutive patients. European Archives of Oto-Rhino-Laryngology. 2006;263:754-758.
PMID 16715302
Not OSA

Rosenberg R, Roach JM, Scharf M, Amato DA. A pilot study evaluating acute use of eszopiclone in patients with mild to moderate obstructive sleep apnea syndrome. Sleep Medicine. 2007;8:464-470.
PMID 17512799
Not drug of interest

Ross SD, Allen IE, Harrison KJ, Kvasz M, Connelly J, Sheinhait IA. Systematic review of the literature regarding the diagnosis of sleep apnea. Evidence Report: Technology Assessment (Summary) (1):1-4, 1998 Dec. 1998;1-4.
PMID 10510270
Systematic review etc published before 2000

Roth T, White D, Schmidt-Nowara W et al. Effects of armodafinil in the treatment of residual excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome: a 12-week, multicenter, double-blind, randomized, placebo-controlled study in nCPAP-adherent adults. Clinical Therapeutics. 2006;28:689-706.
PMID 16861091
Not drug of interest

Rubin AH, Eliaschar I, Joachim Z, Alroy G, Lavie P. Effects of nasal surgery and tonsillectomy on sleep apnea. Bulletin europeen de physiopathologie respiratoire. 1983;19:612-615.
PMID 6652269
Surgical cohort <100/intervention

Ryan CF, Love LL. Unpredictable results of laser assisted uvulopalatoplasty in the treatment of obstructive sleep apnoea. Thorax. 2000;55:399-404.
PMID 10770822
Surgical cohort <100/intervention

Ryan CM, Usui K, Floras JS, Bradley TD. Effect of continuous positive airway pressure on ventricular ectopy in heart failure patients with obstructive sleep apnoea. Thorax. 2005;60:781-785.
PMID 15994252
N<10/intervention

Ryan PJ, Hilton MF, Boldy DA et al. Validation of British Thoracic Society guidelines for the diagnosis of the sleep apnoea/hypopnoea syndrome: can polysomnography be avoided? Thorax. 1995;50:972-975.
PMID 8539678
In 2007 EPC Report

Saarelainen S, Himanen SL, Hasan J, Virkkala J, Koobi T. Whole-body impedance recording--a practical method for the diagnosis of sleep apnoea. Clinical Physiology & Functional Imaging. 2003;23:110-113.
PMID 12641606
In 2007 EPC Report

Sahlman J, Seppa J, Peltonen M, Pukkila M, Partinen M, Tuomilehto H. Surgical intervention represents a feasible option for patients with mild obstructive sleep apnoea. Acta Oto-Laryngologica. 2009;129:1266-1273.
PMID 19863323
No outcomes of interest

Sakurai S, Nishijima T, Takahashi S, Yamauchi K, Arihara Z, Takahashi K. Clinical significance of daytime plasma orexin-A-like immunoreactivity concentrations in patients with obstructive sleep apnea hypopnea syndrome. Respiration. 2004;71:380-384.
PMID 15316212
No analyses of interest

Saletu A, Anderer P, Parapatics S, Matthai C, Matejka M, Saletu B. Effects of a mandibular repositioning appliance on sleep structure, morning behavior and clinical symptomatology in patients with snoring and sleep-disordered breathing. Neuropsychobiology. 2007;55:184-193.
PMID 17700043
Not RCT (Oral vs Cx)

Saletu B, Oberndorfer S, Anderer P et al. Efficiency of continuous positive airway pressure versus theophylline therapy in sleep apnea: comparative sleep laboratory studies on objective and subjective sleep and awakening quality. Neuropsychobiology. 1999;39:151-159.
PMID 10087460
Not randomized

Salmi T, Telakivi T, Partinen M. Evaluation of automatic analysis of SCSB, airflow and oxygen saturation signals in patients with sleep related apneas. Chest. 1989;96:255-261.
PMID 2752807
No reference standard (overnight PSG)

Sampol G, Rodes G, Romero O, Jurado MJ, Lloberes P. Adherence to nCPAP in patients with coronary disease and sleep apnea without sleepiness. Respiratory Medicine. 2007;101:461-466.
PMID 16919928
Not multivariate (KQ 6, CPAP)

Sandberg O, Franklin KA, Bucht G, Eriksson S, Gustafson Y. Nasal continuous positive airway pressure in stroke patients with sleep apnoea: a randomized treatment study. European Respiratory Journal. 2001;18:630-634.
PMID 11716166
Population: stroke

Santos Junior JF, Abrahao M, Gregorio LC, Zonato AI, Gumieiro EH. Genioplasty for genioglossus muscle advancement in patients with obstructive sleep apnea-hypopnea syndrome and mandibular retrognathia. Revista Brasileira de Otorrinolaringologia. 2007;73:480-486.
PMID 17923918
Surgical cohort <100/intervention

Sato M, Suzuki M, Oshima T et al. Long-term follow-up of obstructive sleep apnea syndrome following surgery in children and adults. Tohoku Journal of Experimental Medicine. 2000;192:165-172.
PMID 11249146
Surgical cohort <100/intervention

Scharf MB, Brannen DE, McDannold MD, Berkowitz DV. Computerized adjustable versus fixed NCPAP treatment of obstructive sleep apnea. Sleep. 1996;19:491-496.
PMID 8865507
In-lab study

Scharf MB, Stover R, McDannold MD, Spinner O, Berkowitz DV, Conrad C. Outcome evaluation of long-term nasal continuous positive airway pressure therapy in obstructive sleep apnea. American Journal of Therapeutics. 1999;6:293-297.
PMID 11329112
N<500 (KQ 2)

Scharf SM, Garshick E, Brown R, Tishler PV, Tosteson T, McCarley R. Screening for subclinical sleep-disordered breathing. Sleep. 1990;13:344-353.
PMID 2267477
No validation set analysis

Seemann RP, DiToppa JC, Holm MA, Hanson J. Does laser-assisted uvulopalatoplasty work? An objective analysis using pre- and postoperative polysomnographic studies. Journal of Otolaryngology. 2001;30:212-215.
PMID 11771032
Surgical cohort <100/intervention

Senior BA, Rosenthal L, Lumley A, Gerhardstein R, Day R. Efficacy of uvulopalatopharyngoplasty in unselected patients with mild obstructive sleep apnea. Otolaryngology - Head & Neck Surgery. 2000;123:179-182.
PMID 10964287
Surgical cohort <100/intervention

Serafini FM, MacDowell AW, Rosemurgy AS, Strait T, Murr MM. Clinical predictors of sleep apnea in patients undergoing bariatric surgery. Obesity Surgery. 2001;11:28-31.
PMID 11361164
Verification bias

Sergi M, Rizzi M, Greco M et al. Validity of diurnal sleep recording performed by an ambulatory device in the diagnosis of obstructive sleep apnoea. Respiratory Medicine. 1998;92:216-220.
PMID 9616515
Not diagnostic test of interest

Series F, Marc I. Importance of sleep stage- and body position-dependence of sleep apnoea in determining benefits to auto-CPAP therapy. European Respiratory Journal. 2001;18:170-175.
PMID 11510790
Superceded by other article

Series F, Marc I, Cormier Y, La FJ. Utility of nocturnal home oximetry for case finding in patients with suspected sleep apnea hypopnea syndrome. Annals of Internal Medicine. 1993;119:449-453.
PMID 8357109
In 2007 EPC Report

Series F, Plante J, Lacasse Y. Reliability of home CPAP titration with different automatic CPAP devices. Respiratory Research. 2008;9:56.
PMID 18652688
Not comparison of different PAP types

Series F, St PS, Carrier G. Effects of surgical correction of nasal obstruction in the treatment of obstructive sleep apnea. American Review of Respiratory Disease. 1992;146:t-5.
PMID 1443882
Surgical cohort <100/intervention

Series F, St PS, Carrier G. Surgical correction of nasal obstruction in the treatment of mild sleep apnoea: importance of cephalometry in predicting outcome. Thorax. 1993;48:360-363.
PMID 8511733
Surgical cohort <100/intervention

Shalaby A, Atwood C, Hansen C et al. Feasibility of automated detection of advanced sleep disordered breathing utilizing an implantable pacemaker ventilation sensor. Pacing & Clinical Electrophysiology. 2006;29:1036-1043.
PMID 17038134
Not diagnostic test of interest

Shalaby AA, Atwood CW, Hansen C et al. Analysis of interaction of acute atrial overdrive pacing with sleep-related breathing disorder. American Journal of Cardiology. 2007;99:573-578.
PMID 17293206
In-lab study

Sharma S, Wali S, Pouliot Z, Peters M, Neufeld H, Kryger M. Treatment of obstructive sleep apnea with a self-titrating continuous positive airway pressure (CPAP) system. Sleep. 1996;19:497-501.
PMID 8865508
In-lab study

Shibata N, Nishimura T, Hasegawa K, Hattori C, Suzuki K. Influence of sleep respiratory disturbance on nocturnal blood pressure. Acta Oto-Laryngologica Supplement (550):32-5, 2003. 2003;32-35.
PMID 12737339
Surgical cohort <100/intervention

Shin SH, Ye MK, Kim CG. Modified uvulopalatopharyngoplasty for the treatment of obstructive sleep apnea-hypopnea syndrome: resection of the musculus uvulae. Otolaryngology - Head & Neck Surgery. 2009;140:924-929.
PMID 19467416
Surgical cohort <100/intervention

Shine NP, Lewis RH. Transpalatal advancement pharyngoplasty for obstructive sleep apnea syndrome: results and analysis of failures. Archives of Otolaryngology -- Head & Neck Surgery. 2009;135:434-438.
PMID 19451461
Surgical cohort <100/intervention

Shine NP, Lewis RH. The "Propeller" incision for transpalatal advancement pharyngoplasty: a new approach to reduce post-operative oronasal fistulae. Auris, Nasus, Larynx. 2008;35:397-400.
PMID 18029127
Surgical cohort <100/intervention

Simmons FB, Guilleminault C, Miles LE. The palatopharyngoplasty operation for snoring and sleep apnea: an interim report. Otolaryngology - Head & Neck Surgery. 1984;92:375-380.
PMID 6435056
Inadequate results reporting

Simmons FB, Guilleminault C, Silvestri R. Snoring, and some obstructive sleep apnea, can be cured by oropharyngeal surgery. Archives of Otolaryngology. 1983;109:503-507.
PMID 6870641
Surgical cohort <100/intervention

Simon-Tuval T, Reuveni H, Greenberg-Dotan S, Oksenberg A, Tal A, Tarasiuk A. Low socioeconomic status is a risk factor for CPAP acceptance among adult OSAS patients requiring treatment. Sleep. 2009;32:545-552.
PMID 19413149
No predictors of compliance

Sin DD, Mayers I, Man GC, Ghahary A, Pawluk L. Can continuous positive airway pressure therapy improve the general health status of patients with obstructive sleep apnea?: a clinical effectiveness study. Chest. 2002;122:1679-1685.
PMID 12426271
Not AHI prediction analysis

Singh A, Al-Reefy H, Hewitt R, Kotecha B. Evaluation of ApneaGraph in the diagnosis of sleep-related breathing disorders. European Archives of Oto-Rhino-Laryngology. 2008;265:1489-1494.
PMID 18463886
Test not used to diagnose SA

Sinha AM, Bauer A, Skobel EC, et al. Long-term effects of dynamic atrial overdrive pacing on sleep-related breathing disorders in pacemaker or cardioverter defibrillator recipients. Pacing & Clinical Electrophysiology. 2009; 32 Suppl 1:S219-22.
PMID 19250100
N<10/intervention (as analyzed)

Skatvedt O, Akre H, Godtlibsen OB. Nocturnal polysomnography with and without continuous pharyngeal and esophageal pressure measurements. Sleep. 1996;19:485-490.
PMID 8865506
Not portable test

Skatvedt O, Akre H, Godtlibsen OB. Continuous pressure measurements in the evaluation of patients for laser assisted uvulopalatoplasty. European Archives of Oto-Rhino-Laryngology. 1996;253:390-394.
PMID 8891481
Surgical cohort <100/intervention

Skomro RP, Cotton DJ, Gjevre JA et al. An empirical continuous positive airway pressure trial for suspected obstructive sleep apnea. Canadian Respiratory Journal. 2007;14:159-163.
PMID 17464380
KQ 6 Retrospective

Smatt Y, Ferri J. Retrospective study of 18 patients treated by maxillomandibular advancement with adjunctive procedures for obstructive sleep apnea syndrome. Journal of Craniofacial Surgery. 2005;16:770-777.
PMID 16192855
Surgical cohort <100/intervention

Smith CE, Dauz ER, Clements F et al. Telehealth services to improve nonadherence: A placebo-controlled study. Telemedicine Journal & E-Health. 2006;12:289-296.
PMID 16796496
N<10/intervention

Souter MA, Stevenson S, Sparks B, Drennan C. Upper airway surgery benefits patients with obstructive sleep apnoea who cannot tolerate nasal continuous positive airway pressure. Journal of Laryngology & Otology. 2004;118:270-274.
PMID 15117464
Surgical cohort <100/intervention

Stammnitz A, Jerrentrup A, Penzel T, Peter JH, Vogelmeier C, Becker HF. Automatic CPAP titration with different self-setting devices in patients with obstructive sleep apnoea. European Respiratory Journal. 2004;24:273-278.
PMID 15332397
In-lab study

Stevenson EW, Turner GT, Sutton FD, Doekel RC, Pegram V, Hernandez J. Prognostic significance of age and tonsillectomy in uvulopalatopharyngoplasty. Laryngoscope. 1990;100:820-823.
PMID 2381257
Surgical cohort No complication data

Steward DL. Effectiveness of multilevel (tongue and palate) radiofrequency tissue ablation for patients with obstructive sleep apnea syndrome. Laryngoscope. 2004;114:2073-2084.
PMID 15564825
Surgical cohort <100/intervention

Steward DL, Weaver EM, Woodson BT. Multilevel temperature-controlled radiofrequency for obstructive sleep apnea: extended follow-up. Otolaryngology - Head & Neck Surgery. 2005;132:630-635.
PMID 15806059
Surgical cohort <100/intervention

Steward DL, Weaver EM, Woodson BT. A comparison of radiofrequency treatment schemes for obstructive sleep apnea syndrome. Otolaryngology - Head & Neck Surgery. 2004;130:579-585.
PMID 15138424
Surgical cohort <100/intervention

Stoohs R, Guilleminault C. MESAM 4: an ambulatory device for the detection of patients at risk for obstructive sleep apnea syndrome (OSAS). Chest. 1992;101:1221-1227.
PMID 1582275
In 2007 EPC Report

Stoohs R, Guilleminault C. Investigations of an automatic screening device (MESAM) for obstructive sleep apnoea. European Respiratory Journal. 1990;3:823-829.
PMID 2261972
In 2007 EPC Report

Storre JH, Seuthe B, Fiechter R et al. Average volume-assured pressure support in obesity hypoventilation: A randomized crossover trial. Chest. 2006;130:815-821.
PMID 16963680
Not OSA

Stradling JR, Barbour C, Pitson DJ, Davies RJ. Automatic nasal continuous positive airway pressure titration in the laboratory: patient outcomes. Thorax. 1997;52:72-75.
PMID 9039254
Not comparison of different PAP types

Stradling JR, Davies RJ. Is more NCPAP better? Sleep. 2000;23:Suppl-3.
PMID 10893091
Superceded by other article

Stuck BA, Kopke J, Hormann K et al. Volumetric tissue reduction in radiofrequency surgery of the tongue base. Otolaryngology - Head & Neck Surgery. 2005;132:132-135.
PMID 15632924
Surgical cohort <100/intervention

Stuck BA, Maurer JT, Verse T, Hormann K. Tongue base reduction with temperature-controlled radiofrequency volumetric tissue reduction for treatment of obstructive sleep apnea syndrome. Acta Oto-Laryngologica. 2002;122:531-536.
PMID 12206264
Surgical cohort <100/intervention

Stuck BA, Starzak K, Hein G, Verse T, Hormann K, Maurer JT. Combined radiofrequency surgery of the tongue base and soft palate in obstructive sleep apnoea. Acta Oto-Laryngologica. 2004;124:827-832.
PMID 15370568
Surgical cohort <100/intervention

Su S, Baroody FM, Kohrman M, Suskind D. A comparison of polysomnography and a portable home sleep study in the diagnosis of obstructive sleep apnea syndrome. Otolaryngology - Head & Neck Surgery. 2004;131:844-850.
PMID 15577778
In 2007 EPC Report

Sulit L, Storfer-Isser A, Kirchner HL, Redline S. Differences in polysomnography predictors for hypertension and impaired glucose tolerance. Sleep. 2006;29:777-783.
PMID 16796216
N<500 (KQ 2)

Sun X, Yi H, Cao Z, Yin S. Reorganization of sleep architecture after surgery for OSAHS. Acta Oto-Laryngologica. 2008;128:1242-1247.
PMID 18607962
Surgical cohort <100/intervention

Suzuki M, Saigusa H, Kurogi R, Morita S, Ishizuka Y. Postoperative monitoring of esophageal pressure in patients with obstructive sleep apnea-hypopnea syndrome who have undergone tonsillectomy with uvulopalatopharyngoplasty. Annals of Otology, Rhinology & Laryngology. 2008;117:849-853.
PMID 19102132
Recovery room study

Svanborg E, Larsson H, Carlsson-Nordlander B, Pirskanen R. A limited diagnostic investigation for obstructive sleep apnea syndrome. Oximetry and static charge sensitive bed. Chest. 1990;98:1341-1345.
PMID 2245672
In 2007 EPC Report

Taha BH, Dempsey JA, Weber SM et al. Automated detection and classification of sleep-disordered breathing from conventional polysomnography data. Sleep. 1997;20:991-1001.
PMID 9456464
In 2007 EPC Report

Tarasiuk A, Greenberg-Dotan S, Simon T, Tal A, Oksenberg A, Reuveni H. Low socioeconomic status is a risk factor for cardiovascular disease among adult obstructive sleep apnea syndrome patients requiring treatment. Chest. 2006;130:766-773.
PMID 16963673
Cross-sectional

Tegelberg A, Walker-Engstrom ML, Vestling O, Wilhelmsson B. Two different degrees of mandibular advancement with a dental appliance in treatment of patients with mild to moderate obstructive sleep apnea. Acta Odontologica Scandinavica. 2003;61:356-362.
PMID 14960007
Surgical cohort <100/intervention

Terris DJ, Coker JF, Thomas AJ, Chavoya M. Preliminary findings from a prospective, randomized trial of two palatal operations for sleep-disordered breathing. Otolaryngology - Head & Neck Surgery. 2002;127:315-323.
PMID 12402011
Surgical cohort <100/intervention

Terris DJ, Kunda LD, Gonella MC. Minimally invasive tongue base surgery for obstructive sleep apnoea. Journal of Laryngology & Otology. 2002;116:716-721.
PMID 12437808
Surgical cohort <100/intervention

Thatcher GW, Maisel RH. The long-term evaluation of tracheostomy in the management of severe obstructive sleep apnea. Laryngoscope. 2003;113:201-204.
PMID 12567068
Surgical cohort <100/intervention

Thong JF, Pang KP. Clinical parameters in obstructive sleep apnea: are there any correlations? Journal of otolaryngology - head & neck surgery = Le Journal d'oto-rhino-laryngologie et de chirurgie cervico-faciale. 2008;37:894-900.
PMID 19128723
No analyses of interest

Tiihonen P, Hukkanen T, Tuomilehto H, Mervaala E, Toyras J. Evaluation of a novel ambulatory device for screening of sleep apnea. Telemedicine Journal & E-Health. 2009;15:283-289.
PMID 19382867
No outcomes of interest

Tiihonen P, Paakkonen A, Mervaala E, Hukkanen T, Toyras J. Design, construction and evaluation of an ambulatory device for screening of sleep apnea. Medical & Biological Engineering & Computing. 2009;47:59-66.
PMID 18985400
No outcomes of interest

Tryfon S, Stanopoulos I, Dascalopoulou E, Argyropoulou P, Bouros D, Mavrofridis E. Sleep apnea syndrome and diastolic blood pressure elevation during exercise. Respiration. 2004;71:499-504.
PMID 15467328
No analyses of interest

Tsai WH, Remmers JE, Brant R, Flemons WW, Davies J, Macarthur C. A decision rule for diagnostic testing in obstructive sleep apnea. American Journal of Respiratory & Critical Care Medicine. 2003;167:1427-1432.
PMID 12738600
In 2007 EPC Report

Tsara V, Kaimakamis E, Serasli E, Katsarou Z, Christaki P. Health related quality of life in Greek patients with sleep apnea-hypopnea syndrome treated with continuous positive airway pressure. Sleep Medicine. 2009;10:217-225.
PMID 18280789
Not randomized

Tschopp K, Thomaser EG, Staub C. Therapy of snoring and obstructive sleep apnea using the Velumount palatal device. Orl; Journal of Oto-Rhino-Laryngology & its Related Specialties. 2009;71:148-152.
PMID 19420980
Not RCT

Tsuiki S, Lowe AA, Almeida FR, Kawahata N, Fleetham JA. Effects of mandibular advancement on airway curvature and obstructive sleep apnoea severity. European Respiratory Journal. 2004;23:263-268.
PMID 14979501
Not comparative

Tugrul S, Akinci O, Ozcan PE et al. Effects of sustained inflation and postinflation positive end-expiratory pressure in acute respiratory distress syndrome: focusing on pulmonary and extrapulmonary forms. Critical Care Medicine. 2003;31:738-744.
PMID 12626977
Not OSA

Turkington PM, Sircar M, Saralaya D, Elliott MW. Time course of changes in driving simulator performance with and without treatment in patients with sleep apnoea hypopnoea syndrome. Thorax. 2004;59:56-59.
PMID 14694250
Not RCT (CPAP vs control)

Tvinnereim M, Cole P, Haight JS, Hoffstein V. Diagnostic airway pressure recording in sleep apnea syndrome. Acta Oto-Laryngologica. 1995;115:449-454.
PMID 7653270
Not diagnostic test of interest

Tvinnereim M, Mitic S, Hansen RK. Plasma radiofrequency preceded by pressure recording enhances success for treating sleep-related breathing disorders. Laryngoscope. 2007;117:731-736.
PMID 17415146
Surgical cohort <100/intervention

Ueda H, Almeida FR, Chen H, Lowe AA. Effect of 2 jaw exercises on occlusal function in patients with obstructive sleep apnea during oral appliance therapy: a randomized controlled trial. American Journal of Orthodontics & Dentofacial Orthopedics. 2009;135:430-437.
PMID 19361725
No outcomes of interest

Unterberg C, Luthje L, Szych J, Vollmann D, Hasenfuss G, Andreas S. Atrial overdrive pacing compared to CPAP in patients with obstructive sleep apnoea syndrome. European Heart Journal. 2005;26:2568-2575.
PMID 16126716
In-lab study

Valham F, Mooe T, Rabben T, Stenlund H, Wiklund U, Franklin KA. Increased risk of stroke in patients with coronary artery disease and sleep apnea: a 10-year follow-up. Circulation. 2008;118:955-960.
PMID 18697817
N<500 (KQ 2)

van den Broek E, Richard W, van TH, de VN. UPPP combined with radiofrequency thermotherapy of the tongue base for the treatment of obstructive sleep apnea syndrome. European Archives of Oto-Rhino-Laryngology. 2008;265:1361-1365.
PMID 18347810
Surgical cohort <100/intervention

Van Meerhaeghe A, Delpire P, Stenuit P, Kerkhofs M. Operating characteristics of the negative expiratory pressure technique in predicting obstructive sleep apnoea syndrome in snoring patients. Thorax. 2004;59:883-888.
PMID 15454655
Not a sleep monitor

Van Surrell C, Lemaigre D, Leroy M, Foucher A, Hagenmuller MP, Raffestin B. Evaluation of an ambulatory device, CID 102, in the diagnosis of obstructive sleep apnoea syndrome. European Respiratory Journal. 1995;8:795-800.
PMID 7656952
In 2007 EPC Report

Vazquez JC, Tsai WH, Flemons WW et al. Automated analysis of digital oximetry in the diagnosis of obstructive sleep apnoea. Thorax. 2000;55:302-307.
PMID 10722770
In 2007 EPC Report

Veale D, Chailleux E, Hoorelbeke-Ramon A et al. Mortality of sleep apnoea patients treated by nasal continuous positive airway pressure registered in the ANTADIR observatory. Association Nationale pour le Traitement A Domicile de l'Insuffisance Respiratoire chronique. European Respiratory Journal. 2000;15:326-331.
PMID 10706500
Sleep measures not tested

Vecchierini MF, Leger D, Laaban JP et al. Efficacy and compliance of mandibular repositioning device in obstructive sleep apnea syndrome under a patient-driven protocol of care. Sleep Medicine. 2008;9:762-769.
PMID 17980654
Not comparative

Ventura C, Oliveira AS, Dias R et al. The role of nocturnal oximetry in obstructive sleep apnoea-hypopnoea syndrome screening. Revista Portuguesa de Pneumologia. 2007;13:525-551.
PMID 17898912
Non-English

Verse T, Baisch A, Maurer JT, Stuck BA, Hormann K. Multilevel surgery for obstructive sleep apnea: short-term results. Otolaryngology - Head & Neck Surgery. 2006;134:571-577.
PMID 16564374
Surgical cohort <100/intervention

Verse T, Kroker BA, Pirsig W, Brosch S. Tonsillectomy as a treatment of obstructive sleep apnea in adults with tonsillar hypertrophy. Laryngoscope. 2000;110:1556-1559.
PMID 10983961
Surgical cohort <100/intervention

Verse T, Pirsig W, Junge-Hulsing B, Kroker B. Validation of the POLY-MESAM seven-channel ambulatory recording unit. Chest. 2000;117:1613-1618.
PMID 10858392
In 2007 EPC Report

Vicente E, Marin JM, Carrizo S, Naya MJ. Tongue-base suspension in conjunction with uvulopalatopharyngoplasty for treatment of severe obstructive sleep apnea: long-term follow-up results. Laryngoscope. 2006;116:1223-1227.
PMID 16826064
Surgical cohort <100/intervention

Vilaseca I, Morello A, Montserrat JM, Santamaria J, Iranzo A. Usefulness of uvulopalatopharyngoplasty with genioglossus and hyoid advancement in the treatment of obstructive sleep apnea. Archives of Otolaryngology -- Head & Neck Surgery. 2002;128:435-440.
PMID 11926921
Surgical cohort <100/intervention

Viner S, Szalai JP, Hoffstein V. Are history and physical examination a good screening test for sleep apnea? Annals of Internal Medicine. 1991;115:356-359.
PMID 1863025
No validation set analysis

Virkkula P, Bachour A, Hytonen M et al. Snoring is not relieved by nasal surgery despite improvement in nasal resistance. Chest. 2006;129:81-87.
PMID 16424416
Surgical cohort <100/intervention

von Kanel R, Loredo JS, Ancoli-Israel S, Dimsdale JE. Association between sleep apnea severity and blood coagulability: Treatment effects of nasal continuous positive airway pressure. Sleep & Breathing. 2006;10:139-146.
PMID 16565866
Superceded by other article

Waite PD, Wooten V, Lachner J, Guyette RF. Maxillomandibular advancement surgery in 23 patients with obstructive sleep apnea syndrome. Journal of Oral & Maxillofacial Surgery. 1989;47:1256-1261.
PMID 2585177
Surgical cohort <100/intervention

Waldhorn RE, Herrick TW, Nguyen MC, O'Donnell AE, Sodero J, Potolicchio SJ. Long-term compliance with nasal continuous positive airway pressure therapy of obstructive sleep apnea. Chest. 1990;97:33-38.
PMID 2403899
KQ 6 Retrospective

Walker EB, Frith RW, Harding DA, Cant BR. Uvulopalatopharyngoplasty in severe idiopathic obstructive sleep apnoea syndrome. Thorax. 1989;44:205-208.
PMID 2650012
Surgical cohort <100/intervention

Walker RP, Garrity T, Gopalsami C. Early polysomnographic findings and long-term subjective results in sleep apnea patients treated with laser-assisted uvulopalatoplasty. Laryngoscope. 1999;109:1438-1441.
PMID 10499051
Surgical cohort No complication data

Walker RP, Grigg-Damberger MM, Gopalsami C. Laser-assisted uvulopalatoplasty for the treatment of mild, moderate, and severe obstructive sleep apnea. Laryngoscope. 1999;109:79-85.
PMID 9917045
Surgical cohort <100/intervention

Walker RP, Grigg-Damberger MM, Gopalsami C. Uvulopalatopharyngoplasty versus laser-assisted uvulopalatoplasty for the treatment of obstructive sleep apnea. Laryngoscope. 1997;107:76-82.
PMID 9001269
Surgical cohort <100/intervention

Walker RP, Grigg-Damberger MM, Gopalsami C, Totten MC. Laser-assisted uvulopalatoplasty for snoring and obstructive sleep apnea: results in 170 patients. Laryngoscope. 1995;105:t-43.
PMID 7666729
Surgical cohort <100/intervention

Walker RP, Levine HL, Hopp ML, Greene D, Pang K. Palatal implants: a new approach for the treatment of obstructive sleep apnea. Otolaryngology - Head & Neck Surgery. 2006;135:549-554.
PMID 17011415
Surgical cohort <100/intervention

Wang X-H, Yuan Y-D, Wang B-F, Xiao L-Y, Pan W-S, Shi Y-Z. Auricular acupoint pressing therapy in the treatment of obstructive sleep apnea syndrome. Chinese Journal of Clinical Rehabilitation. 2006;10:165-167.
Cochrane CN-00641789
Superceded by later article

Wassmuth Z, Mair E, Loube D, Leonard D. Cautery-assisted palatal stiffening operation for the treatment of obstructive sleep apnea syndrome. Otolaryngology - Head & Neck Surgery. 2000;123:t-60.
PMID 10889482
Surgical cohort <100/intervention

Watson RK, Thompson AS. Treatment outcome of sleep apnea. Connecticut Medicine. 1992;56:125-129.
PMID 1582204
KQ 6 Retrospective

Weatherwax KJ, Lin X, Marzec ML, Malow BA. Obstructive sleep apnea in epilepsy patients: the Sleep Apnea scale of the Sleep Disorders Questionnaire (SA-SDQ) is a useful screening instrument for obstructive sleep apnea in a disease-specific population. Sleep Medicine. 2003;4:517-521.
PMID 14607345
No validation set analysis

Weaver EM, Kapur V, Yueh B. Polysomnography vs self-reported measures in patients with sleep apnea. Archives of Otolaryngology -- Head & Neck Surgery. 2004;130:453-458.
PMID 15096430
No analyses of interest

Westbrook PR, Levendowski DJ, Cvetinovic M et al. Description and validation of the apnea risk evaluation system: a novel method to diagnose sleep apnea-hypopnea in the home. Chest. 2005;128:2166-2175.
PMID 16236870
In 2007 EPC Report

White DP, Gibb TJ, Wall JM, Westbrook PR. Assessment of accuracy and analysis time of a novel device to monitor sleep and breathing in the home. Sleep. 1995;18:115-126.
PMID 7792491
In 2007 EPC Report

Whitelaw WA, Brant RF, Flemons WW. Clinical usefulness of home oximetry compared with polysomnography for assessment of sleep apnea. American Journal of Respiratory & Critical Care Medicine. 2005;171:188-193.
PMID 15486338
In 2007 EPC Report

Whittle AT, Finch SP, Mortimore IL, Mackay TW, Douglas NJ. Use of home sleep studies for diagnosis of the sleep apnoea/hypopnoea syndrome. Thorax. 1997;52:1068-1073.
PMID 9516901
In 2007 EPC Report

Wiest GH, Harsch IA, Fuchs FS et al. Initiation of CPAP therapy for OSA: does prophylactic humidification during CPAP pressure titration improve initial patient acceptance and comfort? Respiration. 2002;69:406-412.
PMID 12232447
In-lab study

Williams AJ, Yu G, Santiago S, Stein M. Screening for sleep apnea using pulse oximetry and a clinical score. Chest. 1991;100:631-635.
PMID 1889245
In 2007 EPC Report

Williams SC, Rogers NL, Marshall NS, Leung S, Starmer GA, Grunstein RR. The effect of modafinil following acute CPAP withdrawal: a preliminary study. Sleep & Breathing. 2008;12:359-364.
PMID 18311493
In-lab study

Wiltshire N, Kendrick AH, Catterall JR. Home oximetry studies for diagnosis of sleep apnea/hypopnea syndrome: limitation of memory storage capabilities. Chest. 2001;120:384-389.
PMID 11502633
In 2007 EPC Report

Wolfe L, Massie CA, Mutlu GM, Gordon N, Casal E. Comparative efficacy of two expiratory pressure reduction systems in the treatment of obstructive sleep apnea. Chest. 2007;132:665b, 2007.
Cochrane CN-00642710
Not peer reviewed

Woodson BT. A tongue suspension suture for obstructive sleep apnea and snorers. Otolaryngology - Head & Neck Surgery. 2001;124:297-303.
PMID 11240995
Surgical cohort <100/intervention

Woodson BT, Conley SF. Prediction of uvulopalatopharyngoplasty response using cephalometric radiographs. American Journal of Otolaryngology. 1997;18:179-184.
PMID 9164620
Surgical cohort <100/intervention

Woodson BT, Derowe A, Hawke M et al. Pharyngeal suspension suture with repose bone screw for obstructive sleep apnea. Otolaryngology - Head & Neck Surgery. 2000;122:395-401.
PMID 10699817
Surgical cohort <100/intervention

Woodson BT, Fujita S. Clinical experience with lingualplasty as part of the treatment of severe obstructive sleep apnea. Otolaryngology - Head & Neck Surgery. 1992;107:40-48.
PMID 1528601
Surgical cohort <100/intervention

Woodson BT, Robinson S, Lim HJ. Transpalatal advancement pharyngoplasty outcomes compared with uvulopalatopharygoplasty. Otolaryngology - Head & Neck Surgery. 2005;133:211-217.
PMID 16087017
Surgical cohort <100/intervention

Wright J, Johns R, Watt I, Melville A, Sheldon T. Health effects of obstructive sleep apnoea and the effectiveness of continuous positive airways pressure: a systematic review of the research evidence. BMJ. 1997;314:851-860.
PMID 9093094
Systematic review etc published before 2000

Yamadera W. Improvement in excessive daytime sleepiness after surgical treatment for obstructive sleep apnea syndrome. Psychiatry & Clinical Neurosciences. 1995;49:213-221.
PMID 9179940
Surgical cohort <100/intervention

Yamashiro Y, Kryger MH. Nocturnal oximetry: is it a screening tool for sleep disorders? Sleep. 1995;18:167-171.
PMID 7610312
In 2007 EPC Report

Yi B, Zhang XE, Zhang ZK, Wang X, Huang XZ. Orthognathic surgery correction of mandibular hypoplasia accompanying obstructive sleep apnea syndrome. Chinese Journal of Dental Research. 1999;2:59-64.
PMID 10863419
Surgical cohort <100/intervention

Yi HL, Yin SK, Zhang YJ et al. Z-palatopharyngoplasty for obstructive sleep apnea/hypopnea syndrome. Otolaryngology - Head & Neck Surgery. 2009;140:640-645.
PMID 19393403
Surgical cohort <100/intervention

Yin M, Miyazaki S, Ishikawa K. Evaluation of type 3 portable monitoring in unattended home setting for suspected sleep apnea: factors that may affect its accuracy. Otolaryngology - Head & Neck Surgery. 2006;134:204-209.
PMID 16455365
In 2007 EPC Report

Yonekura A, Kawakatsu K, Suzuki K, Nishimura T. Laser midline glossectomy and lingual tonsillectomy as treatments for sleep apnea syndrome. Acta Oto-Laryngologica Supplement (550):56-8, 2003. 2003;56-58.
PMID 12737344
Surgical cohort <100/intervention

Young T, Blustein J, Finn L, Palta M. Sleep-disordered breathing and motor vehicle accidents in a population-based sample of employed adults. Sleep. 1997;20:608-613.
PMID 9351127
Cross-sectional

Young T, Palta M, Dempsey J, Peppard PE, Nieto FJ, Hla KM. Burden of sleep apnea: rationale, design, and major findings of the Wisconsin Sleep Cohort study. WMJ. 2009;108:246-249.
PMID 19743755
Review

Zamarron C, Gude F, Barcala J, Rodriguez JR, Romero PV. Utility of oxygen saturation and heart rate spectral analysis obtained from pulse oximetric recordings in the diagnosis of sleep apnea syndrome. Chest. 2003;123:1567-1576.
PMID 12740275
In 2007 EPC Report

Zamarron C, Pichel F, Romero PV. Coherence between oxygen saturation and heart rate obtained from pulse oximetric recordings in obstructive sleep apnoea. Physiological Measurement. 2005;26:799-810.
PMID 16088069
Duplicate of previous study

Zamarron C, Romero PV, Gude F, Amaro A, Rodriguez JR. Screening of obstructive sleep apnoea: heart rate spectral analysis of nocturnal pulse oximetric recording. Respiratory Medicine. 2001;95:759-765.
PMID 11575898
In 2007 EPC Report

Zamarron C, Romero PV, Rodriguez JR, Gude F. Oximetry spectral analysis in the diagnosis of obstructive sleep apnoea. Clinical Science. 1999;97:467-473.
PMID 10491347
In 2007 EPC Report

Zohar Y, Finkelstein Y, Strauss M, Shvilli Y. Surgical treatment of obstructive sleep apnea. Technical variations. Archives of Otolaryngology -- Head & Neck Surgery. 1993;119:1023-1029.
PMID 8357584
Surgical cohort <100/intervention

Zohar Y, Finkelstein Y, Talmi YP, Bar-Ilan Y. Uvulopalatopharyngoplasty: evaluation of postoperative complications, sequelae, and results. Laryngoscope. 1991;101:t-9.
PMID 2062161
Surgical cohort <100/intervention

Zohar Y, Talmi YP, Frenkel H et al. Cardiac function in obstructive sleep apnea patients following uvulopalatopharyngoplasty. Otolaryngology - Head & Neck Surgery. 1992;107:390-394.
PMID 1383911
Surgical cohort <100/intervention

Zonato AI, Bittencourt LR, Martinho FL, Gregorio LC, Tufik S. Upper airway surgery: the effect on nasal continuous positive airway pressure titration on obstructive sleep apnea patients. European Archives of Oto-Rhino-Laryngology. 2006;263:481-486.
PMID 16450157
Surgical cohort <100/intervention

Zorick F, Roehrs T, Conway W, Fujita S, Wittig R, Roth T. Effects of uvulopalatopharyngoplasty on the daytime sleepiness associated with sleep apnea syndrome. Bulletin europeen de physiopathologie respiratoire. 1983;19:600-603.
PMID 6652267
Surgical cohort <100/intervention

Zou D, Grote L, Peker Y, Lindblad U, Hedner J. Validation a portable monitoring device for sleep apnea diagnosis in a population based cohort using synchronized home polysomnography. Sleep. 2006;29:367-374.
PMID 16553023
In 2007 EPC Report

Zucconi M, Ferini-Strambi L, Castronovo V, Oldani A, Smirne S. An unattended device for sleep-related breathing disorders: validation study in suspected obstructive sleep apnoea syndrome. European Respiratory Journal. 1996;9:1251-1256.
PMID 8804946
In 2007 EPC Report

Key Question 1
Portable v PSG

A. Source and Extractor

Author, Year	Abraham, 2006			**Reference test**	PSG
PMID	17033271	**RefID**	3004	**Index test 1**	Home Cardiorespiratory system
Key Question(s)	KQ 1 (Portable)			**Index test 2**	
Extractor	EMB			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Heart Failure	Consecutive	Yes	nd	US & UK	nd	Yes
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Stable NYHA class III systolic heart failure (EF≤35%) Seen in outpatient cardiac clinic 19-90 y	Change of heart failure medication (except diuretics) x 2 wk or expected Cerebrovascular, neuromuscular, or terminal disease or COPD Dermatologic condition MI w/in 6 wk
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	**Manufacturer (Location)**	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
ALICE 3 or 4 Sandman Embla	Respironics (Murrysville, PA) Mallinckrodt (Phillipsburg, NJ) ResMed (Poway, CA)	Sleep lab	Manually	Rechtschaffen & Kales	Total sleep time
Definition of Apnea:			Absence of airflow ≥10 sec (with or without rib excursion; thus combined central and obstructive apnea)		
Definition of Hypopnea:			nd		
Thresholds used:			**Definitions:**		
RDI ≥5, 10, 15					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	ClearPath System Nx-301	Nexan Inc (Alpharetta, GA)	• Pulse oximeter • 2-lead ECG	No	Sleep lab (& home, but nd)	Simultaneous (≤3 nights apart)	Manual (implied)	nd (implied the same as PSG)	Total recording time	RDI
Definition of Apnea:				Respiratory event: 3% O2 desaturation						
Definition of Hypopnea:				NA						
Thresholds used:				**Definitions:**						
RDI ≥15 = clinically significant SDB										
Comments:	Patients trained on how to apply and manage system at home									

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
50 (50)	68%	55.5 (23-78)	White 88% AA 10% NatAm 2%	32.6 (19-48)	nd 120/74 (88-160/60-94)	AFib/Flutter 10%	100% heart failure (NYHA III) EF 26±14%
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	Yes Congestive Heart Failure

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	10.6±4.4 (1-23) n=46	nd	nd	Minnesota Living with Heart Failure QoL 61.7±21.6 (20-102) “consistent with a NYHA class III HF population)

* Mean±SD. If median, SE, range, IQR, or other, specify these.

Rector TS, Kubo SH, Cohn JN. Validity of the Minnesota Living with Heart Failure questionnaire as a measure of therapeutic response to enalapril or placebo. Am J Cardiol. 1993;71:1106–1107.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI ≥5 n/N (%)	AHI ≥10 n/N (%)	AHI ≥15 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
(0-92.3)	34/44 (77%)	29/44 (66%)	24/44 (54%)		13/44 (29%)	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	TP	FN	TN	FP	Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
Portable (lab) vs PSG	RDI≥5	RDI≥5	20	1	12	11	92%		52%			
	RDI≥10	RDI≥10	15	2	17	10	88%		63%			
	RDI≥15	RDI≥15	8	4	25	7	67%		78%			

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	For the lab index test, there was a statistically significant difference in effects between sites. One of 4 sites was significantly different than others in ANCOVA controlling for TST RDI, site, and reader. The one site had substantially worse accuracy than other 3 sites. Home portable monitor results not reported. Only that it performed almost as well as in the lab.

H. Subgroup Analysis (If present)

If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

n/N	% Dropout	Reasons
1/50	2%	Could not tolerate PSG
6/50	12%	Invalid lab index test 3 technical errors 1 pacemaker interference 1 patient withdrawal 1 could not tolerate PSG (same as above)
(2/49)	4% (of 50)	Invalid home index test 2 technical errors

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	Yes Significant (and substantial) difference among sites Home test data not presented
Adequate description of tests (Yes/No, if no describe)	No. Unclear criteria
Clear description of population studied (Yes/No, if no describe)	Yes
Data loss / not analyzed (%)	12%
Overall Quality (A/B/C)	B

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).

Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Ayappa 2008			**Reference test**	PSG
PMID	18350959	**RefID**	3050	**Index test 1**	Apnea Risk Evaluation System (ARES™) Unicorder in-Lab
Key Question(s)	1 (Dx Portable)			**Index test 2**	Apnea Risk Evaluation System (ARES™) Unicorder at-home
Extractor	DM			**Comments**	Data from 22 healthy subjects were reported but only data from suspected SDB patients was extracted

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Patients referred to a specialized center	Consecutive patients	N	Apr 2005 – Aug 2006	USA	Industry and Govt.	Yes
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Sleep complaints suggestive of SDB	Inability to read English, Inability to wear devices on the forehead
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	**Manufacturer (Location)**	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
PSG	Nasal cannula/ pressure transducer system (Pro-Tech PTAF2, Mukilteo, WA); Piezoelectric strain gauges (EPMSystems, Inc, Midlothian, VA.)	Sleep lab	Manual	Rechtschaffen and Kales criteria	Total Sleep time
Definition of Apnea:			Airflow cessation for 10 secs		
Definition of Hypopnea:			Hypopnea 4% hypopnea (airflow < 50%) with ≥ 3.5 %-age desaturation and 1% resaturation Hypopnea1% hypopneas with ≥ 1% desaturation and resaturation and at least 1 surrogate arousal indicator (head movement, changes in snoring, or changes in pulse rate)		
Thresholds used:			**Definitions:**		
AHI4% ≥ 5, ≥ 10, ≥ 15 RDI >10, ≥ 15					
Comments: Cut-offs used to define OSA not reported					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	Apnea Risk Evaluation System (ARES) Unicorder	Advanced Brain Monitoring (nd)	• O2 sat & pulse rate • Air flow • Snoring • Head movement Actigraphy	Y	Sleep lab & Home	At-home – 2 weeks before PSG, In-lab: simultaneous with PSG	automated with manual review		Both Total sleep time (AHI), Total recording time (RDI)	AHI and RDI
Definition of Apnea:				Same as PSG						
Definition of Hypopnea:				Same as PSG						
Thresholds used:				**Definitions:**						
AHI4% ≥ 5, ≥ 10, ≥ 15 AHI1% >10, ≥ 15 (analog of RDI from PSG)										
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
80 (73)	78%	46 (26-74)	nd	30 (21-70)	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	**Bed partner, %**	**Craniofacial abnormalities/ congenital abnormalities**	**Epworth**	**MSLT**	**Other Clinical symptoms, % (specify)**	**Other characteristics (specify)**
nd	nd	nd	8.8	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	**AHI ≥5 n/N (%)**	**AHI ≥10 n/N (%)**	**AHI ≥15 n/N (%)**	**AHI ≥20 n/N (%)**	**AHI ≥30 n/N (%)**	
nd	nd	nd	nd	nd	nd	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		**N Enrolled**	**N Analyzed**	**Concordance Metric***	**Mean Bias (95% CI)**	**Other Text Description (eg, of bias)**
Index	**Ref**					
ARES in-Lab (AHI4%)	PSG (AHI4%)	77	73	Bland Altman plot	0.7 /h (-1.2, 2.6)	Figure 1 shows all subjects and volunteers, value for SDB subjects only from text

ARES in-Lab (AHI1%)	PSG (RDI)	77	73	Bland Altman plot	3.3 /h (0.8, 5.9)	Figure 2 shows all subjects and volunteers, value for SDB subjects only from text
ARES at-home (AHI4%)	PSG (AHI4%)	77	67	Bland Altman plot	5.2 /h (1.0, 9.4)	Figure 2 shows all subjects and volunteers, value for SDB subjects only from text
ARES at-home (AHI1%)	PSG (RDI)	77	67	Bland Altman plot	10.3 /h (5.9, 14.6)	Figure 2 shows all subjects and volunteers, value for SDB subjects only from text

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

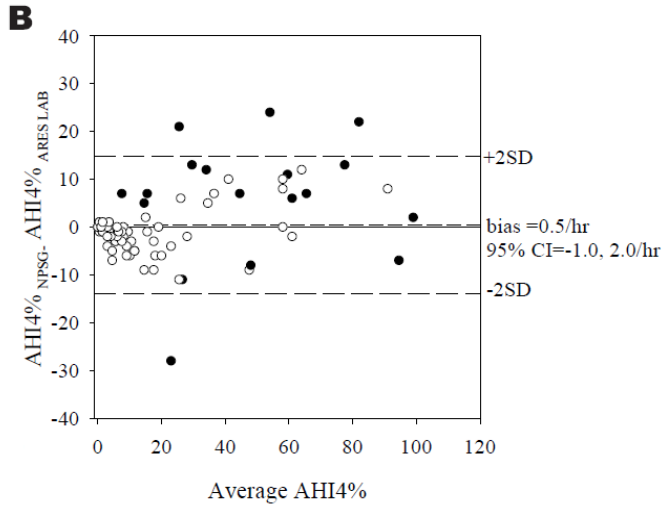


Figure 1

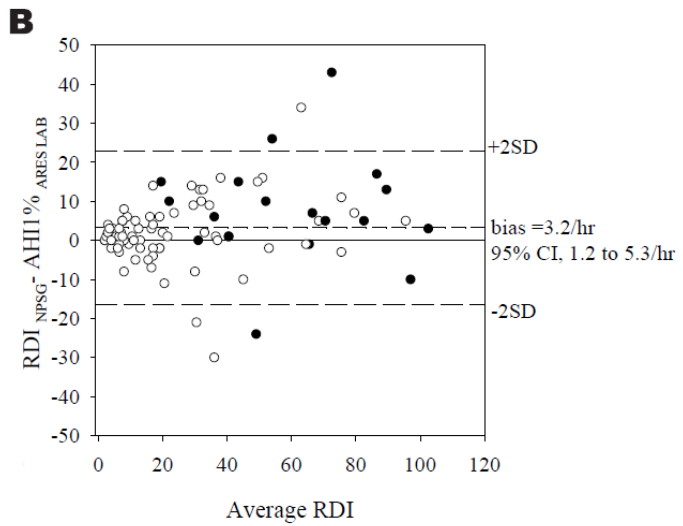

B
50
40
30
20
10
0
-10
-20
-30
-40
-50
RDI NPSG - AHI 1% ARES LAB
+2SD
bias =3.2/hr
95% CI, 1.2 to 5.3/hr
-2SD
0
20
40
60
80
100
120
Average RDI

Figure 2

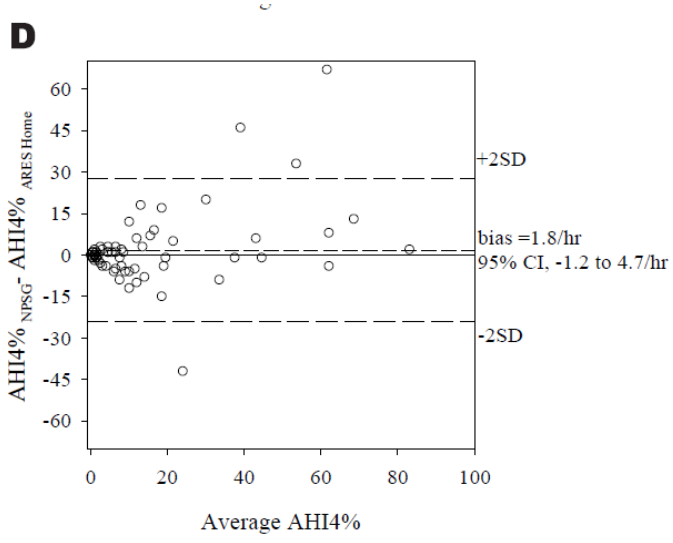


Figure 3

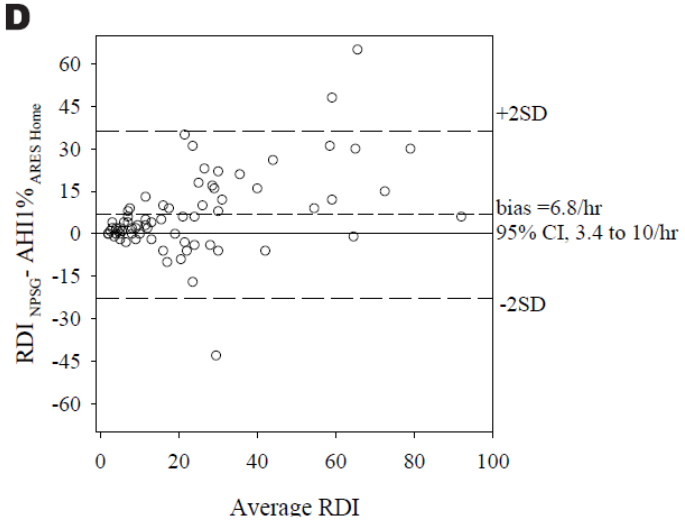


Figure 4

G2. Results: Diagnostic performances (Yellow highlighting indicates that values were calculated from reported data)

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
ARES in-Lab vs PSG	AHI4% >5	AHI4% >5	51	1	16	5	0.98	0.88 - 1	0.76	0.52 - 0.91		
ARES in-Lab vs PSG	AHI4% >5	AHI4% >10	36	1	28	8	0.97	0.84 - 1	0.78	0.6 - 0.89		
ARES in-Lab vs PSG	AHI4% >5	AHI4% >15	31	3	36	3	0.91	0.75 - 0.98	0.92	0.78 - 0.98		
ARES in-Lab vs PSG	AHI1% >10	RDI >10	59	3	8	3	0.95	0.86 - 0.99	0.73	0.39 - 0.93		
ARES in-Lab vs PSG	AHI1% ≥15	RDI ≥15	51	3	17	2	0.94	0.84 - 0.99	0.89	0.65 - 0.98		
ARES at-home vs PSG	AHI4% >5	AHI4% >5	45	4	12	6	0.92	0.8 - 0.97	0.67	0.41 - 0.86		
ARES at-home vs PSG	AHI4% >5	AHI4% >10	31	4	23	9	0.89	0.72 - 0.96	0.72	0.53 - 0.86		
ARES at-home vs PSG	AHI4% >5	AHI4% >15	25	8	28	6	0.76	0.57 - 0.88	0.82	0.65 - 0.93		
ARES at-home vs PSG	AHI1% >10	RDI >10	52	6	7	2	0.9	0.78 - 0.96	0.78	0.4 - 0.96		
ARES at-home vs PSG	AHI1% ≥15	RDI ≥15	42	8	14	3	0.84	0.71 - 0.93	0.81	0.54 - 0.95		

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)

If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
67/77	13%	Reasons not specific for SDB patients (for the whole study): Unicorder not started or tolerated, lack of time, PSG failure (totally, 16% (16/102) drop out rate in overall study)

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	No
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	No (Baseline AHI for 77 subjects not reported, only reported separately for subgroups with data on complete ARES in-lab and at-home, respectively)
Data loss / not analyzed (%)	13%
Overall Quality (A/B/C)	A

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).

Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Chen 2009			**Reference test**	PSG
PMID	19052790	**RefID**	7162	**Index test 1**	ApneaLink with default AASM criteria
Key Question(s)	1 (Dx Portable)			**Index test 2**	ApneaLink with Sandman Sleep Diagnostic System setting (Nellcor Puritan Bennett, Pleasanton, CA, USA)
Extractor	DM			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Suspected sleep disordered breathing patients	Consecutive	No	nd	Canada	nd	nd (Yes for Ref test readers blinded to index test results)
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Suspected sleep disordered breathing	Patients coming for follow up studies for any therapy; patients undergoing split-night studies
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
PSG	nd	Sleep lab	Manual	American Academy of Sleep Medicine (AASM) criteria	Total sleep time
Definition of Apnea:			American Academy of Sleep Medicine (AASM) criteria		
Definition of Hypopnea:			American Academy of Sleep Medicine (AASM) criteria		
Thresholds used:			**Definitions:**		
<5, <10, <15, <20, <30			OSA: AHI≥ 5		
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	ApneaLink	ResMed Corporation (Poway, CA, USA)	• Nasal flow • Built-in pressure sensor	N	Sleep lab	Simultaneous with PSG	Automatic	AASM criteria (as for PSG)	Total recording time	RDI
Definition of Apnea:			Defalut AASM setting: Reduction of inspiratory airflow by 80% to 100% over 10 secs (max 80 ss) Sandman Sleep Diagnostic System setting: 85% or more reduction of normal flow that lasts (max 100 s)							
Definition of Hypopnea:			Defalut AASM setting: Reduction of tidal breathing of 50% from baseline tidal breathing lasting (Max100 secs) Sandman Sleep Diagnostic System setting: 40% reduction of normal flow lasting 10 s (max 120 s)							
Thresholds used:			**Definitions:**							
<5, <10, <15, <20, <30										
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
54 (50)	64%	49 ± 13 yrs	nd	32.2 ± 7.2	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	nd	nd	nd	

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI ≥5 n/N (%)	AHI ≥10 n/N (%)	AHI ≥15 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
30.0 ± 25.8 events/hour (0.6 – 86.3)	44/50 (88%)	nd	32/50 (65%)	nd	17/50 (34%)	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Mean difference (95% LOA)	Other Text Description (eg, of bias)
Index	**Ref**					
ApneaLink (AASM criteria)	PSG	54	50	Bland Altman plot	-6.3 (-25.5, 12.9)	Figure 1
ApneaLink (Sandman setting)	PSG	54	50	Bland Altman plot	-0.5 (-17.9, 16.9)	Figure 2

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

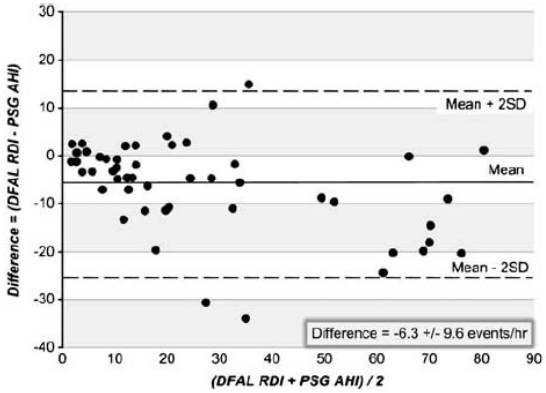
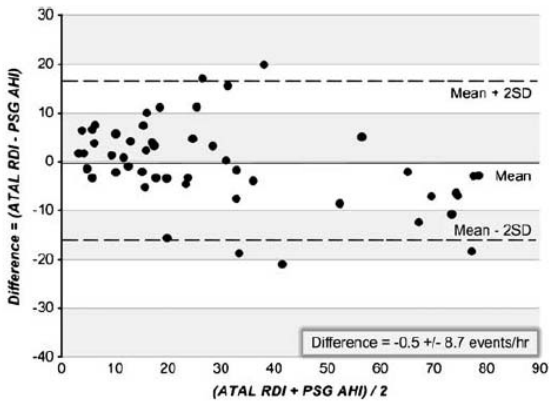


Fig. 2 Bland–Altman Plot with limits of agreement. *Left* The differences between DFAL-RDI (default) and PSG-AHI plotted against their mean for each subject. *Right* The differences between

Figure 1



ATAL-RDI (alternative) and PSG-AHI plotted against their mean for each subject

Figure 2

G2. Results: Diagnostic performances (Yellow highlighting indicates that values were calculated from reported data)

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
ApneaLink (AASM criteria) vs PSG	<5	<5	6	0	29	15	97.7		66.7		0.964	
	<10	<10					95.0		90.0		0.978	
	<15	<15	16	2	28	4	87.5		88.9		0.944	
	<20	<20					88.0		88.0		0.944	
	<30	<30	29	4	16	1	88.2		93.9		0.954	
ApneaLink (Sandman setting) vs PSG	<5	<5	6	0	37	7	93.2		83.3		0.951	
	<10	<10					97.5		90.0		0.983	
	<15	<15	16	2	25	7	90.6		77.8		0.944	
	<20	<20					92.0		84.0		0.934	
	<30	<30	31	2	14	3	94.1		81.8		0.955	

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)

If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
4/50	8%	Declined to take part (1), short records due to technical problems (3)

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	Yes
Data loss / not analyzed (%)	8%
Overall Quality (A/B/C)	A

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).

Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Clark 2009			**Reference test**	PSG
PMID	19222876	**RefID**	186	**Index test 1**	ApneaLink
Key Question(s)	1 (Dx portable)			**Index test 2**	
Extractor	DM			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Patients suspected of having sleep disordered breathing	Consecutive	No	nd	UK	nd	
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	None	None
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	**Manufacturer (Location)**	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
Embletta	ResMed (Sydney, New South Wales, Australia)	Home	automated with manual review	Yes	Total Sleep time
Definition of Apnea:			AASM criteria		
Definition of Hypopnea:			AASM criteria		
Thresholds used:			**Definitions:**		
≥ 15			CPAP Tx needed: AHI ≥ 15		
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	ApneaLink	ResMed (Sydney, New South Wales, Australia)	• Flow: nasal cannula • High-sensitivity pressure sensor,	N	Home	Simultaneous with PSG	automated with manual review	Same as for PSG	Total recording time (RDI)	RDI
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
67 (55)	76%	51 ± 11	nd	35.0 ± 6.9	Systolic BP: 142.5 ± 18.3 Diastolic BP: 87.6 ± 11.3	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	**Bed partner, %**	**Craniofacial abnormalities/ congenital abnormalities**	**Epworth**	**MSLT**	**Other Clinical symptoms, % (specify)**	**Other characteristics (specify)**
nd	nd	nd	13.3 ± 5.2	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	**AHI ≥5 n/N (%)**	**AHI ≥10 n/N (%)**	**AHI ≥15 n/N (%)**	**AHI ≥20 n/N (%)**	**AHI ≥30 n/N (%)**	
21.5 (0 - 87)			25/55 (45%)			

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					
ApneaLink	PSG	54	50	Bland Altman plot	nd	B-A plot in graphical form (Figure 2, pg 3) – data not interpretable

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances (Yellow highlighting indicates that values were calculated from reported data)

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
ApneaLink vs PSG	≥ 15	≥ 15	23	2	29	1	92		96.7			

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)

If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
12/67	18%	ApneaLink recording was unsatisfactory due to failure to activate device (8) and also due to disconnection of nasal cannula (4)

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	Yes (B-A plots are not interpretable with additional information)
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	No
Data loss / not analyzed (%)	18%
Overall Quality (A/B/C)	B

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).

Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	de Almeida 2006			**Reference test**	PSG
PMID	16502297	**RefID**	3209	**Index test 1**	Sleep Check
Key Question(s)	1 (Dx Portable)			**Index test 2**	
Extractor	DM			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Patients referred to sleep center for suspected sleep-related breathing disorders	Consecutive	No	nd	Canada	Government, Foundation, Device provided by manufacturer	Yes (Automatic algorithm)
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	prospective	Patients referred to sleep center for suspected sleep-related breathing disorders; not undergone previous treatment	Patients referred for split night study; patients referred for follow –up of any types of therapy
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
PSG	Sandman Sleep Diagnostic System (nd)	sleep lab	Manual	Rechtschaffen and Kales, 1977	Total sleep time
Definition of Apnea:			AASM, 1999		
Definition of Hypopnea:			AASM, 1999		
Thresholds used:			**Definitions:**		
> 5, >10, >15, >20					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	Sleep Check	IM Systems Inc. (Baltimore)	• Airflow through oro-nasal cannula	N	Sleep lab	Simultaneous with PSG	Automatic	Same as PSG	Total recording time	RDI
Definition of Apnea:				Same as PSG						
Definition of Hypopnea:				Same as PSG						
Thresholds used:				**Definitions:**						
>5, >10, >15, >20										
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
35 (30)	77%	44 ± 12	nd	31.1 ± 8	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	nd	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI ≥5 n/N (%)	AHI ≥10 n/N (%)	AHI ≥15 n/N (%)	AHI ≥20 n/N (%)	AHI >30 n/N (%)	
18.6 ± 22.1	22/30 (73.3)		12/30 (40%)		6/30 (20%)	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	mean difference (95% LOA after adjusting for this mean difference)	Other Text Description (eg, of bias)
Index	Ref					
SleepCheck	PSG	35	30	Bland Altman plot	27.4 (-26.6, 26.6) – if mean difference were not adjusted for in the 95% LOA, new values = (0.8, 54)	

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

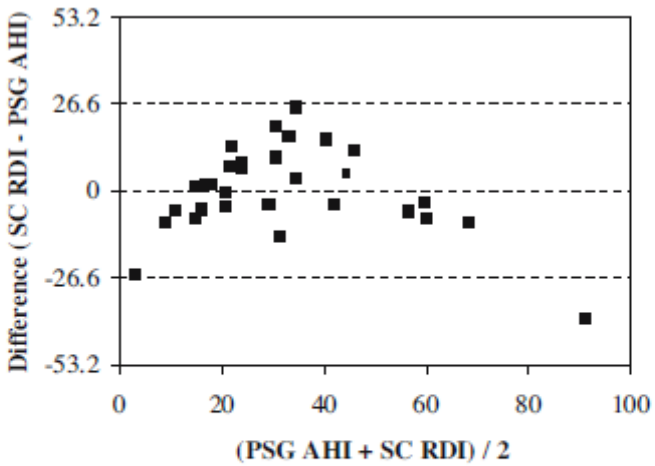


Fig. 2 Bland–Altman plot illustrating the agreement between SleepCheck (*SC*) RDI and PSG AHI after adjusting for the systematic overscoring bias of 27.4. Limits of agreement were 26.6 and −26.6

G2. Results: Diagnostic performances (Yellow highlighting indicates that values were calculated from reported data)

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
SleepCheck vs PSG	>5	>5	19	3	6	2	0.864		0.75		0.886	
	>10	>10					0.857		0.875		0.915	
	>15	>15	10	2	15	3	0.835		0.835		0.898	
	>20	>20					0.889		0.810		0.910	

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
5/30	16%	Did not agree to participate

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	No (co-morbidities not described, no reasons given for 16% not analyzed, small sample size)
Data loss / not analyzed (%)	16%
Overall Quality (A/B/C)	B

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the

limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Erman, 2007			**Reference test**	PSG
PMID	17694728	**RefID**	14219	**Index test 1**	ApneaLink (nasal airflow)
Key Question(s)	1 (Dx Portable)			**Index test 2**	
Extractor	EMB			**Comments**	Device cannot distinguish between central sleep apnea and OSA; data on ApneaLink testing done at home was included but it was only compared to ApneaLink in the lab, not with PSG, hence it was not included

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
T2DM clinic Not specifically people with suspicion of SA	Consecutive	No	nd	US	Industry	Yes (Software analyzes data)

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	T2DM	Known SA PAP or O2 use Rx that can affect sleep Serious respiratory or cardiac condition
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
Grass Telefactor system (Grass Telefactor, West Warwick, RI)	Sleep lab	Manual	Rechtsschaffen & Kales criteria	Total Sleep Time
Definition of Apnea:		Per AASM 1999		
Definition of Hypopnea:		Per AASM 1999		
Thresholds used:		**Definitions:**		
AHI ≥5, 10, 15, 20				

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	**Name (equipment)**	**Channels[A]**	**Actigraphy (Y/N)**	**Setting[B]**	**Timing[C]**	**Scoring (manual, automated, automated with manual review)**	**Scoring system, if not identical that for PSG**	**Denominator [D]**	**RDI or AHI (only with Type II devices)**
IV	Apnea Link	Airflow (nasal cannula)	No	Sleep Lab [and home (different nights)[	Simultaneous [and different night] (PSG done w/in 2 wk after home test)	Automated	by ApneaLink software (using defined thresholds)	Total Study Time	
Definition of Apnea:			Airflow decrease by 80% baseline ≥10 sec						
Definition of Hypopnea:			Airflow decrease by 50%-80% baseline ≥10 sec						
Thresholds used:			**Definitions:**						
Same as PSG									

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

D4. Comparisons Made (Details)

Index Test	Reference Test
ApneaLink in-lab AHI	PSG

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?)	AFib/AFlutter, %	CVD †, % (specify)
68 (59)	49%	57±12 (36-79)	nd	32.6±6.8 (19.8-52.9)	54%	nd	Angina 17% Heart failure 3% Valvular disease 3%
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
100%	nd	nd	nd	nd	nd	Asthma 12% Bronchitis 12% Allergies 37%	T2DM (not necessarily with symptoms suggestive of SA)

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	no	

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI [RDI] (Range)	AHI ≥5 (%)	AHI ≥15 (%)	AHI ≥10 // 20 (%)*
nd	69%	37%	47% // 31%

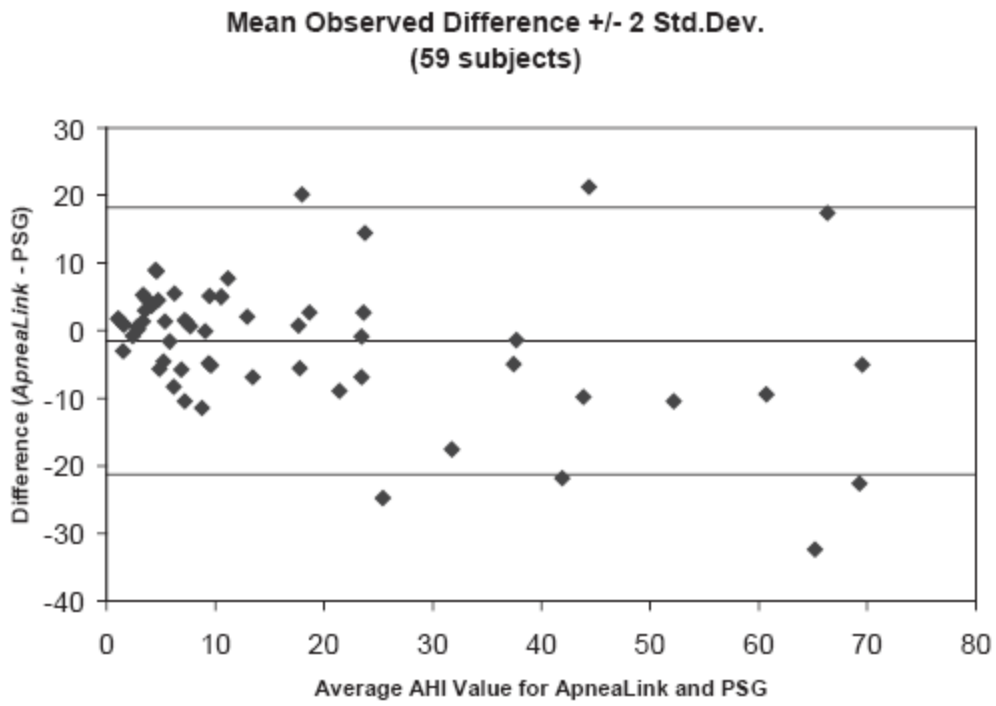
AHI: Apnea-hypopnea index; RDI: respiratory distress index

* Fill in this column only if any cut-offs other than 5 & 15 are used. Replace "?" with number.

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (LOA)	Other Text Description (eg, of bias)
Index	Ref					
ApneaLink (lab)	PSG	68	59	LOA (B-A)	~ -2 (-22, 18) (Estimated from figure)	For AHI≤30, no systematic bias. >30, absolute discrepancy widens; ApneaLink tends to understate AHI

* Bland Altman plot; LOA, Limits of Agreement; NOT correlation coefficients and OLS regression



G2. Results: Diagnostic performances (Yellow highlighting indicates that values were calculated from reported data)

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	TP	FN	TN	FP	Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
ApneaLink (lab) v PSG	AHI≥5	AHI≥5	35	6	9	9	85.4	nd	50.0	nd	0.863	
	10	10	23	5	26	5	82.1		83.9		0.862	
	15	15	20	2	35	2	90.9		94.6		0.977	
	20	20	15	3	38	3	83.3		92.7		0.967	

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

n/N	% Dropout	Reasons
9/63	14%	5: Withdrew consent prior to PSG (unknown reasons) 4: ApneaLink recording time <2 hr

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	Yes
Data loss / not analyzed (%)	6 or 14%, depending on how defined (see I)
Overall Quality (A/B/C)	A

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments
Also data on ApneaLink at home vs ApneaLink in lab (not extracted here)

A. Source and Extractor

Author, Year	Garcia-Diaz 2007			**Reference test**	PSG
PMID	17356086	**RefID**	11254	**Index test 1**	Respiratory polygraphy (RP) device with actigraphy (Apnoescreen II) – Observer A
Key Question(s)	1 (Dx Portable)			**Index test 2**	Respiratory polygraphy (RP) device with actigraphy (Apnoescreen II) – Observer B
Extractor	DM			**Comments**	2 observers were used to analyze data from the index device and data from both of the observers has been extracted

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Referred to Specialized center	Consecutive	No	nd	Spain	No conflicts of interest	Yes

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	prospective	Suspected SAHS subjects	Physical or mental impairment that ruled out the use of the equipment
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
Somnostar 4100	Sleep lab	Manual	Rechtschaffen and Kales criteria	Both Total sleep time (AHI) and Total recording time (RDI)
Definition of Apnea:		Complete cessation of oronasal airflow lasting ≥ 10 s.		
Definition of Hypopnea:		Decrease in oronasal airflow of ≥ 50% for a duration of ≥ 10 s, accompanied by desaturation (*ie*, a decrease in Sao2 of ≥ 4%) and/or an EEG arousal response (as defined by AASM criteria)		
Thresholds used:		**Definitions:**		
≥ 10, ≥ 15, ≥ 30,				

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
III	Apnoescreen II [AP-II]	• continuous monitoring of oronasal airflow (thermistor) • respiratory movements (bands) • tracheal sounds • ECG • Sao2 • heart rate (digital pulse oximetry with a sampling frequency of 5 s) • Body position (mercury sensor) • Wrist actigraphy.	Y	Sleep lab	Simultaneous with PSG	Manual	Software (Matrix Sleep Analysis software)	Both Total sleep time (AHI) and Total recording time (RDI)	RDI

Definition of Apnea:	Complete cessation of oronasal airflow lasting ≥ 10 s.
Definition of Hypopnea:	Reduction in airflow of _ 50% lasting for ≥10 s, accompanied by a decrease in Sao2 of at least 4%.
Thresholds used:	**Definitions:**

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?)	AFib/AFlutter, %	CVD †, % (specify)
65 (62)	87%	54±10	nd	30.1±3.9	44% (≥14/90 or Rx) 139/87	nd	Ischemic heart disease or stroke: 15%
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.

‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
87%	nd	nd	12 ± 3.7		Observed apneas 66%	FEV1<70%: 11% PaO2<80: 21%

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI [RDI] (Range)	AHI ≥5 (%)	AHI ≥10 (%)	AHI ≥15 (%)	AHI ≥30 (%)
30.3 ± 33	71	59.7	51.6	38.7

AHI: Apnea-hypopnea index; RDI: respiratory distress index
* Fill in this column only if any cut-offs other than 5 & 15 are used. Replace "?" with number.

G1. Results: Concordance [agreement between measurements – assume no gold standard] (Yellow highlighting indicates that values were calculated from reported data)

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Overall mean difference between the AHI during PSG and the RDI during the RP (LOA)**	Other Text Description (eg, of bias)
Index	Ref					
Lab RP (Obs A)	PSG	65	62	B-A LOA (AHI-RDI)	2.8±10.5 (0.13, 5.5) [-18, 23]	
Lab RP (Obs B)	PSG				1.03±10.3 (-1.6, 3.6) [-19, 21]	
Home RP (Obs A)	PSG				3.1±17 (-1.1, 7.5) [-30, 36]	
Home RP (Obs B)	PSG				1.6±16.4 (-2.5, 5.8) [-31, 34]	

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

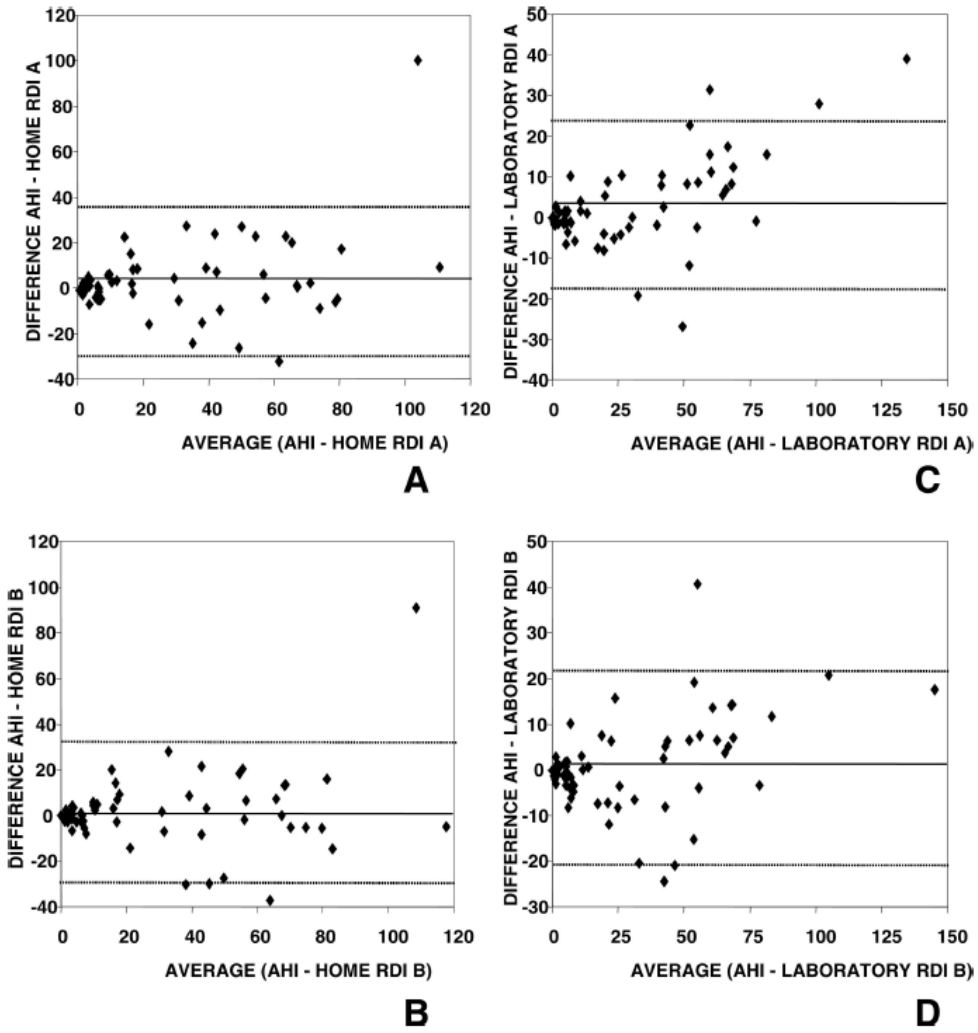


FIGURE 1. Bland-Altman plots comparing the AHI during polysomnography with RDI in the different analyses of RP. *Top left*, *A*, and *top right*, *C*: observer A. *Bottom left*, *B*, and *bottom right*, *D*: observer B. Continuous line = mean differences; broken lines = limits of agreement (*ie*, mean ± 1.96 SD of the differences).

G2. Results: Diagnostic performances (Yellow highlighting indicates that values were calculated from reported data)

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	TP	FN	TN	FP	Sens	(95% CI)	Spec	(95% CI)	ROC AUC (95% CI)	Other
In-lab respiratory polygraphy (RP) **Observer A** vs PSG	> 10	> 10	35	2	24	1	94.6	87.3-100	96	88.3-100	0.977 (0.937-1)	
In-lab respiratory polygraphy (RP) **Observer A** vs PSG	> 15	> 15	32	0	29	1	100		96.7	90.2-100	0.998 (0.992-1)	
In-lab respiratory polygraphy (RP) **Observer A** vs PSG	> 30	> 30	23	1	36	2	95.8	87.8-100	94.7	87.6-100	0.986 (0.964-1)	
In-lab respiratory polygraphy (RP) **Observer B** vs PSG	> 10	> 10	35	2	22	3	94.6	87.3–100	88	75.2–100	0.974 (0.931–1)	
In-lab respiratory polygraphy (RP) **Observer B** vs PSG	> 15	> 15	32	0	29	1	100		96.7	90.2–100	0.997 (0.989–1)	
In-lab respiratory polygraphy (RP) **Observer B** vs PSG	> 30	> 30	23	1	36	2	95.8	87.8–100	94.7	87.6–100	0.987 (0.965–1)	
At Home respiratory polygraphy (RP) **Observer A** vs PSG	> 10	> 10	32	5	25	0	86.4	75.4-97.5	100		0.969 (0.934-1)	
At Home respiratory polygraphy (RP) **Observer A** vs PSG	> 15	> 15	28	4	29	1	87.5	76-98.9	96.7	90.2-100	0.972 (0.936-1)	
At Home respiratory polygraphy (RP) **Observer A** vs PSG	> 30	> 30	22	2	36	2	91.7	80.6-100	94.7	87.6-100	0.986 (0.964-1)	
At Home respiratory polygraphy (RP) **Observer B** vs PSG	> 10	> 10	31	6	23	2	83.8	71.9–95.6	92	81.3–100	0.976 (0.947–1)	
At Home respiratory polygraphy (RP) **Observer B** vs PSG	> 15	> 15	27	5	29	1	84.4	71.8–96.9	96.7	90.2–100	0.977 (0.944–1)	
At Home respiratory polygraphy (RP) **Observer B** vs PSG	> 30	> 30	23	1	36	2	95.8	87.8–100	94.7	87.6–100	0.985 (0.962–1)	

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

n/N	% Dropout	Reasons
3/65	5	technical failure in PSG (1), withdrew (2)

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	Yes
Data loss / not analyzed (%)	5%
Overall Quality (A/B/C)	A

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Goodrich, 2009			**Reference test**	PSG
PMID	18083629	**RefID**	11276	**Index test 1**	lifeshirt
Key Question(s)	1			**Index test 2**	
Extractor	NO			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Patients were part of a separate study investigating the relationship between GERD and sleep apnea	? convenience sample	nd	nd	USA	nd	nd
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	prospective	Symptoms suggestive of OSA(regular snoring reports, gasping or choking for air while attempting to sleep , daytime sleepiness), heart burn at least 3 times per week 22-69yrs	History of abdominal surgery, significant respiratory illnesses such as COPD, asthma, neurological or psychological dxs requiring medication and significant medical disorders such as Chronic renal failure, liver disease or barrettes esophagus
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	**Manufacturer (Location)**	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
nd	nd	lab	Manual	Recthschaffen and Kales's criteria	
Definition of Apnea:			drop in airflow of at least 80%, with continuing respiratory efforts seen in the chest and abdomen for at least 10secs		
Definition of Hypopnea:			a decrease in airflow of ≥ 30% with an oxygen desaturation of ≥ 3%		
Thresholds used:			**Definitions:**		
AHI≥5 AHI≥30					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	Life shirt	Vivometrics; (Ventura,CA).	• Respiration • Heart rate • O2 sat • Motor activity	n	lab	Simultaneous	automated with manual review		Total recording time (RDI)	
Definition of Apnea:				Decrease in tidal volume of > 75% compared to baseline with continued breathing efforts observed in ribcage and ≥3% oxygen desaturation						
Definition of Hypopnea:				Decrease in tidal volume ≥ 25% and ≤ 50% compared to baseline in addition to ≥3% oxygen desaturation						
Thresholds used:				**Definitions:**						
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name *	**Description of Test (only if not on our list)**
Thresholds Used (Cut-Offs included)	
Comments:	

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
50(40)	73	44	nd	nd	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	100	nd	nd	nd	nd	Y(GERD)

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	nd	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI ≥5 n/N (%)	AHI ≥10 n/N (%)	AHI ≥15 n/N (%)	AHI ≥20 n/N (%)	AHI ≥25 n/N (%)	AHI ≥30* n/N (%)
5 to 105.3	39(78)	24(48)	15(30)	13(26)	10(20)	8(16)

AHI: Apnea-hypopnea index; RDI: respiratory distress index
* Fill in this column only if any cut-offs other than 5 & 15 are used. Replace "?" with number.

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Mean difference (95% LOA)	Other Text Description (eg, of bias)
Index	**Ref**					
Lifeshirt	PSG	50	48	Bland altman plot	1.02 (-16.36, 16.36)	

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

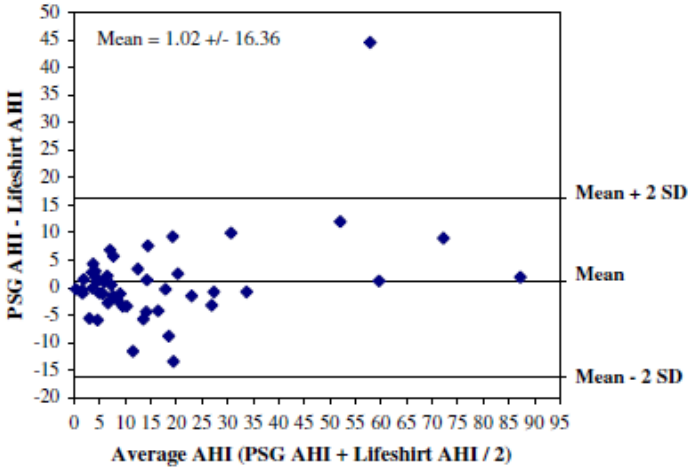


Fig. 1. Bland–Altman plot.

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
Life shirt vs PSG	≥5	≥5					0.85		0.67		0.76	
	≥10	≥10					0.92		0.88		0.90	
	≥15	≥15					0.87		0.82		0.84	
	≥20	≥20					0.85		0.94		0.90	
	≥25	≥25					1.00		0.97		0.99	
	≥30	≥30					0.88		1.00		0.94	

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
1/50		Technical errors in Lifeshirt
1/50		Data could not be read from PSG

J. Methodological Quality

Prospective or Retrospective?	y
Verification bias? (Yes/No; if yes describe)	n
Blinding? (Yes/No)	nd
Analytic problem? (Yes/No, if yes describe) *	n
Adequate description of tests (Yes/No, if no describe)	y
Clear description of population studied (Yes/No, if no describe)	y
Data loss / not analyzed (%)	4%
Overall Quality (A/B/C)	B

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Heneghan 2008			**Reference test**	PSG
PMID	18595434	**RefID**	11327	**Index test 1**	Holter ECG analysis algorithm
Key Question(s)	1 (Dx Portable)			**Index test 2**	
Extractor	DM			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Patients with suspected OSAS and healthy male subjects	Consecutive	N	nd	Ireland	Government and Foundation	Yes
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Males; Free from other medical disorders ; not started on regular medication and healthy controls	nd
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
nd	nd	sleep lab	manual	AASM	Total sleep time
Definition of Apnea:			No airflow for ≥ 10 sec		
Definition of Hypopnea:			Reduction in airflow for ≥ 10 sec with oxygen desaturation > 4% and/or arousal		
Thresholds used:			**Definitions:**		
<5, ≥ 5 - <15, ≥ 15 - <30, ≥ 30					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	Holter analysis	Biomedical Systems (MO, USA)	• ECG	N	Sleep lab	Simultaneous with PSG	Manual	Same as PSG	Total Recording time	RDI
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						
<5, ≥ 5 - <15, ≥ 15 - <30, ≥ 30				OSA: AHI≥ 15						
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
98 (92)	100%	42 yrs	nd	33.9	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	11.9	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI <5 n/N (%)	AHI ≥5 - <15 n/N (%)	AHI ≥10 n/N (%)	AHI ≥15 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
32.7	27/92 (29.3%)	15/92 (16.3%)	nd	50/92 (54.4%)	nd	nd	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					
ECH Holter Algorithm	PSG	98	92	Bland Altman plot	Figure 2	Value and 95% LOA not reported

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

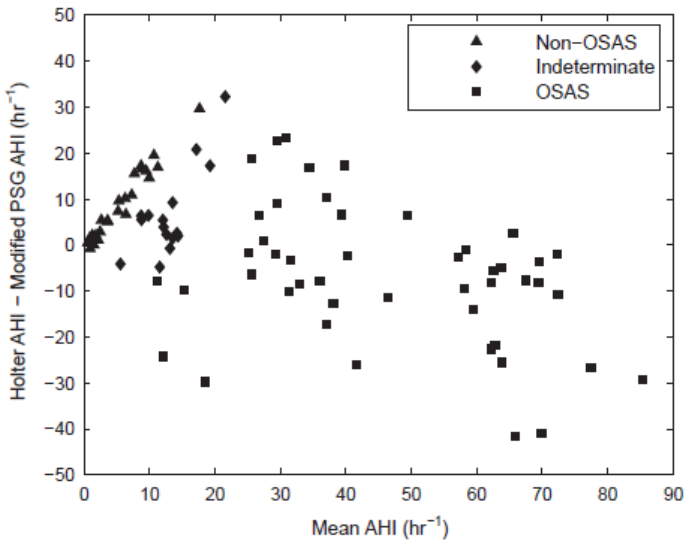


Figure 2—Bland-Altman plot of estimated AHI obtained from ECG analysis and modified PSG AHI obtained from PSG, *excluding* central apnea and hypopneas. One subject with a modified PSG AHI of 167 is not shown to improve the figure's clarity.

G2. Results: Diagnostic performances (Yellow highlighting indicates that values were calculated from reported data)

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
ECH Holter Algorithm vs PSG	≥ 15	≥ 15	46	4	29	13	0.92		0.69			
ECH Holter Algorithm vs PSG	≥ 5 - <15	≥ 5 - <15	9	6	66	11	0.6		0.86			
ECH Holter Algorithm vs PSG	< 5	< 5	10	17	62	3	0.37		0.95			

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
6/98	6%	Poor quality ECG Holter recording

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	Yes (Results of B-A plot not interpretable; Overall group results not presented)
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	Yes
Data loss / not analyzed (%)	6%
Overall Quality (A/B/C)	B

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in

category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Heneghan 2008			**Reference test**	PSG
PMID	18853941	**RefID**	11326	**Index test 1**	ECG-Oximetry analysis
Key Question(s)	1 (Dx Portable)			**Index test 2**	Oximetry
Extractor	DM			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Patients with suspected OSAS	Consecutive	No	nd	Ireland	nd *(Authors only state that this was not an industry sponsored study)*	Yes
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Patients suspected of sleep apnea scheduled to undergo PSG	known cardiac arrhythmia; implanted permanent pacemaker in situ
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
Jaeger-Toennies system	Erich Jaeger GmbH, Germany	Sleep lab	Manual	Criteria of Rechtschaffen and Kales	Total sleep time
Definition of Apnea:			AASM 1999		
Definition of Hypopnea:			AASM 1999		
Thresholds used:			**Definitions:**		
<5, ≥ 5 - <15, ≥ 15 - <30, ≥ 30					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	Holter-Oximeter	NorthEast Monitoring, Inc. (USA)	• ECG • SpO2	N	Sleep Lab	Simultaneous with PSG	Automatic (using linear discriminant analysis)	Same as PSG	Total recording time	RDI
Definition of Apnea:				As per algorithm						
Definition of Hypopnea:				As per algorithm						
Thresholds used:				**Definitions:**						
<5, ≥ 5 - <15, ≥ 15 - <30, ≥ 30										
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
63 (59)	88%	51	nd	30.9	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	11.3	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI <5 n/N (%)	AHI ≥5 - <15 n/N (%)	AHI ≥15 - <30 n/N (%)	AHI ≥30 n/N (%)	
	11/59 (18.7%)	17/59 (28.8%)	11/59 (18.7%)	20/59 (33.8%)	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% LOA)	Other Text Description (eg, of bias)
Index	Ref					
Holter-Oximetry	PSG	63	59	Bland Altman plot	-0.9 /hr (-18 /hr, 16.2/hr)	Fig 1
Oximetry	PSG	63	59	Bland Altman plot	1.1 /hr (-16.5 /hr, 18.4/hr) – *using digitizer*	Fig 4

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

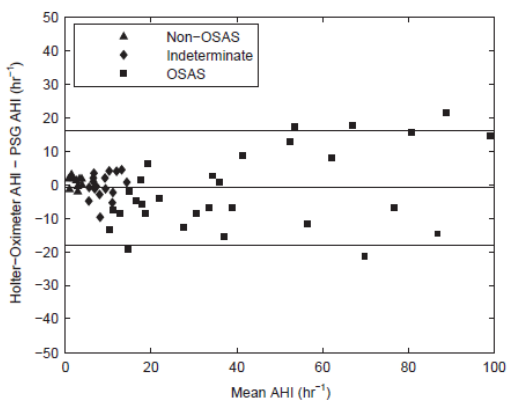


Figure 1—Bland-Altman plot of estimated AHI obtained from ECG-oximetry analysis and reference AHI obtained from PSG. Non-OSAS: AHI < 5, Indeterminate: AHI 5 to < 15; OSAS: AHI ≥ 15. One subject with a PSG AHI of 171/h is not shown to improve the figure's clarity.

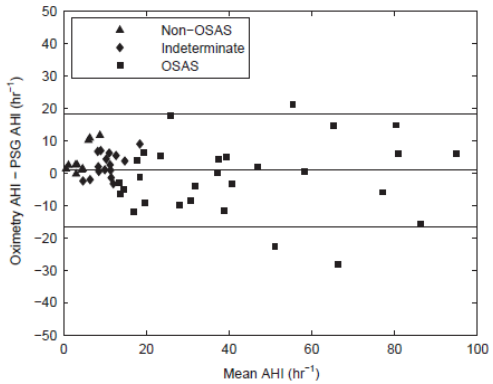


Figure 4—Bland-Altman plot of reference AHI and AHI estimated using the oximetry-only system. One subject with a PSG AHI of 171/h is not shown to improve the figure's clarity.

G2. Results: Diagnostic performances (Yellow highlighting indicates that values were calculated from reported data)

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
ECG-Oximetry vs PSG	≥ 5	≥ 5	45	3	11	0	93.8	(86.9,100)	100			
	≥ 10	≥ 10					81.6	(69.3,93.9)	90.5	(77.9,100)		
	≥ 15	≥ 15	23	8	27	1	74.2	(58.8,89.6)	96.4	(89.6,100)		

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)

If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
4/59	7%	

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	No (Baseline comorbidity not reported)
Data loss / not analyzed (%)	7%
Overall Quality (A/B/C)	A

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).

Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Nakano 2008			**Reference test**	PSG
PMID	18480104	**RefID**	3633	**Index test 1**	SOMNIE single-channel airflow monitor
Key Question(s)	1 (Dx Portable)			**Index test 2**	
Extractor	DM			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Referred for sleep disorder	Consecutive	Yes (Tenri and Fukuoka)		Japan		nd (reference test analyzers blinded to index test results)
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	≥18 & <65 yrs ; referred for suspected sleep apnoea; eligible to undergo diagnostic PSG;	none
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
Tenri MME-3116; Fukuoka: EEG7414	Nihon Kohden (Tokyo, Japan)	Sleep lab	Manual	Kales and Rechtschaffen criteria	Total sleep time
Definition of Apnea:			≥50% airflow reduction > 10 secs		
Definition of Hypopnea:			<50% airflow reduction >10 secs with ≥ 3% oxygen desaturation or an arousal		
Thresholds used:			**Definitions:**		
≥5, ≥15, ≥30					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	SOMNIE	NGK Spark Plug Co. Ltd (Nagoya, Japan)	• Airflow	N	Home (2 nights) & Sleep lab (3rd night)	Home- 2 days before PSG, Sleep lab: simultaneous with PSG	Automatic	Same as PSG	Total Recording Time	RDI
Definition of Apnea:				Same as PSG						
Definition of Hypopnea:				Same as PSG						
Thresholds used:				**Definitions:**						
>5.3, >11.4 , >19.6 events/h										
Comments:	The cut-offs equivalent to AHI of 5, 15 & 30 were derived by regression analysis on a retrospective sample of records									

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
100(100)	80%	45.3	?East Asian	26.9	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	1%	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
80%	nd	nd	nd	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI ≥5 n/N (%)	AHI ≥15 n/N (%)	AHI ≥30 n/N (%)	ODI 3% events /hr Mean (range)
30.5 (9.5-65.2)	89/100 (89%)	65/100 (65%)	52/100 (52%)	20.8 (5.8-41.3)

AHI: Apnea-hypopnea index; RDI: respiratory distress index
* Fill in this column only if any cut-offs other than 5 & 15 are used. Replace "?" with number.

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% LOA)	Other Text Description (eg, of bias)
Index	Ref					
SOMNIE	PSG	100	100	Bland Altman plot, LOA ± 2SD	-9.5 (-30.4 – 11.4)	Fig a, AHI of PSG vs RDI
SOMNIE	PSG	100	100	Bland Altman plot, LOA ± 2SD	-1.2 (-12.9 – 10.6)	Fig b, AH (apnea & hypopneas per hour of recording of PSG) vs RDI

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

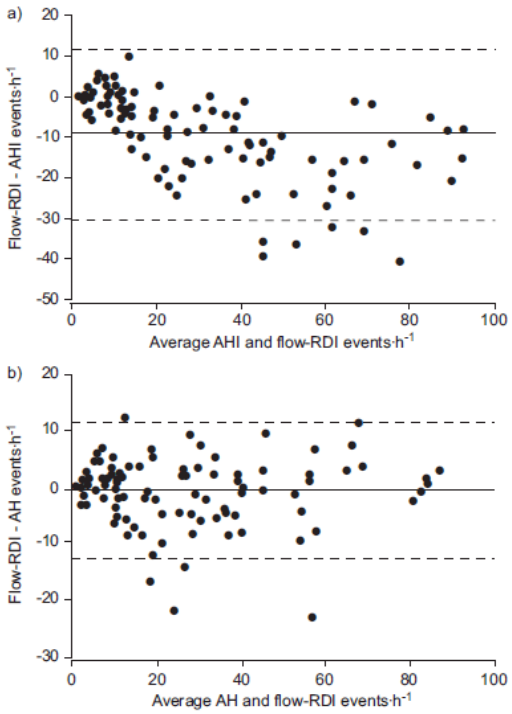


FIGURE 3. Bland and Altman plots. Difference between the flow-respiratory disturbance index (flow-RDI) determined by the in-laboratory SOMNIE and apnoea/hypopnoea index (AHI) determined by the simultaneous polysomnography was plotted against the average value of the two methods. a) Ordinary AHI (per hour of sleep) was used; b) apnoea/hypopnoea number per hour of recording (AH) was used instead. ———: mean difference; – – – – –: 95% limit of agreement.

G2. Results: Diagnostic performances (Yellow highlighting indicates that values were calculated from reported data)

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (95%CI*)	Other
			TP	FN	TN	FP						
SOMNIE vs PSG	>5.3 events/h	>5	85	4	9	2	0.96	0.91–1.00	0.82	0.59–1.00	0.95 (0.90–0.99)	
	>11.4 events/h	>15	59	6	29	6	0.91	0.84–0.98	0.82	0.70–0.95	0.96 (0.92–0.99)	
	>19.6 events/h	>30	46	6	46	2	0.89	0.80–0.97	0.96	0.90–1.00	0.98 (0.94–1.00)	

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

Subgroups	**Comparison (Index v Ref)**	**Index cutoff**	**Reference standard cutoff**	**Sn data**		**Sp data**		**Sens**	**(95% CI)**	**Spec**	**(95% CI)**	**ROC AUC (95%CI*)**	**Other**
				TP	**FN**	**TN**	**FP**						
Female	SOMNIE vs PSG	>5.3 events/h	>5					0.88		0.67		0.88	
		>11.4 events/h	>15					0.75		0.83		0.89	
		>19.6 events/h	>30					1.00		0.94		1.0	
BMI < 25 kg/m^2	SOMNIE vs PSG	>5.3 events/h	>5					0.97		0.71		0.94	
		>11.4 events/h	>15					0.78		0.89		0.92	
		>19.6 events/h	>30					0.91		0.92		0.97	
AHI < 15 events/hr	SOMNIE vs PSG	>5.3 events/h	>5					0.83		0.82		0.81	

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	**% Dropout or analysis failure**	**Reasons**
0/100	0%	

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	Yes
Data loss / not analyzed (%)	0%
Overall Quality (A/B/C)	A

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).

Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Nigro, 2009			**Reference test**	PSG
PMID	18830731	**RefID**	14606	**Index test 1**	O2 Sat: WristOx 3100
Key Question(s)	1			**Index test 2**	
Extractor	EB			**Comments**	

B. Study description

Author, Year Country PMID	**N enrolled total**	**Sampling population [A]**	**Recruitment method [B]**	**Mean age (SD/Range)**
Nigro, 2009 Argentina 18830731	168	Being investigated for possible SA	Consecutive patients	51±14

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe) *	No
Analytic problem? (Yes/No, if yes describe) **	
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	No. Incomplete description of Sx & comorbidities
Data loss / not analyzed (%)	12/166 = 7%
Overall Quality (A/B/C)	B

* Only for Type II studies in a large population
** e.g., paired tests on two readings in one patient;
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

D.1. Participant characteristics and baseline "severity/risk"

Study characteristics		Inclusion criteria	Exclusion criteria
Study design	Cross-sectional Prospective	Overall Suspected SA: snoring with or w/o other symptoms such as apneas and/or somnolence ≥18 y	Overall Use of O2, CPAP, or noninvasive mechanical respiratory assistance during PSG *Elimination criteria:* Diagnosis of central SA by PSG Artifactual PSG or O2 sat
		Controls:	Controls:
Comments			

D.2

N enrolled, total	Male, %	Age, y	BMI*	NIDDM, %	HTN, % (how defined?)	AFib/AFlutter, %	CVD †, % (specify)
166 (168-2 refusals)	77%	51±14	28.3 (25.5-33.4)	nd	nd	nd	nd
Smokers, % (define)	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**	
nd	nd	nd	nd	nd	nd	No	

* Mean±SD. If median, SE, range, IQR, or other, specify these; † Including CVD, CAD, IHD, previous MI, previous stroke, etc.; ‡Motor vehicle accident.; ** Either score on a test (which test?) or % with cognitive dysfunction

D.3

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	nd	nd

* Define and indicate if expressed in Mean±SD. If median, SE, range, IQR, or other, specify these.

E. PSG: Polysomnography (facility-based)

Median AHI (IQR)	AHI ≥5 (%)	AHI ≥15 (%)	AHI ≥30 (%)
13.8 (4-29)	66% (19+24+23)	47% (24+23)	23%

AHI: Apnea-hypopnea index; RDI: respiratory distress index

F. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

F1. PSG

Equipment	Setting	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
BIOPC or NEUROTRACE	Sleep lab	Manual	Standard	Total sleep time (AHI)
Thresholds Used		**Definition**		
AHI ≥5				
AHI≥10				
AHI≥15				

* Total sleep time (AHI) versus Total recording time (RDI)

F2. Other Devices

Type	Name (equipment)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
O2 Sat	Nonin WristOx 3100	NA	No	Sleep lab	Simultaneous	Automatic	Desat >12 sec (SO2<90%)	Total recording time (RDI) [based on PSG] minus artifact time	
Thresholds Used			**Definition**						
ADI2>12.2/19.3			O2 desaturation >2% >12 sec >X times/hour						
ADI3>4.4/10.5/13.4/32			O2 desaturation >3% >12 sec >X times/hour						
ADI5>4.3			O2 desaturation >5% >12 sec >X times/hour						
also ADI4 and ADI6									

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurment
D Total sleep time (AHI) versus Total recording time (RDI)

F2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

F3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)					
Index	Ref									
O2 sat	PSG	166	154							

A Bland Altman plot; Limits of Agreement; NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Gold standard cutoff	TP	FN	TN	FP	Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Comment
O2 sat v PSG	ADI2>12.2	AHI≥5					100	(96.4-100)	57.69	(43.2-71.3)	0.959	"greater Sn"
	ADI2>19.3	AHI≥5					89.22	(81.5-94.5)	94.23	(84.0-98.7)		"higher accuracy"
	ADI5>4.3	AHI≥5					92.75	(52.6-72.1)	100	(93.1-100)	0.907	"greater Sp"
	ADI2>12.2	AHI≥10					100	(95.8-100)	44.12	(32.1-56.7)	0.957	Sn
	ADI3>10.5	AHI≥10					88.37	(79.6-94.3)	94.12	(85.6-98.3)	0.965	acc
	ADI5>4.3	AHI≥10					74.42	(63.9-83.2)	100	(94.7-100)	0.930	Sp
	ADI3>4.4	AHI≥15					100	(95.0-100)	49.38	(38.1-60.7)	0.945	Sn
	ADI3>13.4	AHI≥15					87.67	(77.9-94.2)	90.12	(81.5-95.6)		acc
	ADI3>32	AHI≥15					42.47	(31.0-54.6)	100	(95.5-100)		Sp

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

H. Subgroup Analysis (If present)

If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

A. Source and Extractor

Author, Year	Pang 2007			**Reference test**	PSG
PMID	17903588	**RefID**	11638	**Index test 1**	WatchPAT
Key Question(s)	1			**Index test 2**	
Extractor	DM			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Referred to Sleep Center for PSG	Consecutive	N	nd (over 3 month period)	USA	nd	Yes

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Suspicion of OSA	nd
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	**Manufacturer (Location)**	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
nd	nd	sleep lab	manual	nd	Total sleep time
Definition of Apnea:			no airflow for ≥ 10 secs		
Definition of Hypopnea:			reduction of airflow for ≥10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow and with at least 4% oxygen desaturation or the presence of an arousal		
Thresholds used:			**Definitions:**		
>5, >15, >35					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels [A]	Actigraphy (Y/N)	Setting [B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	WatchPAT	nd	• Pulse oximetry • Peripheral tonometry • Actigraphy	Y	Sleep lab	Simultaneous with PSG	Automated	Software (Itmar Ltd)	Total sleep time (AHI)	
Definition of Apnea:				nd						
Definition of Hypopnea:				nd						
Thresholds used:				**Definitions:**						
>5, >15, >35										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
37 (32)	32	50 ± 12	nd	34.6 ± 5.2 kg/m^2 (range 21.2 ± 46.8)	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	13.9 ± 3.7	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI [RDI] (Range)	AHI ≥5 [RDI≥5] (%)	AHI ≥15 [RDI≥15] (%)	
34.87 ± 20.2	nd	nd	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	TP	FN	TN	FP	Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
WatchPAT vs PSG	>5	>5					94		80			
	>15	>15					96		79			
	>35	>35					83		72			

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

H. Subgroup Analysis (If present)

If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

n/N	% Dropout	Reasons
5/37	14	Inadequate sleep time

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	Yes (Inadequate reporting of results does not allow us to calculate TP, FP, FN, TN)
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	No (prevalence of AHI >5, >15, >35 not presented)
Data loss / not analyzed (%)	14%
Overall Quality (A/B/C)	C

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).

Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B

(moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Pepin, 2009			**Reference test**	PSG
PMID	19028140	**RefID**	11663	**Index test 1**	ECG/nasal pressure holter monitoring visual
Key Question(s)	1			**Index test 2**	ECG/nasal pressure holter monitoring automated
Extractor	NO			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Referred to sleep center	Consecutive	n	nd	France	nd	y
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	prospective	patients with suspected OSAS	nd
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	**Manufacturer (Location)**	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
nd	nd	lab	Rechtschaffen and Kales' criteria		
Definition of Apnea:			Airflow amplitude less than 10% of baseline lasting ≥ 10secs		
Definition of Hypopnea:			50% airflow amplitude decrease or a 30–50% airflow reduction plus a micro-arousal or a 3% oxygen desaturation		
Thresholds used:			**Definitions:**		
AHI ≥20					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
III	ECG Holter (SpiderviewTM)	nd	• 1 Nasal pressure • 3 ECG channels	n	lab	simultaneous	Manual(visual)	Same	Total recording time	
Definition of Apnea:				Airflow amplitude less than 10% of baseline lasting ≥ 10secs						
Definition of Hypopnea:				50% airflow amplitude decrease for 10secs or reduction in NP amplitude ended by an anatomic associated micro arousal (significant acceleration of heart rate visible on ECG e.g. +20bpm)						
Thresholds used:				**Definitions:**						
35 events/hr determined by ROC analysis										
Comments:	The same ECG holter device was used and recordings for automated Nasal pressure were analyzed with the SynelabSAS. An apnea was defined by NP signal amplitude reduction of at least 80% compared to the five previous valid cycles with at least 10 s duration. Hypoapnea was defined as a reduction in ansal pressure of at least 50% compared to the five previous valid cycles for at least 10secs .									

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
34(19)[1]	63	47(12)	nd	25.4(4.5)	26% had history of CVD problems, HTN, stroke and coronary artery disease		
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	n

[1]19 patients made up the test set, 10 patients made up development set (not extracted)
* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	10(6)	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI ≥5 n/N (%)	AHI ≥10 n/N (%)	AHI ≥15 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
20.4(18.8)						

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Index	Ref	N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
ECG/nasal pressure holter monitoring visual	PSG	34	19	Bland altman		

ECG/nasal pressure holter monitoring automated	PSG	34	19	Bland altman		

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

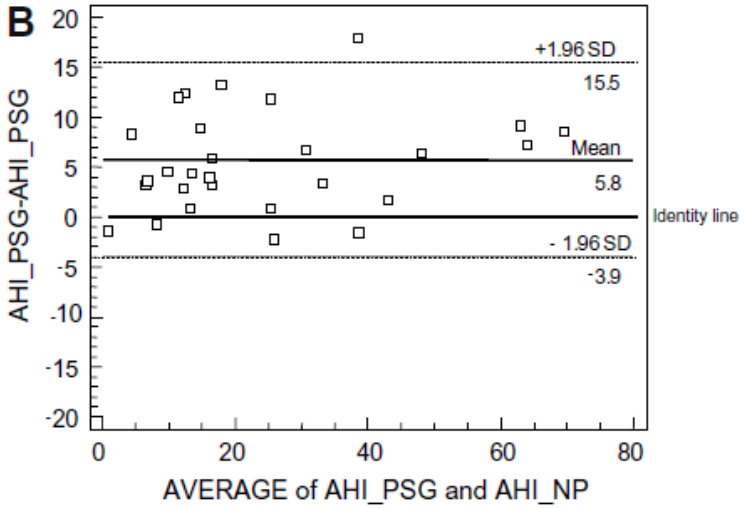


Fig. 2. Validation of Holter ECG with nasal pressure signal versus polysomnography. (A) Correlation between AHI provided by Holter ECG plus nasal pressure visual analysis (AHI-NP) and polysomnography (AHI-PSG). (B) Bland and Altman plot showing the number of events scored using the two techniques.

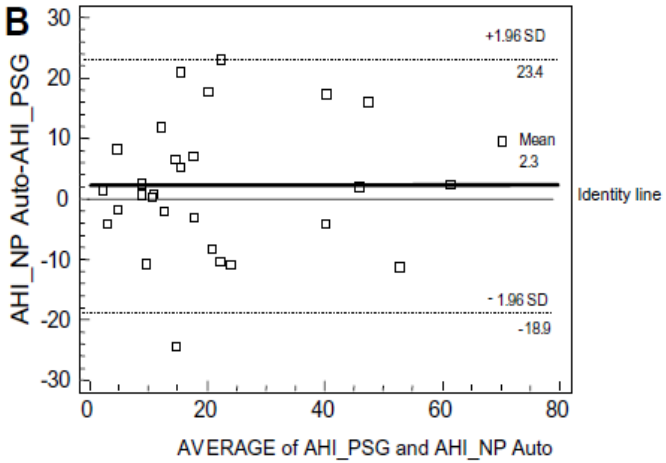


Fig. 3. Validation of Holter ECG with nasal pressure signal automatic analysis versus polysomnography. (A) Correlation between AHI provided by Holter ECG plus nasal pressure automatic analysis (AHI-NP auto) and polysomnography (AHI-PSG). (B) Bland and Altman plot showing the number of events scored using the two techniques.

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	NPV/PPV
			TP	FN	TN	FP						
ECG/nasal pressure holter monitoring visual vs PSG	35events/hr	AHI≥20					57		100		0.97(SEM 0.05)	80[b]/100
ECG/nasal pressure holter monitoring automated vs PSG	35events/hr	AHI≥20					71		100		0.85(SEM 0.05)	86[c]/100

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –
[b] 93% when adjusted for prevalence of dxs
[c] 95% when adjusted for prevalence of dxs

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons

J. Methodological Quality

Prospective or Retrospective?	y
Verification bias? (Yes/No; if yes describe)	n
Blinding? (Yes/No)	y
Analytic problem? (Yes/No, if yes describe) *	n
Adequate description of tests (Yes/No, if no describe)	y
Clear description of population studied (Yes/No, if no describe)	N(no exclusion criteria)
Data loss / not analyzed (%)	15%
Overall Quality (A/B/C)	B

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Reda 2001			**Reference test**	PSG
PMID	11593166	**RefID**	15742	**Index test 1**	Pharyngoesophageal manometry
Key Question(s)	1 (Dx Portable)			**Index test 2**	
Extractor	DM			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Patients with sleep-related breathing disorders	Case series	No	nd	UK	nd	Yes
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Age 20 - 70 years; listed for full PSG for sleep apnea;	Esophageal stricture
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

E)quipment	**Manufacturer (Location)**	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
nd	nd	Sleep lab	nd	nd	Total sleep time
Definition of Apnea:			nd		
Definition of Hypopnea:			nd		
Thresholds used:			**Definitions:**		
<15, 15-20, 20-40, >40					
Comments:	No data on PSG provided				

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	Pharyngoesophageal manometry with Digitraper	Gaeltec Ltd (Dunvegan, Isle of Skye, Scotland, UK)	• Pharyngoesophageal pressure monitor	N	Sleep lab	Simultaneous with PSG	Automatic	nd	Total recording time	RDI
Definition of Apnea:				nd						
Definition of Hypopnea:				nd						
Thresholds used:				**Definitions:**						
<15, 15-20, 20-40, >40										
Comments:	Conversion of manometric finding to the thresholds of AHI are not reported									

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
59(59)	nd	range 20-70y	nd	nd	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
100%	nd	nd	nd	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI ≥5 n/N (%)	AHI 15-20 n/N (%)	AHI ≥20-40 n/N (%)	AHI >40 n/N (%)	
	35/59 (59.3%)	5/59 (8%)	20/59 (34%)	10/59 (17%)	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Mean Difference (95% CI or LOA)**	Other Text Description (eg, of bias)
Index	**Ref**					
Pharyngoesophageal monitoring	PSG	59	59	B-A plot	0.22 (95% CI: -0.931, 1.382) (95% LOA: -8.68, 9.02)	

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances (Yellow highlighting indicates that values were calculated from reported data)

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
Pharyngoesophageal monitoring vs PSG	<15	<15	24	0	35	0	100		100			
	15-20	15-20	4	1	52	2	80		96			
	20-40	20-40	18	2	38	1	90		97			
	>40	>40	10	0	49	0	100		100			

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	The results from the development phase (prediction of AHI) are combined with results from the validation. The development phase was non-blinded

H. Subgroup Analysis (If present)

If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
0/59	No dropouts	

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	No (Development phase was non-blinded)
Analytic problem? (Yes/No, if yes describe) *	Yes (B-A plot not presented, no adjustment for including results from non-blinded part of the study)
Adequate description of tests (Yes/No, if no describe)	No (Threshold calculation for device not presented, apnea/hypopnea detection not reported)
Clear description of population studied (Yes/No, if no describe)	No (no data on population)
Data loss / not analyzed (%)	0%
Overall Quality (A/B/C)	C

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).

Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments
The sens and specificity seem to be unusually good for a device that only measures pharyngeal pressure. The validation of this device was done by including the subjects from whom the data for classification of apnea was obtained.

A. Source and Extractor

Author, Year	Santos-Silva 2009			**Reference test**	PSG
PMID	19480230	**RefID**	14768	**Index test 1**	Type 3 Portable Monitor (Stardust II)
Key Question(s)	1 (Dx portable)			**Index test 2**	
Extractor	DM			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Patients with suspected sleep apnea and healthy subjects	Consecutive	N	nd	Brazil	Foundation and Industry	Yes
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
RCT	Prospective	Suspicion of OSA, ≥ 21 yrs, able to provide informed consent, able to follow study procedures	Existence of severe chronic lung disease, diabetes; those receiving oxygen or mechanical ventilation; those with neurological disorders; and those using sedative hypnotics, stimulants, alcohol, or drugs of abuse
Comments	Randomization determined sequence of tests: Stardust alone at home, Stardust with PSG in lab, PSH alone in Lab		

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	**Manufacturer (Location)**	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
EMBLA S7000	Embla Systems, Inc (Broomfield, CO, USA)	Sleep Lab	Manual	AASM criteria	Total Sleep Time
Definition of Apnea:			AASM criteria 1999		
Definition of Hypopnea:			AASM criteria 1999		
Thresholds used:			**Definitions:**		
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
III	Stardust II	Respironics Inc (USA)	• Airflow - pressure based airflow through a nasal cannula • respiratory effort - piezoelectric sensor in a belt placed mid-thorax • Oximetry - SpO2 • pulse rate • body position	N	At-home & In-Lab	At-home: Either a day before or a day after, depending on randomization sequence In-lab: simultaneous with PSG	Manual	Same as PSG	Total recording Time	RDI
Definition of Apnea:				Same as PSG						
Definition of Hypopnea:				Same as PSG						
Thresholds used:				**Definitions:**						
≥ 5, ≥ 15, ≥ 30										
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
82(80)	57%	47 ± 14	nd	28 ± 5	Systolic: 129 ± 17 mmHg Diastolic: 85 ± 15 mmHg	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Awakenings Reported, % (specify)	Risk as per Berlin Questionnaire – High/Low (%)
87%	nd	nd	10.4 ± 5.8		86%	68% / 32%

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI >5 n/N (%)	AHI ≥10 n/N (%)	AHI ≥15 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
From PSG when done alone: 23 ± 34 From PSG when done with STD: 26 ± 28	78% of patients, 30% of healthy subjects (N for both groups not reported)	nd	nd	nd	nd	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Mean difference (95% LOA)	Other Text Description (eg, of bias)
Index	Ref					
PSG in-lab	STD at-home	82	80	Bland Altman plot	-0.7 (-24, 22.6)	Figure A
PSG in-lab	STD in-lab (done with PSG)	82	80	Bland Altman plot	-4.0 (-26.6, 18.6)	Figure B
PSG in-lab (done with STD)	STD at-home	82	80	Bland Altman plot	1.6 (-22.2, 25.4)	Figure C
PSG in-lab (done with STD)	STD in-lab (done with PSG)	82	80	Bland Altman plot	-1.1 (-24.9, 22.8)	Figure D

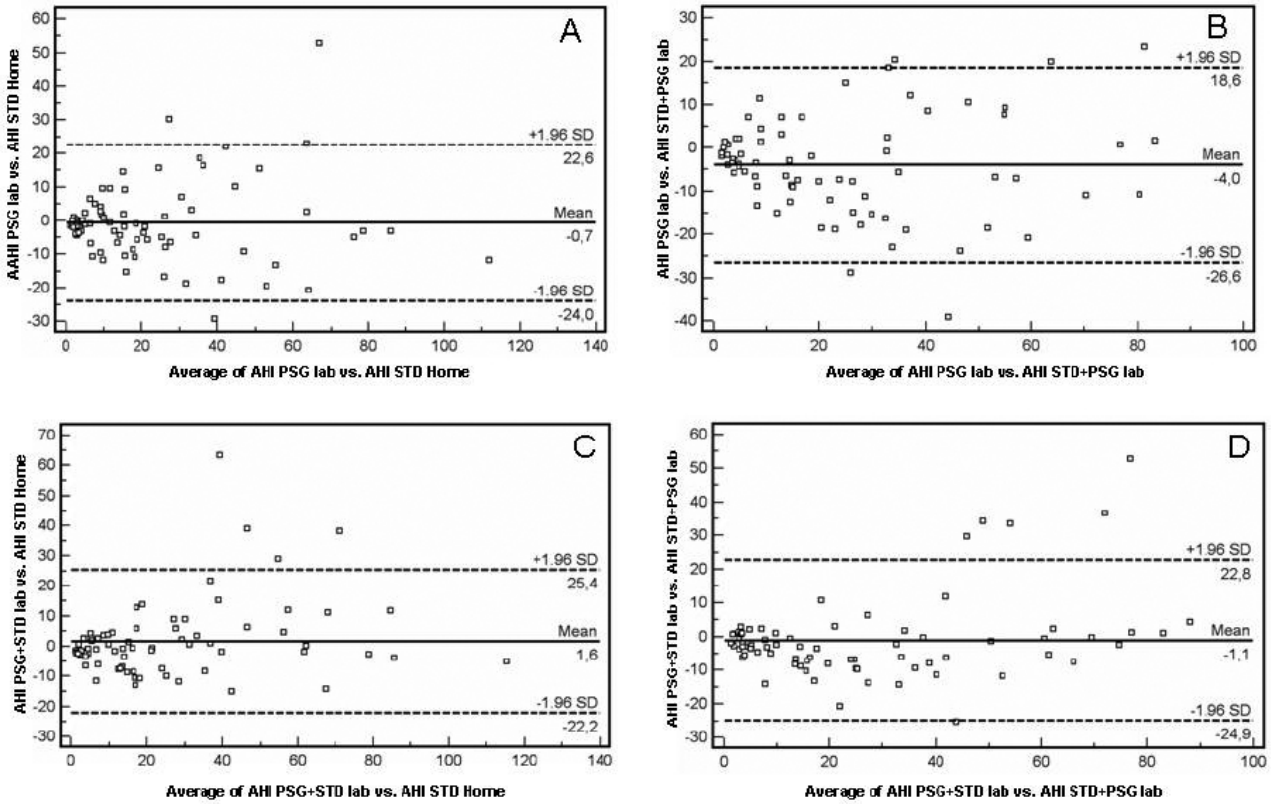


Figure 3—Bland Altman analysis between AHIs from STDs and PSGs considering the 4 recordings. **A**: PSG lab vs. STD Home; **B**: PSG lab vs. STD+PSG lab; **C**: PSG+STD lab vs. STD Home; **D**: PSG+STD lab vs. STD+PSG lab.

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
STD at-home vs PSG in-lab	≥ 5	≥ 5					93		59		0.90	
STD at-home vs PSG in-lab (done with STD)	≥ 5	≥ 5					95		62		0.95	
STD in-lab (done with PSG) vs PSG in-lab	≥ 5	≥ 5					92		48		0.91	
STD in-lab (done with PSG) vs PSG in-lab (done with STD)	≥ 5	≥ 5					98		62		0.97	
STD at-home vs PSG in-lab	≥ 15	≥ 15					85		80		0.92	
STD at-home vs PSG in-lab (done with STD)	≥ 15	≥ 15					86		78		0.95	
STD in-lab (done with PSG) vs PSG in-lab	≥ 15	≥ 15					94		71		0.93	
STD in-lab (done with PSG) vs PSG in-lab (done with STD)	≥ 15	≥ 15					97		74		0.98	
STD at-home vs PSG in-lab	≥ 30	≥ 30					77		93		0.95	
STD at-home vs PSG in-lab (done with STD)	≥ 30	≥ 30					74		96		0.96	
STD in-lab (done with PSG) vs PSG in-lab	≥ 30	≥ 30					86		79		0.95	
STD in-lab (done with PSG) vs PSG in-lab (done with STD)	≥ 30	≥ 30					96		92		0.98	

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
2/82	2%	Incomplete recording

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	yes
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	No (Baseline AHI prevalence not reported)
Data loss / not analyzed (%)	2%
Overall Quality (A/B/C)	A

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Schafer 1997			**Reference test**	PSG
PMID	9154670	**RefID**	12804	**Index test 1**	MESAM 4 (Non-Laboratory monitoring system (NLMS))
Key Question(s)	1 (Dx Portable)			**Index test 2**	
Extractor	DM			**Comments**	BMI ≥ 29 kg/m^2 and Observed apneas (% of subjects) and involuntary falling asleep (% of subjects) were added to the MESAM 4 results to give additional sensitivities and specificity calculations. These are not extracted as the details of how the variables were merged is not provided.

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Suspected sleep-related breathing disorders	case series	No	nd	Germany	nd	Yes
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Suspected sleep-related breathing disorders, mainly OSA or snoring	nd
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	**Manufacturer (Location)**	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
nd	NewMedics (Ohringen, Germany)	Sleep lab	Manual	Rechtschaffen & Kales, 1986	Total recording time (RDI)
Definition of Apnea:			No airflow for > 10 s		
Definition of Hypopnea:			> 50% reduction in airflow with O_2 desaturation of ≥ 4% or arousal		
Thresholds used:			**Definitions:**		
≥ 5, ≥ 10, ≥ 15, ≥ 20, ≥ 25					
Comments: ≥ 10 used to diagnose OSA					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	MESAM 4	MAP Medizintechnik (Martinsried, Germany)	• heart rate • oxygen • saturation • snoring sounds • body position	N	Home	Six weeks	Manual	Scoring all instances of oxygen desaturation of ≥ 4% or ≥ 2% when accompanied by a visible change in heart rate	Total sleep time	ODI
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						
≥ 5, ≥ 10, ≥ 15, ≥ 20, ≥ 25										
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
114 (114)	88%	56 ± 11	nd	30.8 ± 6.8	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring (%)*	**Bed partner, %**	**Craniofacial abnormalities/ congenital abnormalities**	**Epworth**	**MSLT**	**Other Clinical symptoms, % (specify)**	**Other characteristics (specify)**
94.6%	nd	nd	nd	nd	Observed apneas: 75.9%; Daytime sleepiness: 85%; Involuntary falling asleep: 72.8%	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean RDI (Range)	AHI ≥5 n/N (%)	AHI ≥10 n/N (%)	AHI ≥15 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
29.2 ± 24.3	nd	70.2%				

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					
MESAM 4	PSG	114	114	Bland Altman plot	From Figure 2 (Mean ± SD lines are not marked)	

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

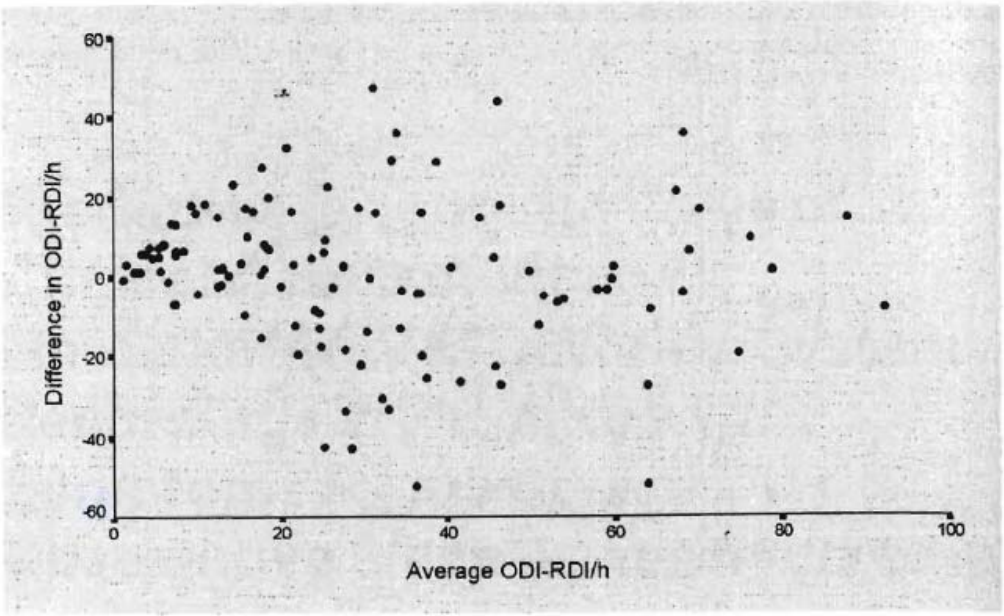


Fig. 2. Plot of the difference in ODI by home-based monitoring and RDI by polysomnography against their mean.

G2. Results: Diagnostic performances (Yellow highlighting indicates that values were calculated from reported data)

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
MESAM 4 vs PSG	≥ 5	≥ 5					0.96		0.15			
	≥ 10	≥ 10	76	4	14	20	0.95		0.41			
	≥ 15	≥ 15					0.83		0.62			
	≥ 20	≥ 20					0.68		0.74			
	≥ 25	≥ 25					0.60		0.85			

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)

If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
0/114	No dropouts	

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	Yes (Since they were not consecutive subjects, there is a possibility of selection bias)
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	Yes
Data loss / not analyzed (%)	0%
Overall Quality (A/B/C)	B

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).

Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B

(moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Smith 2007			**Reference test**	PSG
PMID	18036089	**RefID**	11799	**Index test 1**	Embletta in-Lab
Key Question(s)	1			**Index test 2**	Embletta at-home
Extractor	DM			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Chronic heart failure patients	Consecutive	N	nd	UK	Foundation	nd

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Age 18 -80 years symptomatic (NYHA II-IV) CHF patients Stable for 1 month on optimal medical therapy left ventricular systolic dysfunction (LVEF <45% on echo)	Acute coronary syndrome within 3 mths Primary valvular heart disease Stroke with residual neurological deficit.
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	**Manufacturer (Location)**	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
Computerized recording system	Compumedics, (Abbotsford, Australia)	sleep lab	Manual	Rechtschafen and Kales,1963	Total sleep time (AHI) and Total recording time (RDI)
Definition of Apnea:			American Academy of Sleep Medicine 1999		
Definition of Hypopnea:			American Academy of Sleep Medicine 1999		
Thresholds used:			**Definitions:**		

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated , automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	Embletta	Embletta (Flaga, Iceland)	• Airflow • Effort • SaO_2 • Body position	nd (Body position's mentioned but not how it's measured)	Sleep lab / At home	In sleep lab: simultaneous/ at home: range of 1-7 days (median 2 days) between device and PSG	Manual	Software	Total recording time	RDI
Definition of Apnea:				Same as PSG						
Definition of Hypopnea:				Same as PSG						
				The Embletta can only record the total number of apnoeas and hypopneas per hour in bed						
Thresholds used:				**Definitions:**						
A + H < 10, A + H 10-20, A + H >20										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the

same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
20 (20)	70%	61 ± 10	nd	29 ± 6	nd	15%	65% (Ischaemic heart disease) 35% (Dilated cardiomyopathy)
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	Mean Left ventricular ejection fraction expressed as %: 33 ± 12	Yes (chronic heart failure patients)

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	**Bed partner, %**	**Craniofacial abnormalities/ congenital abnormalities**	**Epworth**	**MSLT**	**Other Clinical symptoms, % (specify)**	**Other characteristics (specify)**
nd	nd	nd	8 ± 4	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI [RDI] (Range)	**AHI ≥5 [RDI≥5] (%)**	**AHI ≥15 [RDI≥15] (%)**	
25.7 ± 22.2	nd	55	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Mean (95% LOA) **	Other Text Description (eg, of bias)
Index	**Ref**					
Embletta in-Lab	PSG	20	20	Bland Altman plot (Mean Bias in Apnea + Hypoapnea per hour)	5 ± 7 /hour (-8 to +18)	A+H values from Embletta and A+H values from PSG
Embletta in-Lab	PSG	20	20	Bland Altman plot (Mean Bias in Apnea + Hypoapnea per hour)	6 ± 9 /hour (-11 to +24)	A+H values from Embletta and AHI values from PSG
Embletta at-home	PSG	20	20	Bland Altman plot (Mean Bias in Apnea + Hypoapnea per hour)	10 ± 15 /hour (-18 to +39)	A+H values from Embletta and A+H values from PSG
Embletta at-home	PSG	20	20	Bland Altman plot (Mean Bias in Apnea + Hypoapnea per hour)	12 ± 19 /hour (-25 to +49)	A+H values from Embletta and AHI values from PSG

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	TP	FN	TN	FP	Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
home Embletta vs. PSG (AHI ≥15)	A+H/h in bed ≥ 10	AHI ≥15	7	5	7	1	87.5		58.3			
	A+H/h in bed ≥ 20	AHI ≥15	3	8	8	1	75		50			

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

n/N	% Dropout	Reasons
20 (20)	0	

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	nd
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	Yes
Data loss / not analyzed (%)	No dropouts
Overall Quality (A/B/C)	B

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Szyszko 2009			**Reference test**	PSG
PMID	18971289	**RefID**	11833	**Index test 1**	Holter Monitor
Key Question(s)	1 (Dx Portable)			**Index test 2**	
Extractor	DM			**Comments**	Data from 20 control group patients was not extracted as PSG was not carried out on that group

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
patients with high suspicion of OSA	Case series	N	nd	Argentina	? non-profit - Programa de Estudio y Tratamiento de las Arritmias Cardı´acas (PRONETAC).	Yes
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	1/2 of following: history of hypertension; smoking; craniofacial dismorphy; family history of OSA; endocrinological disorders; BMI ≥ 30 kg/m^2; neck circumference > 17 in (men), 6 in (women) - 4 cm added if pt hypertensive; Epworth sleepiness score (ESS) ≥ 10	Ongoing pathological states; Autonomic disorders; history of cardiac arrhythmias; implanted permanent pacemakers or cardioverter defibrillators
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	**Manufacturer (Location)**	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
ATI	nd	Sleep lab	Automated	Standard scoring system	Total sleep

Delphos PSG 2003					time
Definition of Apnea:			Cessation of oronasal airflow > 10 s		
Definition of Hypopnea:			50% airflow reduction with 4% oxygen desaturation		
Thresholds used:			**Definitions:**		
≥ 10					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	**Name (equipment)**	**Manufacturer (Location)**	**Channels[A]**	**Actigraphy (Y/N)**	**Setting[B]**	**Timing[C]**	**Scoring (manual, automated, automated with manual review)**	**Scoring system, if not identical that for PSG**	**Denominator [D]**	**RDI or AHI (only with Type II devices)**
IV	Holter Analysis	Software from Del Mar Reynolds Lifescreen Version 2.59 (Hertford, UK)	• Heart rate • ECG	N	Sleep lab	Simultaneous with PSG	Automated	Same as PSG	Total Recording time	RDI
Definition of Apnea:				Same as PSG						
Definition of Hypopnea:				Same as PSG						
Thresholds used:				**Definitions:**						
≥ 10										
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
20 (20)	50%	49 (15)	nd	41.3 ± 11.7 kg/m^2	50%	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
15%	nd	nd	nd	nd	nd	nd	no

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	10.9 ± 5.2	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI ≥5 n/N (%)	AHI ≥10 n/N (%)	AHI ≥15 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
24.1 ± 26.2 (5 - 119)	nd	14/20 (70%)	nd	nd	nd	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	mean difference (95% LOA)	Other Text Description (eg, of bias)
Index	Ref					
Holter Monitor	PSG	20	20	Bland Altman Plot	4.7 (-30.1 - 39.4)	

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

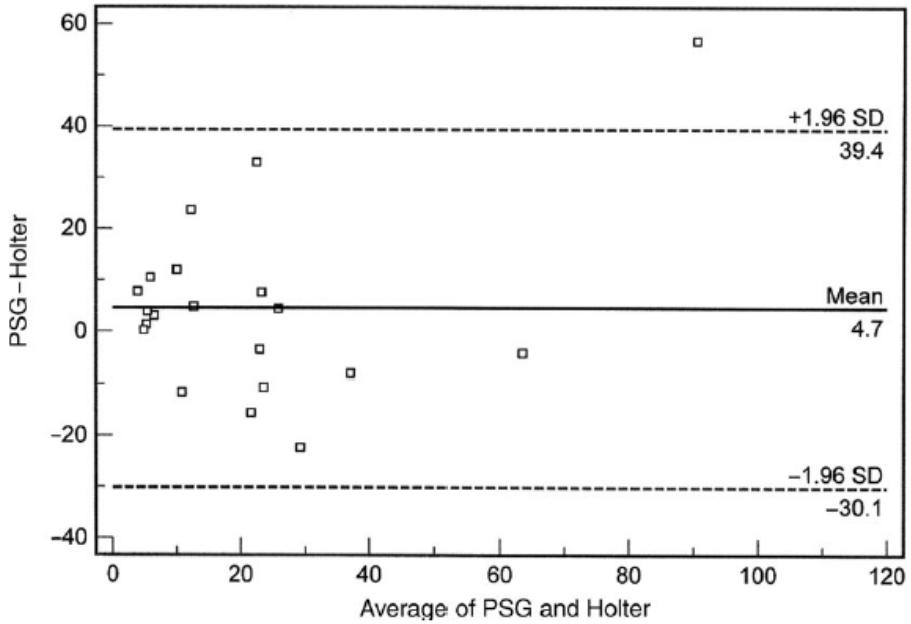


Figure 3 Graphic representation of the measured agreement between polysomnography and Holter-based determination according to Bland and Altman's method.

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (95% CI)	Other
			TP	FN	TN	FP						
Holter vs PSG	RDI ≥ 10	AHI ≥ 10	11	3	5	1	78.5	48.2-94.2	83.3	25.8-89.7	0.81 (0.6-1.0)	

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
0/20	0%	

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	Yes
Data loss / not analyzed (%)	0%
Overall Quality (A/B/C)	A

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	To 2009			**Reference test**	PSG
PMID	19210658	**RefID**	11866	**Index test 1**	ARES (apnoea risk evaluation system)
Key Question(s)	1 (Dx Portable)			**Index test 2**	
Extractor	DM			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Patients with suspected OSAS referred for assessment at a specialist respiratory clinic	nd	N	in 2007	China	Foundation and University (Hong Kong Lung Foundation and the Respiratory Research Fund of The Chinese University of Hong Kong.)	Yes
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Patients with significant sleepiness interfering with daily activities; Two of the following: choking or gasping during sleep, recurrent awakenings from sleep, unrefreshed by sleep, daytime fatigue and impaired concentration	Pregnant women; patients who declined; patients who could not comply with the set-up of the device
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	**Manufacturer (Location)**	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
Siesta	Compumedics (Australia)	Hospital	Manual	criteria of Rechtschaffen and Kales	Total sleep time
Definition of Apnea:			No airflow for ≥ 10 s with respiratory effort		
Definition of Hypopnea:			> 50% airflow reduction or a discernible reduction in airflow with ≥ 3% dip in oxygen saturation and/or an arousal, lasting for ≥ 10 s		
Thresholds used:			**Definitions:**		
<5, 5-15, >15-30, >30					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
III	Apnoea Risk Evaluation System (ARES) Unicorder	Advanced Brain Monitoring (Carlsbad, CA, USA)	• Airflow and respiratory effort • Blood oxygen saturation • pulse rate • snoring levels • head movement • head position	N	Hospital	Simultaneous with PSG	Automated with manual review	Same as PSG	Total recording time	RDI

Definition of Apnea:	same as PSG
Definition of Hypopnea:	same as PSG
Thresholds used:	**Definitions:**
<5, 6-20, 21-40, 41-60, >60	
Comments:	

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
184 (141) – n=175 for baseline characteristics	75%	49	nd	28.7	52% (nd on definition)	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Cerebrovascular accident, % (specify)**	**Is this a Special Population? (which?)**
17%	nd	nd	nd	nd	nd	7%	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	10.4	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI <5 n/N (%)	AHI ≥5-15 n/N (%)	AHI ≥15-30 n/N (%)	AHI >30 n/N (%)
39.3	5.7%	15.6%	23.4%	55.3%

AHI: Apnea-hypopnea index; RDI: respiratory distress index

* Fill in this column only if any cut-offs other than 5 & 15 are used. Replace "?" with number.

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	mean (95% CI or LOA)**	Other Text Description (eg, of bias)
Index	Ref					
ARES Unicorder	PSG	184	141	Bland Altman Plot	From Figure 1 (Uninterpretable even with Digitizer)	Using 3% oxygen desaturation as the scoring criterion
ARES Unicorder	PSG	184	141	Bland Altman Plot	From Figure 2 (Uninterpretable even with Digitizer)	Using 1% oxygen desaturation and head movement as the scoring criteria

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

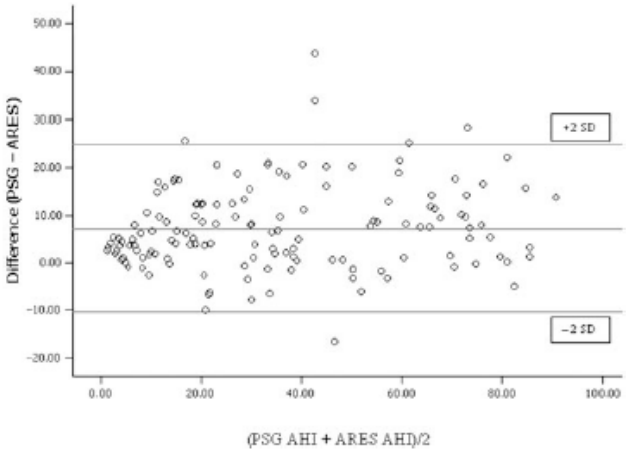


Figure 1 Bland–Altman plot using 3% desaturation as the only scoring criterion. ARES, apnoea risk evaluation system; PSG, polysomnography.

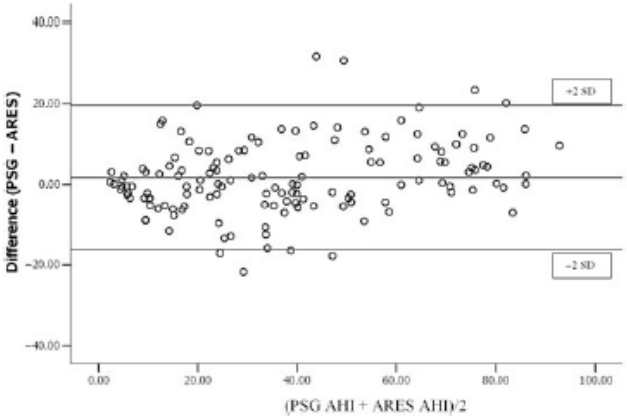


Figure 2 Bland–Altman plot with 1% desaturation and head movement included as the scoring criterion. ARES, apnoea risk evaluation system; PSG, polysomnography.

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (95% CI)	Other
			TP	FN	TN	FP						
ARES Unicorder vs PSG	≥ 5 at 4% oxygen desaturation	≥ 5	112	21	8	0	0.84	0.77,0.90	1	NA	0.96 (0.93–0.99)	
	≥ 5 at 3% oxygen desaturation	≥ 5	118	15	8	0	0.89	0.84,0.94	1	NA	0.97 (0.95–1.00)	
	≥ 5 at 1% oxygen desaturation	≥ 5	129	4	5	3	0.97	0.94,0.99	0.63	0.55,0.71	0.98 (0.95–1.00)	

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
43/184	23%	Refusal to participate (9), ARES recording failure due to poor signal output (21), PSG failure (8), ARES and PSG failure (5)

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	Yes (B-A plots not interpretable)
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	No
Data loss / not analyzed (%)	23%
Overall Quality (A/B/C)	B

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Tonelli de Oliveira, 2009			**Reference test**	PSG
PMID	19201709	**RefID**	11870	**Index test 1**	Home portable monitoring
Key Question(s)	1			**Index test 2**	Lab portable monitoring
Extractor	NO			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Yes. Referred patients	consecutive	n	2004-2006	Brazil	Brazilian Government	y
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Suspected OSAS >18yrs	Pregnant women Comorbidities Patients residing outside the metropolitan area of Porto Alegre
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	**Manufacturer (Location)**	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
Nd(standard methods. EEG, electrooculogram, submental and anterior pretibial electromyograms and ECG	nd	Sleep lab	manual	nd	Total recording time
Definition of Apnea:			standard AASM		
Definition of Hypopnea:			standard AASM		
Thresholds used:			**Definitions:**		
Mild OSA AHI 5 to 15 Moderate AHI 15 to 30 Severe >30					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
III	Somnocheck	Weinmann GmbH, Hamburg, Germany	• Nasal airflow monitor • Position sensor, pressure transducer • O2 sat • Pulse rate	n	Sleep lab (1 night) Home (1 night)	simultaneous	manual	nd	Total recording time >4hours of recording	
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the

same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used		
Name *	Berlin questionnaire	**Description of Test (only if not on our list)**
Thresholds Used (Cut-Offs included)		
Comments:		

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
157(149 lab pm, 121 homepm)	73	45(12)	nd	29.1(5.5)	29.9	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	47	nd	nd	nd	nd	nd	n

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	**Bed partner, %**	**Craniofacial abnormalities/ congenital abnormalities**	**Epworth**	**MSLT**	**Other Clinical symptoms, % (specify)**	**Other characteristics (specify)**
nd	nd	nd	11(5)	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

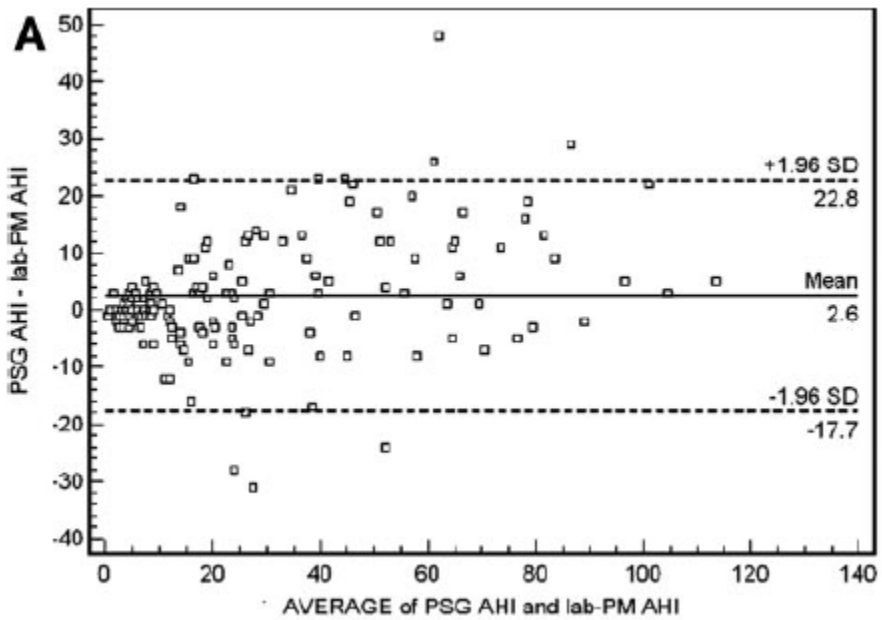
Mean AHI (Range)	**AHI ≥5 n/N (%)**	**AHI ≥10 n/N (%)**	**AHI ≥15 n/N (%)**	**AHI ≥20 n/N (%)**	**AHI ≥30 n/N (%)**	
30.2 (27.8) mean(sd) 21(7.5-45) median (IQR)						

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	**Ref**					
Home portable monitoring	PSG	157	121	Bland Altman plot		
Lab portable monitoring	PSG	157	149			

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression



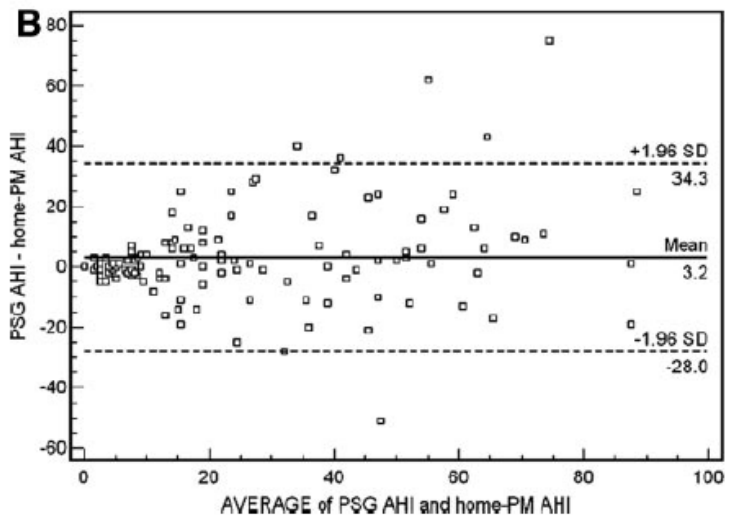


FIGURE 2. Bland-Altman plots. Difference between PSG AHI and home-PM AHI. *Top, A:* AHI performed simultaneously at the laboratory. *Bottom, B:* AHI performed simultaneously at home.

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	+LR/-LR
			TP	FN	TN	FP						
Home pm vs PSG	7	AHI≥5					96.15	92.5-99.8	64.7	42.0-87.4	0.96	2.7/0.05
	9	AHI≥10					90.7	82.7-95.2	82.9	67.3-91.9	0.92	5.2/0.11
	9	AHI≥15					81.3	71.1-88.5	88.4	78.8-94.0	0.91	4.6/0.22
	33	AHI≥30					80.0	68.3-91.7	92.1	86-98.2	0.92	10.1/0.21

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	**% Dropout or analysis failure**	**Reasons**
16/157		<4 hours of recording
5/157		Lost airflow signal
6/157		Lost oximetry
1/157		Did not tolerate equipment (home pm)
1/157		Forgot to wear equipment
Comments on Results:	16% loss to follow up in home pm, significantly greater than 5% loss to follow up in lab pm	

J. Methodological Quality

Prospective or Retrospective?	prospective
Verification bias? (Yes/No; if yes describe)	n
Blinding? (Yes/No)	y
Analytic problem? (Yes/No, if yes describe) *	n
Adequate description of tests (Yes/No, if no describe)	y
Clear description of population studied (Yes/No, if no describe)	y
Data loss / not analyzed (%)	18%
Overall Quality (A/B/C)	A

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Watkins 2009			**Reference test**	PSG
PMID	19786903	**RefID**	19	**Index test 1**	RU*Sleeping* RTS
Key Question(s)	1 (Dx portable)			**Index test 2**	
Extractor	DM			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Commercial motor drivers at high risk for OSA as per Consensus Conference Criteria (American College of Chest Physicians, the American College of Occupational and Environmental, National Sleep Foundation)	Consecutive	No	Sept 2007 – Oct 2008	USA	nd	nd
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Commercial motor drivers at high risk for OSA as per Consensus Conference Criteria	nd
Comments	From the results, it appears that a previous diagnosis by PSG should be included in the exclusion criteria.		

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
nd	nd	Sleep lab	nd	nd	Total sleep time
Definition of Apnea:			nd		
Definition of Hypopnea:			nd		
Thresholds used:			**Definitions:**		
>5, >10, >15, >20, >30					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	RU*Sleeping* RTS	Respironics (Murrysville, PA)	• Airflow (nasal cannula)	N	Community (during driver orientation)	~6-8 weeks before PSG	nd	nd	Total recording time (RDI)	RDI
Definition of Apnea:				nd						
Definition of Hypopnea:				nd						
Thresholds used:				**Definitions:**						
>5, >10, >15, >20, >30										
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
159 (34)	nd	nd	nd	nd	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	Yes (commercial drivers at high risk for OSA)

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	nd	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI >5 n/N (%)	AHI ≥10 n/N (%)	AHI ≥15 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
18.5 (0.8–117)	26/34 (76)	nd	nd	nd	8/34 (24%)	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
RU*Sleeping* RTS vs PSG	> 5	> 15	26	0	3	5	1		0.42			
	> 10	> 15					1		0.71			
	> 15	> 15					0.7		0.83			
	> 20	> 15					0.7		0.83			
	> 30	> 15	3	5	25	1	0.43		0.96			

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
125/159	78%	Termination of employment (76), previous history of PSG diagnosis (50). There is a discrepancy in the total number of dropouts (125) versus sum of the subjects who terminated their employment and had a PSG done earlier (126). This is not explained.

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	nd
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	No (The details of the PGS were not provided)
Clear description of population studied (Yes/No, if no describe)	No (demographic and co-morbidity data not provided, inclusion and exclusion criteria not well defined, the participant flow was not well described, loss to follow up not calculated correctly-wrong denominator)
Data loss / not analyzed (%)	78%
Overall Quality (A/B/C)	C

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	White, 1994			**Reference test**	PSG
PMID	7923843	**RefID**	16937	**Index test 1**	SaO2
Key Question(s)	KQ 1 (Portable)			**Index test 2**	SaO2 + snoring sound
Extractor	EMB			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Referred for possible UPPP	Consecutive (implied)	No	nd	UK	nd	Yes

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Referred for consideration of UPPP	nd
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	**Manufacturer (Location)**	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
nd	nd	Sleep lab	Manual	nd	Total sleep time
Definition of Apnea:			GOULD G.A., WHYTE K.F., RHIND G.B. et al. (1988) The sleep hypopnoea syndrome. Am. Rev. Respir. Dis. 137, 895-900		
Definition of Hypopnea:					
Thresholds used:			**Definitions:**		
AHI 10, 15, 20					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	Brox 3700e (pulse oximeter and finger probe)	Ohmeda (Louisville, KY)	• O2 sat	No	Sleep lab	Simultaneous	Manual (graphed on paper tape)	NA	Total sleep time (implied)	RDI
Definition of Apnea:				NA						
Definition of Hypopnea:				NA						
Thresholds used:				**Definitions:**						
Definite Unlikely Equivocal				Diagnostic of OSA No evidence of OSA Technically unsatisfactory or uninterpretable All based on observers' judgment (apparently)						

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	As above Sound level meter (90±15 cm above head)	As above nd	• O2 sat • Sound level	No	Sleep lab	Simultaneous	Manual (graphed on paper tape)	Not described	Total sleep time (implied)	RDI
Definition of Apnea:				NA						
Definition of Hypopnea:				NA						
Thresholds used:				**Definitions:**						
Definite Unlikely Equivocal				Diagnostic of OSA No evidence of OSA Technically unsatisfactory or uninterpretable All based on observers' judgment (apparently)						

A Describe Flow and Effort channels / indicate nd if not described in the study

B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
37 (37)	68%	37±16	nd	nd	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	UPPP being considered

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI [RDI] (Range)	AHI ≥5 (%)	AHI ≥15 (%)	AHI ≥10 // 20 (%)*
nd		7/39 (18%)	21/39 (54%) // 5/39 (13%)

AHI: Apnea-hypopnea index; RDI: respiratory distress index
* Fill in this column only if any cut-offs other than 5 & 15 are used. Replace "?" with number.

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	TP	FN	TN	FP	Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
SaO2 vs PSG	NA	AHI≥10	7	14	18	0	0.30		1.00			
		AHI≥15	5	2	30	2	0.71		0.94			
		AHI≥20	5	0	32	2	1.00		0.94			
SaO2+sound	NA	AHI≥10	13	8	18	0	0.62		1.00			
		AHI≥15	6	1	25	7	0.86		0.78			
		AHI≥20	5	0	26	8	1.00		0.76			

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

n/N	% Dropout	Reasons
	0	

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	Yes 37 patients, 39 sets of tests
Adequate description of tests (Yes/No, if no describe)	No (no explanation on how index test results defined
Clear description of population studied (Yes/No, if no describe)	No (almost no data on population)
Data loss / not analyzed (%)	No
Overall Quality (A/B/C)	C

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments
Index tests assessed by 2 independent observers. Equivocal studies (unsatisfactory or uninterpretable) categorized as negative (for Sn/Sp). When 2 observers disagreed, categorized as negative (Sn/Sp). SaO2: 9/39 disagreements between observers (4 equivocal-unlikely (both “negative”), 5 equivocal-definite);1 technically unsatisfactory SaO2+sound: 8/39 disagreements between observers (4 equivocal-unlikely (both “negative”), 4 equivocal-definite); nd on how many technically unsatisfactory

A. Source and Extractor

Author, Year	Wong 2008			**Reference test**	PSG
PMID	18411561	**RefID**	14970	**Index test 1**	Nasal Airflow
Key Question(s)	KQ 1 Portable			**Index test 2**	MAPI
Extractor	EMB			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Sleep center referral	Consecutive	No	nd	Australia	Industry Government	Yes

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Suspected sleep-disordered breathing scheduled for PSG 18-55 yo	None
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	**Manufacturer (Location)**	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
Alice4	Respironics (Murrysville, PA)	Sleep lab	Manually	AASM, 1999 Rechtschaffen & Kales, 1968	Total sleep time
Definition of Apnea:			Airflow cessation ≥10 sec		
Definition of Hypopnea:			Reduction in airflow ≥10 sec with EEG arousal or 3% desat		
Thresholds used:			**Definitions:**		
OSA: AHI ≥10 Severe OSA: AHI ≥30					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	FlowWizard	DiagnoseIT (Sydney, Australia)	• Nasal airflow monitor	No	Lab (1 night) Home (3 consecutive nights)	nd	Automated	NA	Recording time with adequate data. Averaged over 3 consecutive nights	RDI
Definition of Apnea:				Absolute flow signal dropped below a near-zero threshold ≥10 sec (excluding >120 sec)						
Definition of Hypopnea:				Absolute flow signal dropped 50% of nominal maximum flow ≥10 sec						
Thresholds used:				**Definitions:**						
"Flow monitor AHI" 10, 30										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used			
Name *	Multivariable Apnea Prediction Index (MAPI)	**Description of Test (only if not on our list)**	Maislin 1995 Snoring, breathing stops, choking
Thresholds Used (Cut-Offs included)			
Comments:			

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
34 (33)	97%	42±10	nd	30.2±5.4	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	**Bed partner, %**	**Craniofacial abnormalities/ congenital abnormalities**	**Epworth**	**MSLT**	**Other Clinical symptoms, % (specify)**	**Other characteristics (specify)**
nd	nd	nd	11.9±4.7	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI [RDI] (Range)	**AHI ≥5 [RDI≥5] (%)**	**AHI ≥15 [RDI≥15] (%)**	**AHI ≥10 // 30 (%)***
31.5±27.2 (0-100)	nd	nd	79% // 39%

AHI: Apnea-hypopnea index; RDI: respiratory distress index
* Fill in this column only if any cut-offs other than 5 & 15 are used. Replace "?" with number.

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N	N	Concordance	Value (LOA)	Other Text Description (eg, of
Index	**Ref**	**Enrolled**	**Analyzed**	**Metric***		**bias)**
FlowWizard (home, 3 night average)	PSG	34	31	B-A LOA	1.8±17.1 (-32.4, 36.0)	Greater differences seen with high AHI
FlowWizard (lab)	PSG	34	31	B-A LOA	7.1±11.1 (-14.8, 29.0)	

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

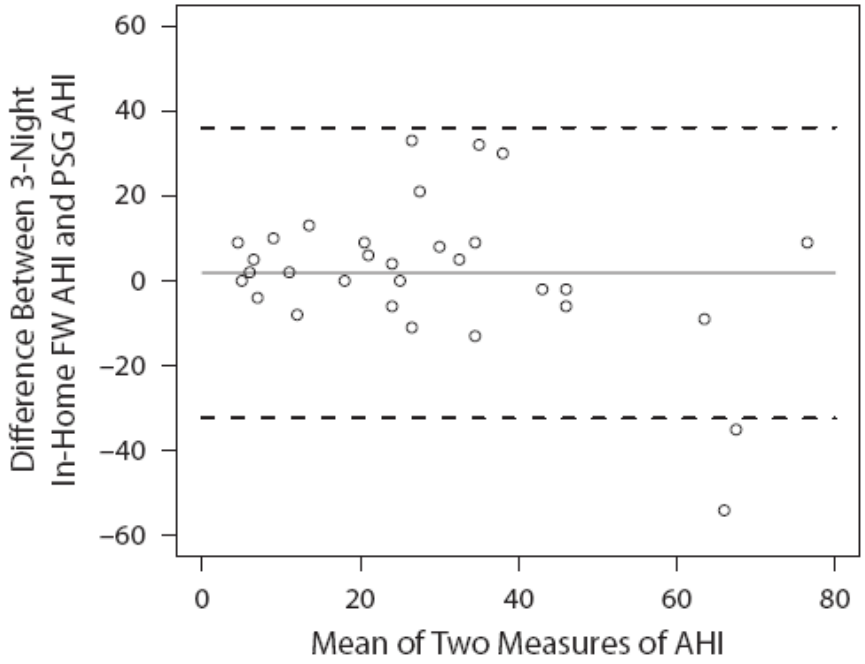


Figure 2. Bland and Altman (1986) plot comparing the apnea–hypopnea index (AHI) derived from three nights on flow monitor (FW) with AHI scored in an in-laboratory polysomnogram (PSG).

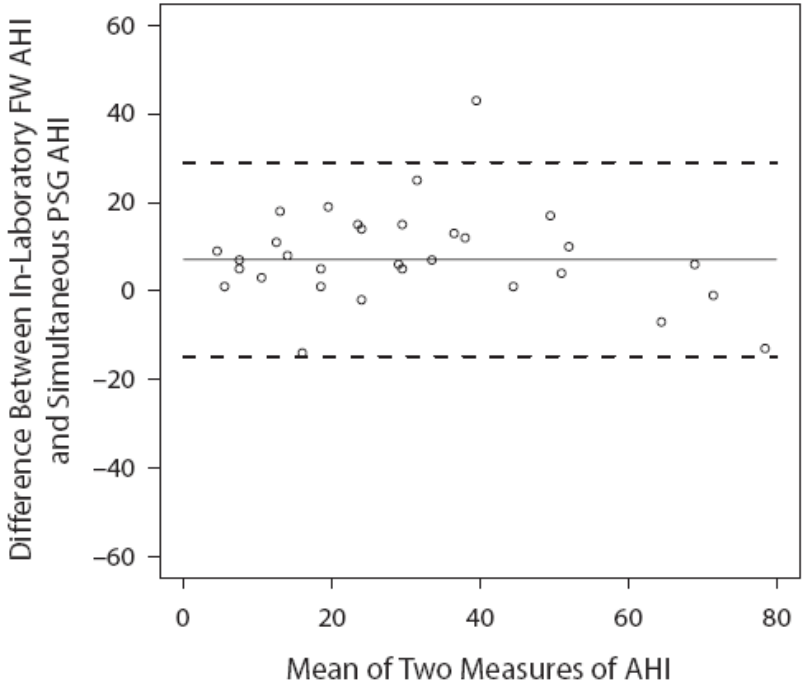


Figure 5. Bland and Altman (1986) plot comparing AHI from the in-laboratory PSG and the simultaneous flow monitor recording.

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	TP	FN	TN	FP	Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
FlowWizard (home, 3 night) v PSG	FW AHI>8	AHI≥10	24	0	3	4	100		43		0.96	
	FW AHI>12		23	1	5	2	96		71			
	FW AHI>18		22	2	6	1	92		86			Highest DOR
	FW AHI>21		21	3	7	0	88		100		Q*	
FlowWizard (home, 1 night) v PSG	FW AHI	AHI≥10									0.92	
FlowWizard (lab) v PSG	FW AHI>18	AHI≥10	23	1	5	2	96		71		0.95	Highest DOR
FlowWizard (home, 3 night) v PSG	FW AHI>21	AHI≥30	11	0	10	10	100		50		0.85	
	FW AHI>28		10	1	15	5	91		75		Q*	Highest DOR
	FW AHI>45		4	7	18	2	36		90			
	FW AHI>59		2	9	20	0	18		100			
FlowWizard (home, 3 night) v PSG	FW AHI	AHI≥30									0.89	
MAPI v PSG		AHI≥10									0.68	
Combined FlowWizard (home, 3 night) & MAPI v PSG		AHI≥10									0.96	

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

n/N	% Dropout	Reasons
3/34	9	1 withdrew 2 had inadequate data on all 3 nights

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	No
Data loss / not analyzed (%)	9%
Overall Quality (A/B/C)	A (though poor description of population)

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Yagi 2009			**Reference test**	PSG
PMID	18635324	**RefID**	11956	**Index test 1**	Apnomonitor 5
Key Question(s)	1 (Dx Portable)			**Index test 2**	
Extractor	DM			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Adults with suspected sleep apnea syndrome	Consecutive patients	N	Mar 2005 – Oct 2006 (18 months)	Japan	nd	Yes
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	nd	nd
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	**Manufacturer (Location)**	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
Alice 4	Respironics Inc. (Murrysville, PA,USA)	Sleep lab	automated with manual review	nd	Total sleep time
Definition of Apnea:			No airflow for ≥ 10 s		
Definition of Hypopnea:			≥ 30% reduction in airflow with 3% reduction in SpO2 or with an arousal for ≥ 10 s		
Thresholds used:			**Definitions:**		
≥ 15					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	Apnomonitor 5	Chest Co. (Tokyo, Japan)	• Oronasal thermistor • pulse oximeter • chest and abdominal belts • tracheal sound monitor • position detector	N	Sleep lab	Simultaneous with PSG	automated with manual review	nd	Total recording time	RDI
Definition of Apnea:				≥ 75% reduction in airflow through the mouth and nose lasting for ≥ 10 s						
Definition of Hypopnea:				<75% and ≥ 50% reduction in airflow accompanied by either oxygen desaturation ≥ 3%.						
Thresholds used:				**Definitions:**						
≥ 15										
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name * **Thresholds Used (Cut-Offs included)** **Comments:**	**Description of Test (only if not on our list)**

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
22(22)	77%	53 ± 13 (31-74)	?East Asian	25.7 ± 4.4 kg/m^2 (18.8–39.3)	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	nd	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI ≥5 n/N (%)	AHI ≥10 n/N (%)	AHI ≥15 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
43.9 ± 21.2	nd	nd	nd	nd	nd	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
Apnomonitor vs PSG	≥ 15	≥ 15					0.95					

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
0/22	0%	

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	Yes (No data on specificity, AUC, full analysis/analysis plan for validation of Apnomonitor is not reported)
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	No (AHI cut-0ff prevalences, comorbidities)
Data loss / not analyzed (%)	0%
Overall Quality (A/B/C)	C

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

Key Question 1
Miscellaneous v PSG

A. Source and Extractor

Author, Year	Chung 2008			**Reference test**	PSG
PMID	18431116	**RefID**	14146	**Index test 1**	STOP Questionnaire
Key Question(s)	1 (Dx Misc)			**Index test 2**	STOP-Bang Questionnaire
Extractor	DM			**Comments**	Only data from the validation phase is extracted. Data from the development phase (n=245) and the pilot phase (n=34) were not extracted.

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Preoperative patients	Case series	Yes	nd	Canada	Foundation and Hospital funds	Yes
Comments	Selection bias is evident, as only 211/2721 (8%) of the patients invited for PSG actually were assessed by that method.					

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	≥ 18 yr; ASA physical status of I- IV; scheduled to undergo elective procedures in general surgery, gynecology, orthopedics, urology, plastic surgery, ophthalmology, or neurosurgery	Unwilling or unable to give informed consent; diagnosed with OSA or sleep breathing disorder; expected to have abnormal electroencephalographic findings (e.g., brain tumor, epilepsy surgery, patients with deep brain stimulator)
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
nd	nd	sleep lab	manual	standard scoring criteria	Total sleep time
Definition of Apnea:			AASM, 1999		
Definition of Hypopnea:			AASM, 1999		
Thresholds used:			**Definitions:**		
>5, >15, >30					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
			•							
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used			
Name *	1)STOP Questionnaire 2)STOP-Bang Questionnaire	**Description of Test (only if not on our list)**	STOP - *S*noring, *T*iredness during daytime, *O*bserved apnea, and high blood *P*ressure (STOP). STOP-Bang – STOP + *B*MI, *A*ge, *N*eck circumference, and *G*ender
Thresholds Used (Cut-Offs included)	High risk of OSA vs Low Risk of OSA		
Comments:			

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
2127 (177)	50%	55 ± 13	nd	30 ± 6	41% (nd)	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Asthma, % (specify)**	**Is this a Special Population? (which?)**
18%	nd	32%	nd	nd	6%	14%	Yes (pre-op patients)

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	ASA Physical Status, % (specify)	Other characteristics (specify)
nd	nd	nd	nd	nd	I-6% II-57% III-36% IV- 1%	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI > 5 n/N (%)	AHI > 15 n/N (%)	AHI > 30 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
20 ± 6	122/177 (68.9)	70/177 (39.5)	39/177 (22.03)	nd	nd	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
STOP vs PSG	High vs low	>5	80	42	33	22	65.6	56.4, 73.9	60.0	45.9, 73.0	0.703	
		>15	52	18	57	50	74.3	62.4, 84.0	53.3	43.4, 63.0	0.722	
		>30	31	8	67	71	79.5	63.5, 90.7	48.6	40.0, 63.0	0.769	
STOP-Bang vs PSG	High vs low	>5	102	20	31	24	83.6	75.8, 89.7	56.4	42.3, 69.7	0.806	
		>15	65	5	46	61	92.9	84.1, 97.6	43.0	33.5, 52.9	0.782	
		>30	39	0	51	87	100	91.0, 100.0	37.0	28.9, 45.6	0.822	

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
0/177	0%	Only because the validation study was conducted on patients who had data from both the questionnaire as well as the PSG; Otherwise, dropout was 91.4% if we consider all patients who were given the STOP questionnaire. If we only consider the people who consented to the PSG but did not turn up, the drop out was 211/416 (49.3%)

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	Yes (Selection bias; only 211/2467 patients came for PSG)
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	Yes
Data loss / not analyzed (%)	0% (Only because the validation study was conducted on patients who had data from both the questionnaire as well as the PSG-see above)
Overall Quality (A/B/C)	C

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Chung 2008			**Reference test**	PSG
PMID	18431117	**RefID**	7172	**Index test 1**	STOP Questionnaire
Key Question(s)	1 (Dx Misc), 4 (Predictor of post-op complications)			**Index test 2**	Berlin Questionnaire
				Index test 2	American Society of Anesthesiologists (ASA) Surgical checklist
Extractor	DM			**Comments**	(i) Sensitivity, Specificity and AUC of STOP Questionnaire vs PSG is extracted in Chung 2008 (PMID: 18431116); that data is not re-extracted here. STOP has been included to answer KQ4. (ii) All extracted study elements are same as in Chung 2008 (PMID: 18431116), except for the results. **(iii) Data for KQ4 has been extracted separately.**

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Preoperative patients	Case series	Yes	nd	Canada	Foundation and Hospital funds	Yes
Comments	Selection bias is evident, as only 211/2721 (8%) of the patients invited for PSG actually were assessed by that method.					

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	≥ 18 yr; ASA physical status of I- IV; scheduled to undergo elective procedures in general surgery, gynecology, orthopedics, urology, plastic surgery, ophthalmology, or neurosurgery	Unwilling or unable to give informed consent; diagnosed with OSA or sleep breathing disorder; expected to have abnormal electroencephalographic findings (e.g., brain tumor, epilepsy surgery, patients with deep brain stimulator)
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
nd	nd	sleep lab	manual	standard scoring criteria	Total sleep time
Definition of Apnea:			AASM, 1999		
Definition of Hypopnea:			AASM, 1999		
Thresholds used:			**Definitions:**		
>5, >15, >30					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
			•							
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used			
Name *	3)STOP Questionnaire 4)Berlin Questionnaire 5)American Society of Anesthesiologists (ASA) Screening Checklist for OSA in Surgical Partients	**Description of Test (only if not on our list)**	STOP - *S*noring, *T*iredness during daytime, *O*bserved apnea, and high blood *P*ressure (STOP). Berlin -
Thresholds Used (Cut-Offs included)	High risk of OSA vs Low Risk of OSA		
Comments:	**Berlin is not validated in surgical patients, and ASA checklist is not validated in any population**		

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
2127 (211)	50%	55 ± 13	nd	30 ± 6	41% (nd)	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Asthma, % (specify)**	**Is this a Special Population? (which?)**
18%	nd	32%	nd	nd	6%	14%	Yes (pre-op patients)

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	ASA Physical Status, % (specify)	Other characteristics (specify)
nd	nd	nd	nd	nd	I-6% II-57% III-36% IV- 1%	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI > 5 n/N (%)	AHI > 15 n/N (%)	AHI > 30 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
20 ± 6	122/177 (68.9)	70/177 (39.5)	39/177 (22.03)	nd	nd	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
Berlin vs PSG	High vs low	>5	84	38	31	24	68.9	59.8, 76.9	56.4	42.3, 69.7	0.690	
		>15	55	15	54	53	78.6	67.1, 87.5	50.5	40.6, 62.3	0.672	
		>30	34	5	64	74	87.2	72.6, 95.7	46.4	37.9, 55.1	0.668	
ASA Checklist vs PSG	High vs low	>5	88	34	21	34	72.1	63.3, 79.9	38.2	25.4, 52.3	0.783	
		>15	55	15	40	67	78.6	67.1, 87.5	37.4	28.2, 47.3	0.730	
		>30	34	5	50	88	87.2	72.6, 95.7	36.2	28.2, 44.8	0.617	

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
0/177	0%	Only because the validation study was conducted on patients who had data from both the questionnaire as well as the PSG; Otherwise, dropout was 91.4% if we consider all patients who were given the STOP questionnaire. If we only consider the people who consented to the PSG but did not turn up, the drop out was 211/416 (49.3%)

J. Methodological Quality

Prospective or Retrospective?	Prospective	
Verification bias? (Yes/No; if yes describe)	No	
Blinding? (Yes/No)	Yes	
Analytic problem? (Yes/No, if yes describe) *	Yes (Selection bias; only 211/2467 patients came for PSG)	
Adequate description of tests (Yes/No, if no describe)	Yes	
Clear description of population studied (Yes/No, if no describe)	Yes	
Data loss / not analyzed (%)	0% (Only because the validation study was conducted on patients who had data from both the questionnaire as well as the PSG-see above)	
Overall Quality (A/B/C)	C	

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Crocker 1990			**Reference test**	PSG
PMID	2368960	**RefID**	13086	**Index test 1**	Statistical model developed from clinical data and questionnaire responses
Key Question(s)	1 (Dx Misc)			**Index test 2**	
Extractor	DM			**Comments**	Data from 100 patients used in developing the model is reported but not extracted.

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Patients referred for suspected abnormal breathing	Consecutive	N	July 1987 - May 1988	Australia	nd	nd
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Retrospective	Patients referred for suspected abnormal breathing	
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
PSG with Oximeter-Biox rIA or 3700	Respitrace Corporation (Ardsley, NY), Oximeter - Ohmeda (CO)	Sleep lab	nd	Rechtschaffen & Kales 1968	Total sleep time
Definition of Apnea:			Cessation of airflow at the nose and mouth for ≥ 10 s		
Definition of Hypopnea:			Decrease in ≥ 50% airflow for ≥ 10 s with a decrease in the uncalibrated thoracoabdominal tracing		
Thresholds used:			**Definitions:**		
> 15					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator[D]	RDI or AHI (only with Type II devices)
			•							
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used			
Name *	nd	**Description of Test (only if not on our list)**	Statistical model to predict the probability of a patient having AHI > 15, based on logistic regression of data from a 24 item questionnaire and clinical characteristic
Thresholds Used (Cut-Offs included)	> 15		
Comments:			

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y Mean ± SEM	Race	BMI* Mean ± SEM	HTN, % (how defined?) or BP (mean ± SEM)	AFib/AFlutter, %	CVD †, % (specify)
114 (105)	82%	**51.4 ± 1.1**	**nd**	30.4 ± 0.5	**57% (***HTN= diastolic BP ≥ 95 or on medication)* **Systolic BP:** 141 ± 2 mmHg **Diastolic BP:** 91 ± 1 **mmHg**	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
75%	nd	nd	nd	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI ≥5 n/N (%)	AHI ≥10 n/N (%)	AHI > 15 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
nd	nd	nd	36 / 105 (34.3%)	nd	nd	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
Statistical Model from Questionnaire and clinical features vs PSG	Probability of OSA > 0.15	> 15	33	3	35	34	0.92		0.51			

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
9/114	8%	

J. Methodological Quality

Prospective or Retrospective?	Retrospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	nd
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	No (mean AHI not reported, comorbidities not reported)
Data loss / not analyzed (%)	0%
Overall Quality (A/B/C)	B

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Gurubhagavatula 2001			**Reference test**	PSG
PMID	11734444	**RefID**	15338	**Index test 1**	Clinical prediction rule: Combination of Multivariable Apnea Prediction (MAP) questionnaire score and oximetry results
Key Question(s)	1 (Dx Misc)			**Index test 2**	
Extractor	DM			**Comments**	Only the data from validation sample is extracted. For baseline characteristics, the data is from all of the group – both estimation and validation patient groups.

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Referred for evaluation of sleep apnea	nd	No	nd	USA	Govt. (NIH)	Yes
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	All patients referred for sleep evaluation	Dx of OSA or obesity-hypoventilation syndrome or using supplemental oxygen
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
nd	nd	sleep lab	Manual	Rechtschaffen and Kales	Total recording time (RDI)
Definition of Apnea:			AASM, 1999		
Definition of Hypopnea:			AASM, 1999		
Thresholds used:			**Definitions:**		
≥ 5, ≥ 30					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
			•							
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used			
Name *	Clinical prediction rule: Combination of Multivariable Apnea Prediction (MAP) questionnaire score and oximetry results	**Description of Test (only if not on our list)**	MAP score predicts apnea risk using a score between 0 and 1, with 0 representing low risk and 1 representing high risk. Oximetry desaturation index (ODI) using a 3% drop (ODI3) as well as a 4% drop (ODI4) in oxygen saturation. Optimal model parameters obtained by the bootstrapping technique
Thresholds Used (Cut-Offs included)	**Objective 1** (Dx sleep apnea – RDI ≥ 5): Upper bound for MAP score = 0.58 (range 0.5–0.8), Lower bound for MAP score = 0.14 (range 0.1–0.2) ODI threshold =5.02 desaturations/h (range 5–10). **Objective 2** (Select patients for split night studies RDI ≥ 30): Upper bound for MAP score = 0.9 (range 0.9–0.9) Lower bound for MAP score = 0.38 (range 0.2–0.5), ODI threshold= 21/h (range 10–25).		
Comments:			

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
421 (359)	68%	47 ± 13 years	72.2% white, 24.2% black 3.6% other.	32.4 ± 8.8 kg/m^2	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	no

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	nd	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean RDI (Range)	RDI ≥5 n/N (%)	AHI ≥10 n/N (%)	RDI ≥15 n/N (%)	AHI ≥20 n/N (%)	RDI ≥30 n/N (%)	
25.9 ± 29.5 events/h [median 12 , range 0-110]	69.4%	nd	47.1%	nd	33%	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95 % CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
Clinical Prediction rule vs PSG	Upper bound for MAP score = 0.58 (range 0.5–0.8), Lower bound for MAP score = 0.14 (range 0.1–0.2) ODI threshold =5.02 desaturations/h (range 5–10).	≥ 5					0.941		0.667			
	Upper bound for MAP score = 0.9 (range 0.9–0.9) Lower bound for MAP score = 0.38 (range 0.2–0.5), ODI threshold= 21/h (range 10–25).	≥ 30					0.833		0.947			

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
62/421	15% for estimation sample, 0% for validation sample	Referred for "split-night" study (46), previous OSA Dx (12), using supplemental oxygen (3), incomplete MAP questionnaire (1)

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	No
Data loss / not analyzed (%)	0%
Overall Quality (A/B/C)	A

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Kapuniai 1988			**Reference test**	PSG
PMID	3227223	**RefID**	12428	**Index test 1**	Apnea Score derived from the Hawaii Sleep Questionnaire (HSQ)
Key Question(s)	1 (Dx Misc)			**Index test 2**	
Extractor	DM			**Comments**	Data from 43 patients in the development set was not extracted

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Adult sleep disorder center patients	Consecutive	N	nd	USA	Non-profit (Leahi Trust and George F. Straub Trust)	nd
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Patients at the sleep disorder center without regard to their complaints or final diagnosis	nd
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
nd	nd	sleep lab	Manual	nd	
Definition of Apnea:			nd, only duration ≥ 10 s		
Definition of Hypopnea:			nd, only duration ≥ 10 s		
Thresholds used:			**Definitions:**		
> 5, > 10					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
			•							
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used			
Name *	Apnea Score derived from the Hawaii Sleep Questionnaire (HSQ)	**Description of Test (only if not on our list)**	The HSQ includes questions on characteristics in sleep apnea patients: (a) stopping breathing during sleep, (b) loud snoring, and (c) waking from sleep gasping or short of breath. Additional questions on sex, age, height, weight, sleep history and history of tonsillectomy or adenoidectomy. The final model included self-reports of loud snoring, breathing cessation during sleep and adenoidectomy.
Thresholds Used (Cut-Offs included)	≥ 3		
Comments:	A score ≥ 3 puts the person in the apnea group, and <3 is a non-apneic subject		

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
53 (53)	79%	46 ± 14.2 (17-78) years	White: 38% Oriental: 30% Hawaiian-part-Hawaiian: 19% Other: 13%).	nd	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	Yes (patients with sleep disorders)

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	nd	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI ≥5 n/N (%)	AHI ≥10 n/N (%)	AHI ≥15 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
nd	nd	nd	nd	nd	nd	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
Apnea score vs PSG	≥ 3	>5					0.59		0.69			
	≥ 2 (No adenoidectomy score)	>5					0.70		0.65			
	≥ 2 (No adenoidectomy score)	>10					0.78		0.67			

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
0/53	0%	

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	nd
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	No (PSG results not reported)
Data loss / not analyzed (%)	0%
Overall Quality (A/B/C)	B

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Kushida 1997			**Reference test**	PSG
PMID	9341055	**RefID**	12475	**Index test 1**	Morphometric model including BMI and neck circumference
Key Question(s)	1 (Dx Misc)			**Index test 2**	BMI ≥ 25 kg/m^2
				Index test 3	Neck circumference ≥ 40 cms
Extractor	DM			**Comments**	Model development data from 30 subjects (15 OSAS, 15 controls) and cross-validated in the 423 subjects by bootstrap method was not extracted;

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Referred for sleep disorders	Consecutive	No	nd	USA	Government (NIH)	Yes
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Visiting sleep clinic for first time	previous diagnosis of OSAS, other sleep disorders, or insomnia
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
nd	nd	sleep lab	manual	nd	Total recording time
Definition of Apnea:			nd		
Definition of Hypopnea:			nd		
Thresholds used:			**Definitions:**		
≥ 5					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
			•							
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used			
Name *	Morphometric model	**Description of Test (only if not on our list)**	**Model: P + (Mx - Mn) + 3 X OJ + 3 X [Max (BMI -25, 0)] X (NC / BMI)** P = palatal height (in millimeters); Mx is the maxillary intermolar distance (in millimeters) between the mesial surfaces of the crowns of the maxillary second molars; Mn is the mandibular intermolar distance (in millimeters) between the mesial surfaces of the crowns of the mandibular second molars; OJ is the overjet (in millimeters), or the horizontal overlap of the crowns of the maxillary and mandibular right central incisors; BMI is the body mass index (kg/m2; ideal BMI < 25); Max (BMI -25, 0) refers to the larger of the two quantities: BMI - 25, or zero. If BMI is <= 25, then [Max (BMI - 25, 0)] is zero; if BMI > 25, then BMI - 25 is inserted into the formula NC is neck circumference (in centimeters) measured at the level of the cricothyroid membrane.
Thresholds Used (Cut-Offs included)	≥ 70		
Comments:			

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
423 (300)	75%	47 (15-75)	White: 240/300 (80%) African American: 10 (3.3%) Asian/pacific Islander: 28/300 (9.3%) Native American: 22/300 (7.4%)	32	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	10.9	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean RDI (Range)	RDI ≥5 n/N (%)	RDI ≥10 n/N (%)	RDI ≥15 n/N (%)	RDI ≥20 n/N (%)	RDI ≥30 n/N (%)	
Those with OSAS: 40.7 ± 42.8 Those without OSAS: 0.8 ± 0.8 Mean: 34.6	nd	nd	nd	nd		

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
Morphometric model vs PSG	≥ 70	≥ 5	248	6	46	0	0.976	(0.95-0.989)	1.00	(0.92-1.0)	0.996	
BMI vs PSG	≥ 25 kg/m^2	≥ 5	235	19	34	12	0.925	(0.893-0.958)	0.739	(0.612-0.866)	0.938	
Neck circumference vs PSG	≥ 40 cms	≥ 5	154	100	43	3	0.606	(0.546-0.666)	0.934	(0.863-1.0)	0.898	

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
123/423	29%	Deferred PSG (57); Previous diagnosis of OSAS or another sleep disorder or had a history of upper airway surgery or use of orthodontic sleep apnea devices, nasal CPAP or supplementary oxygen therapy (66)

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	Yes (123 patients did not have a PSG due to another diagnosis, selection bias)
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	Yes
Data loss / not analyzed (%)	29%
Overall Quality (A/B/C)	C

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Netzer 1999			**Reference test**	4-Channel Portable Monitor (Eden Tec recorder)
PMID	10507956	**RefID**	16588	**Index test 1**	Berlin Questionnaire
Key Question(s)	1 (Dx Questionnaire)			**Index test 2**	
Extractor	DM			**Comments**	Even though the Berlin Questionnaire is now a validated tool, in this study, it was being validated in a "development set", and not tested further in an "evaluation" set.

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
general population visiting primary care physician	Consecutive	Yes	nd	USA	Industry. University, NIH and VA Medical Service	Yes
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Patients who visited the study physician for any reason.	None
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
Eden Tec recorder	Nellcor Puritan Bennett (Minneapolis, Minnesota)	Home	Manual	nd	Total recording time
Definition of Apnea:			nd		
Definition of Hypopnea:			nd		
Thresholds used:			**Definitions:**		
>5, >15, >30					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
			•							
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used		
Name *	Berlin Questionnaire	**Description of Test (only if not on our list)**
Thresholds Used (Cut-Offs included)	High Risk: Classified as "high risk" in 2 of 3 symptom categories - (a) snoring (b) wake time sleepiness and drowsy driving (c) h/o high blood pressure or BMI >30 kg/m^2 Low Risk: All others	
Comments:		

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
1008 (744)	41.7%	49 ± 18	nd	29 ± 7.2	26.1% (Self reported)	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
52.2%	nd	nd	nd	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean RDI (Range)	RDI > 5 n/N (%)	RDI > 15 n/N (%)	RDI > 30 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
High-risk group: 21.1 ± 18.5 (0, 101) Low-risk group: 4.7 ± 7.0 (0, 37)	66/100 (66%)	38/100 (38%)	13/100 (13%)			

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
Berlin Questionnaire vs 4-Channel Eden Tec recorder	high-risk (high risk in 2/3 categories) vs low-risk	≤ 5	26	8	59	7	0.77		0.89			
		> 5	57	9	26	8	0.86		0.77			
		> 15					0.54		0.97			
		> 30					0.17		0.97			

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	Even though there is no obvious verification bias, there is a noticeable bias as 69 of the first 75 patients (arranged in alphabetical order of their names) in the high-risk group (92%) who were invited to participate in the sleep studies underwent the sleep study, as compared to 31 of the first 65 patients (48%) in the lower-risk group (also arranged in alphabetical order of their names).

H. Subgroup Analysis (If present)

If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
264/1008	26%	Time constraints, unavailability of staff, patient refusal.
40/140	29%	37 declines, 3 no data collected

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	Yes (Probable selection Bias with respect to participant response rate of the invitation to participate in the sleep study in both the high- and low-risk groups)
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	No
Data loss / not analyzed (%)	26% (Questionnaire), 29% (Comparison with sleep study)
Overall Quality (A/B/C)	C

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).

Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Onen, 2008			**Reference test**	PSG
PMID	18775037	**RefID**	14639	**Index test 1**	Observation-based Nocturnal Sleep Inventory (ONSI)
Key Question(s)	KQ 1			**Index test 2**	
Extractor	EMB			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Referred to sleep center	Consecutive	No	2005-2006	France	Government Savings bank foundation	Yes

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Suspected of having sleep apnea Referred to a geriatric sleep center Caucasian ≥70 y	Heart failure Nocturnal O2 supplementation Severe dementia (MMSE<10) Major psychiatric disorder Too sick for evaluation Inability to use CPAP Previous PSG or care for SA
Comments	Suspected of SA because of snoring, excessive daytime sleepiness, overweight or obesity (at least 1 of 3 as reported by patient, caregiver or relative).		

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
Embla	Flaga hf. (Reykjavik, Iceland)	Sleep lab	nd	Rechtschaffen & Kales ASDA 1992	Sleep time
Definition of Apnea:			Cessation of airflow ≥10 sec		
Definition of Hypopnea:			Reduction of airflow >50% or chest respiratory effort 10 sec (4% desat was considered significant)		
Thresholds used:			**Definitions:**		
AHI >15					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels A	Actigraphy (Y/N)	Setting B	Timing C	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator D	RDI or AHI (only with Type II devices)
			•							
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used			
Name *	Observation-based Nocturnal Sleep Inventory (ONSI)	**Description of Test (only if not on our list)**	Nurse observations made in five standardized hourly bedside visits over the course of 1 night. (See comments)
Thresholds Used (Cut-Offs included)			
Comments:	At each visit, approximately 5 minutes of listening and observation is required to detect three nocturnal conditions that characterize sleep-disordered breathing: interrupted breathing (apnea), gasping, or choking; snoring; and awakening (See below) Performed in person's room (90% in hospital or nursing home)		

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

Table A1. ONSI Instructions

Lights-Off Time: Date: . . .	Interrupted Breathing (Apnea), Gasping, or Choking	Snoring	Awakening
Visit#1, **about 2 hours after lights-off**			
Time: . . .	☐☐	☐☐	☐☐
Comments: . . .	**yes no**	**yes no**	**yes no**
Visit#2, **about 1 hour after previous visit**			
Time: . . .	☐☐	☐☐	☐☐
Comments: . . .	**yes no**	**yes no**	**yes no**
Visit#3, **about 1 hour after previous visit**			
Time: . . .	☐☐	☐☐	☐☐
Comments: . . .	**yes no**	**yes no**	**yes no**
Visit#4, **about 1 hour after previous visit**			
Time: . . .	☐☐	☐☐	☐☐
Comments: . . .	**yes no**	**yes no**	**yes no**
Visit#5, **about 1 hour after previous visit**			
Time: . . .	☐☐	☐☐	☐☐
Comments: . . .	**yes no**	**yes no**	**yes no**

ONSI = Observation-based nocturnal sleep inventory.

An observer (nurse or care giver) making standardized visits to the patient's bed during the night completes the Observation-based Nocturnal Sleep Inventory. All precautions should be taken to ensure that the patient will have minimum disturbance from environmental conditions. During the period of observation and between visits, it is recommended that the door of the patient's room be left slightly ajar to avoid disturbing him or her by having to open the door. To obtain reliable results from the sleep inventory, the patient must be in a single room.

Nocturnal visits protocol:

1. Lights-off time should be noted.
2. Two hours after lights-off, the observer should make at least five visits at approximately 1-hour intervals.
3. At each visit, the observer should stand approximately 2 m from the patient's head. To ensure that the patient is not woken up, the preferred position of the observer is the foot of the bed.
4. At each visit, there should be approximately 5 minutes of listening and observation of the patient's behavior while asleep or awake, including breathing regularity, breathing interruptions (lasting approximately 10 seconds or more), gasping, choking, snoring, and any other particular events such as agitation, shouting, wandering, and nycturia.
5. At each visit, the three items (*interrupted breathing, gasping, or choking; snoring; and awakening*) should be checked "yes" or "no." One or more "yes" can be obtained and vice versa. For example, a patient who snores for 2 or 3 minutes can than stop breathing and finally wake up. In this case, the observer should respond with "yes" in all three cases. Furthermore, it is preferable for the observer to write a short commentary on the specific events.

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
121 (115)	50%	79±5	Caucasian 100%	29.4±5.9	nd	nd	nd (no heart failure)
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	NA	MMSE 25.0±3.5	nd		Geriatric. 90% hospitalized or in a nursing home

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
59%	<10% (likely)	nd	nd	nd	Daytime sleepiness 78% Daytime sleepiness & snoring 37%	

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI ≥5 [RDI≥5] (%)	AHI ≥15 (%)	
28.3		71 (62%)	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					
		121	111			

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	TP	FN	TN	FP	Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
ONSI v PSG	≥2 snoring episodes or ≥1 apnea episode	AHI≥15	61	7	35	8	89.7	82-97	81.4	70-93		"Most overall accuracy"
	≥5 snoring or ≥1 apnea		38	30	43	0	56	44-68	100	--		
	≥3 snoring or ≥1 apnea		50	18	40	3	74	63-84	93	85-100		

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

n/N	% Dropout	Reasons
10/121	8%	4 inadequate PSG due to agitation or non-cooperation 1 acute heart failure 1 unstable DM requiring frequent nocturnal awakenings by nurse 4 inadequate ONSI

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	Yes (incomplete ROC data; other thresholds should have been reported)
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	Yes
Data loss / not analyzed (%)	8%
Overall Quality (A/B/C)	B

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Reda 2001			**Reference test**	PSG
PMID	11593166	**RefID**	15742	**Index test 1**	Pharyngoesophageal manometry
Key Question(s)	1 (Dx Misc)			**Index test 2**	
Extractor	DM			**Comments**	

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Patients with sleep-related breathing disorders	Case series	No	nd	UK	nd	Yes
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Age 20 - 70 years; listed for full PSG for sleep apnea;	Esophageal stricture
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

E)quipment	**Manufacturer (Location)**	**Setting (eg, Sleep lab)**	**Scoring (manual, automated, automated with manual review)**	**Standard scoring system used? If not, describe criteria used**	**Denominator***
nd	nd	Sleep lab	nd	nd	Total sleep time
Definition of Apnea:			nd		
Definition of Hypopnea:			nd		
Thresholds used:			**Definitions:**		
<15, 15-20, 20-40, >40					
Comments:	No data on PSG provided				

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	Pharyngoesophageal manometry with Digitraper	Gaeltec Ltd (Dunvegan, Isle of Skye, Scotland, UK)	• Pharyngoesophageal pressure monitor	N	Sleep lab	Simultaneous with PSG	Automatic	nd	Total recording time	RDI
Definition of Apnea:				nd						
Definition of Hypopnea:				nd						
Thresholds used:				**Definitions:**						
<15, 15-20, 20-40, >40										
Comments:	Conversion of manometric finding to the thresholds of AHI are not reported									

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name *	**Description of Test (only if not on our list)**
Thresholds Used (Cut-Offs included)	
Comments:	

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
59(59)	nd	range 20-70y	nd	nd	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
100%	nd	nd	nd	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI ≥5 n/N (%)	AHI 15-20 n/N (%)	AHI ≥20-40 n/N (%)	AHI >40 n/N (%)	
	35/59 (59.3%)	5/59 (8%)	20/59 (34%)	10/59 (17%)	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Mean Difference (95% CI or LOA)**	Other Text Description (eg, of bias)
Index	**Ref**					
Pharyngoesophageal monitoring	PSG	59	59	B-A plot	0.22 (95% CI: -0.931, 1.382) (95% LOA: -8.68, 9.02)	

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
Pharyngoesophageal monitoring vs PSG	<15	<15	24	0	35	0	100		100			
	15-20	15-20	4	1	52	2	80		96			
	20-40	20-40	18	2	38	1	90		97			
	>40	>40	10	0	49	0	100		100			

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	The results from the development phase (prediction of AHI) are combined with results from the validation. The development phase was non-blinded

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
0/59	No dropouts	

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	No (Development phase was non-blinded)
Analytic problem? (Yes/No, if yes describe) *	Yes (B-A plot not presented, no adjustment for including results from non-blinded part of the study)
Adequate description of tests (Yes/No, if no describe)	No (Threshold calculation for device not presented, apnea/hypopnea detection not reported)
Clear description of population studied (Yes/No, if no describe)	No (no data on population)
Data loss / not analyzed (%)	0%
Overall Quality (A/B/C)	C

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments
The sens and specificity seem to be unusually good for a device that only measures pharyngeal pressure. The validation of this device was done by including the subjects from whom the data for classification of apnea was obtained.

A. Source and Extractor

Author, Year	Rodsutti 2004			**Reference test**	PSG
PMID	15283004	**RefID**	12758	**Index test 1**	**Clinical Prediction Rule** derived from age, sex, body mass index, snoring and stopping breathing during sleep
Key Question(s)	1 (Dx Misc)			**Index test 2**	
Extractor	DM			**Comments**	Data from derivation set (n=837) was reported but not extracted.

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Referred by physicians for suspected sleep-disordered breathing	Consecutive	No	Jan 2003 – Apr 2003	Australia	nd	nd
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	prospective	≥ 18 yrs	nd
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
SensorMedic Alpha	Sensormedics, VIASYS Healthcare (22705 Savi Ranch Parkway, Yorba Linda, California 92867-4645, USA)	Sleep lab	Manual	Standard criteria	Total sleep time
Definition of Apnea:			Complete cessation of airflow ≥ 10 s		
Definition of Hypopnea:			≥ 50% reduction in airflow ≥ 10 s or <50% reduction in airflow ≥ 10 s with >3% oxygen desaturation or an arousal		
Thresholds used:			**Definitions:**		
≥ 5					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator[D]	RDI or AHI (only with Type II devices)
			•							
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used

Name *	Clinical Prediction rule	**Description of Test (only if not on our list)**	Sum of the individual scores for the following five variables: Age, Sex, Snoring, Stops breathing, BMI
Thresholds Used (Cut-Offs included)	Low risk < 2.5 Moderate risk 2.5 - < 4.2 High risk ≥ 4.2		

Variable	Score
Age,y	
≥ 60	2.2
45-59	1.5
30-44	1.0
<30	0
Sex	
Male	1.1
Female	0
Snoring	
Yes	0.9
No	0
Stopping breathing	
Yes	0.9
No	0
BMI	
≥ 40	2.2
30 - 39.9	1.4
25 - 29.9	1
< 25	0
Total score Range	**0 – 7.3**

Comments:

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
243 (243)	63%	51 yrs	nd	32.8 ± 7	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Stopped Breathing while sleeping, % (specify)	Other characteristics (specify)
76%	nd	nd	nd	nd	57%	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI ≥5 n/N (%)	AHI ≥10 n/N (%)	AHI ≥15 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
nd	175/243 (72%)					

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
Clinical Prediction Rule vs PSG	nd	≥ 5									0.789	
	< 2.5	≥ 5	0	47	175	21	0		0.89			
	2.5 - < 4.2	≥ 5	34	44	141	24	0.44		0.85			
	≥ 4.2	≥ 5	141	45	34	23	0.76		0.60			

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
0/243	no dropouts	

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	No (Only for the derivation set, not for the validation set)
Data loss / not analyzed (%)	0%
Overall Quality (A/B/C)	A

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Rowley 2000			**Reference test**	PSG
PMID	11083602	**RefID**	12766	**Index test 1**	Clinical Prediction formula #1 – based on witnessed apneas, hypertension, BMI, age
Key Question(s)	1 (Dx Misc)			**Index test 2**	Clinical Prediction formula #2 – based on snoring, BMI. age, sex
Extractor	DM			**Index test 3**	Clinical Prediction formula #3 – based on snoring. gasping/choking, hypertension, neck circumference
				Index test 4	Clinical Prediction formula #4 – based on snoring, gasping, witnessed apneas, BMI, age. sex
				Comments	All these Clinical Prediction rules have been validated previously; Appendix of the original paper contains the formulas used to calculate the score

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Patients referred for sleep-disordered breathing	All patients (consecutive)	No	July 1 1996 – Oct 31, 1997	USA	nd	nd
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	All patients referred for polysomnography	Previous diagnosis of obstructive sleep apnea; if final diagnosis was not obstructive sleep apnea; Unable to give informed consent
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
Model 78d	Grass Instruments, (Quincy, MA)	Sleep lab	Manual	Rechtschaffen and Kales, 1968	Total sleep time
Definition of Apnea:			cessation of airflow for ≥ 10 s		
Definition of Hypopnea:			Airflow reduction for ≥ 10 s with a 3% drop in the oxyhemoglobin saturation or an arousal		
Thresholds used:			**Definitions:**		
≥ 10, ≥ 20					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
			•							
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used			
Name *	Clinical Prediction formula #1 - #4	**Description of Test (only if not on our list)**	**Clinical Prediction formula #1** *Probability of OSA= 1/ {1 + $e^{-(-13.9+0.06a+2.98b+0.23c+1.35d)}$}* *where a = age; b= I if witnessed apneas present, 0 if witnessed apneas absent; c=BMI; d = 1 if patient has hypertension, 0 if hypertension absent* **Clinical Prediction formula #2** *e^x/ (1+e^x) where, x = -10.5132 + 0.9164*sex + 0.0470*age + 0.1869*BMI+1.932*snoring; where sex= 1 for male, 0 for female, snoring = 1 for present, 0 for absent* **Clinical Prediction formula #3** Sleep apnea clinical score (SACS)=(10 $^{(-2.132 + 0.069*NC + 0.31*H+ 0.206'*HS+0.224*PR)}$ + 1) where NC=neck circumference; H=1 if hypertension, 0 if hypertension absent, HS=1 if habitual snorer, 0 if not, PR = 1 if reports nocturnal choking/gasping, 0 if no nocturnal choking/gasping **Clinical Prediction formula #4** *e^x/ (1+e^x) where, x* = -8.160+1.299*Index1+O.163*BMI-0.025*BMI*Index1+0.032*age +1.278*sex where, sex=1 if male, 0 if female, index1=the mean of non-missing values for frequency of snorting/gasping; loud snoring; breathing stops/chokes
Thresholds Used (Cut-Offs included)	As per results table		
Comments:			

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
425 (370)	52%	Median 47 years (IQR: nd -56)	nd	37.1 kg/m2 (30.7 - 46.6)	52% (Systolic blood pressure > 160 mmHg or diastolic blood pressure >95 mmHg or on anti-hypertensive medications.)	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
77%	nd	nd	nd	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Median AHI (Range)	AHI ≥5 n/N (%)	AHI ≥10 n/N (%)	AHI ≥15 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
18.8 (6.7-52.3).	nd	248/370 (67%)	nd	180/370 (49%)	nd	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
Clinical Prediction formula #1 vs PSG	0.15 (SACS score to predict AHI ≥ 10 from original validation dataset)	≥ 10	208	40	48	74	84		39		0.669	
Clinical Prediction formula #1 vs PSG	0.95 (SACS score to predict AHI ≥ 10 in the current dataset)	≥ 20	60	121	170	19	33		90		0.7	
Clinical Prediction formula #2 vs PSG	0.20 (SACS score to predict AHI ≥ 10 from original validation dataset)	≥ 10	238	10	16	106	96		13		0.695	
Clinical Prediction formula #2 vs PSG	0.95 (SACS score to predict AHI ≥ 10 in the current dataset)	≥ 20	62	120	164	25	34		87		0.722	
Clinical Prediction formula #3 vs PSG	10 (SACS score to predict AHI ≥ 10 from original validation dataset)	≥ 10	188	59	66	56	76		54		0.696	
Clinical Prediction formula #3 vs PSG	35 (SACS score to predict AHI ≥ 10 in the current dataset)	≥ 20	62	120	168	21	34		89		0.733	
Clinical Prediction formula #4 vs PSG	0.5 (SACS score to predict AHI ≥ 10 from original validation dataset)	≥ 10	216	32	43	79	87		35		0.736	
Clinical Prediction formula #4 vs PSG	0.85 (SACS score to predict AHI ≥ 10 in the current dataset)	≥ 20	71	111	175	13	39		93		0.757	

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

Sug-group	Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
				TP	FN	TN	FP						
Men	Clinical Prediction formula #1 vs PSG	0.15 (SACS score to predict AHI ≥ 10 from original validation dataset)	≥ 10									0.761	
Women	Clinical Prediction formula #1 vs PSG	0.15 (SACS score to predict AHI ≥ 10 from original validation dataset)	≥ 10									0.633	
Men	Clinical Prediction formula #2 vs PSG	0.20 (SACS score to predict AHI ≥ 10 from original validation dataset)	≥ 10									0.801	
Women	Clinical Prediction formula #2 vs PSG	0.20 (SACS score to predict AHI ≥ 10 from original validation dataset)	≥ 10									0.626	
Men	Clinical Prediction formula #3 vs PSG	10 (SACS score to predict AHI ≥ 10 from original validation dataset)	≥ 10									0.707	
Women	Clinical Prediction formula #3 vs PSG	10 (SACS score to predict AHI ≥ 10 from original validation dataset)	≥ 10									0.648	
Men	Clinical Prediction formula #4 vs PSG	0.5 (SACS score to predict AHI ≥ 10 from original validation dataset)	≥ 10									0.801	
Women	Clinical Prediction formula #4 vs PSG	0.5 (SACS score to predict AHI ≥ 10 from original validation dataset)	≥ 10									0.611	

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
55/425	13%	Did not attend scheduled polysomnography and refused one later

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	Yes
Data loss / not analyzed (%)	13%
Overall Quality (A/B/C)	A

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).

Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Sharma 2006			**Reference test**	PSG
PMID	17085831	**RefID**	14796	**Index test 1**	Modified Berlin Questionnaire
Key Question(s)	1 (Dx Misc)			**Index test 2**	
Extractor	DM			**Comments**	The Berlin Questionnaire was customized to the Indian setting (re: questions on driving) but the scoring remained the same. The screening questionnaire used was not a validated one.

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Patients attending the medical outpatient department of a tertiary care center	case series	No	April 2000 to April 2002.	India	nd	nd
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	18-60 yrs, qualifying as per screening questions; residents of New Delhi and nearby areas	alcoholism, chronic anxiolyatic / sedative drug use, associated respiratory, renal, hepatic or cardiovascular disease; upper respiratory tract infection in past 1 week; pregnancy; critical illness
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
Alice 3	Healthdyne Technologies (USA)	Sleep lab	Manual	Standard criteria	Total sleep time
Definition of Apnea:			AASM, 1999		
Definition of Hypopnea:			AASM, 1999		
Thresholds used:			**Definitions:**		
> 5					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
			•							
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used			
Name *	Modified Berlin Questionnaire	**Description of Test (only if not on our list)**	High risk for obstructive sleep apnoea= High risk in 2 of 3 symptom categories Category 1: High risk was defined as persistent symptoms (>3to 4 times/wk) in two or more questions about snoring Category 2: High risk was defined as persistent symptoms (>3 to 4 times/wk) in two or more questions about wake time sleepiness. Category 3: High risk was defined as a history of high blood pressure as per the Joint National Committee on Prevention, Detection, valuation, and Treatment of High Blood Pressure (JNC VI) or a body mass index (BMI)17 >25 kg/m^2
Thresholds Used (Cut-Offs included)	High risk vs Low risk		
Comments:	The Berlin Questionnaire was customized to the Indian setting (re: questions on driving) but the scoring remained the same. The screening questionnaire used was not a validated one.		

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
180 (104)	80%	40	South Asian	28.2	56% (systolic > 140 mmHg, Diastolic > 90 mmHg)	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd	nd	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI ≥5 n/N (%)	AHI ≥10 n/N (%)	AHI ≥15 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
nd	62/104 (59.6%)	nd	nd	nd	nd	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
Modified Berlin Questionnaire vs PSG	High risk vs low risk	> 5	53	9	40	2	0.86		0.95			

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
76/180	no reason reported	

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	nd
Analytic problem? (Yes/No, if yes describe) *	Yes (screening questionnaire is not validated, modified Berlin questionnaire is not validated even though it is scored the same fashion as the original)
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	Yes
Data loss / not analyzed (%)	42%
Overall Quality (A/B/C)	C

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Zerah-Lancner 2000			**Reference test**	PSG
PMID	11112139	**RefID**	12993	**Index test 1**	Predictive index for SAS based on pulmonary function data,
Key Question(s)	1 (Dx Misc)			**Index test 2**	
Extractor	DM			**Comments**	Data from Development set (168 obese snorers) was reported but not extracted.

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Patients referred for snoring and suspected sleep apnea	Consecutive	No	nd	France	nd	Yes
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	Obese snorers suspected sleep apnea	Alcoholism; use of hypnotic medicine, upper respiratory tract disorders; previous treatment for sleep apnea; cardiopulmonary disease or airway obstruction, history /clinical neuromuscular disease
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
nd	nd	Sleep lab	nd	nd	Total sleep time
Definition of Apnea:			AASM, 1999		
Definition of Hypopnea:			AASM, 1999		
Thresholds used:			**Definitions:**		
≥ 15					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
			•							
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used			
Name *	Predictive index for SAS based on pulmonary function data,	**Description of Test (only if not on our list)**	probability (p) of having a polysomnography positive for SAS: logit (p)= -136 sGrs + 2.5 (100 - Sa_{O2}) + 4.2 where Specific respiratory conductance (sGrs) (in $cmH_20^{-1} * s^{-1}$) = Respiratory conductance (Grs) / Functional reserve capacity (FRC) Sa_{O2} = daytime arterial oxygen saturation in % *The estimated value of p was derived from logit (p)= $log_e(p/1-p)$, from 0 to 1 range.*
Thresholds Used (Cut-Offs included)	0.5		
Comments:			

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
101 (101)	nd	nd	nd	28.8	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Other Clinical symptoms, % (specify)	Other characteristics (specify)
nd	nd	nd				

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI ≥5 n/N (%)	AHI ≥10 n/N (%)	AHI ≥15 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
23.8 For those with AHI <15 (n=50): 5.7±4.2 For those with AHI≥ 15 (n=51): 41.6±23.6	79/101 (78.2%)	nd	51/101 (51%)	nd	30/101 (29.7%)	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
Prediction rule from Respiratory tests vs PSG	0.5	≥ 15	51	0	42	8	1.0		0.84			

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
0/101	No dropouts	

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	No
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	No (no data on demographics, co-morbidities)
Data loss / not analyzed (%)	0%
Overall Quality (A/B/C)	B

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

Key Question 2
Phased Testing

A. Source and Extractor

Author, Year	Gurubhagavatula 2004			Reference test	PSG
PMID	15142866	RefID	12318	Index test 1	Symptoms
				Index test 2	BMI
				Index test 4	Multivariable clinical prediction rule using Multivariable Apnea Prediction (MAP) questionnaire
				Index test 4	Multivariable Apnea Prediction (MAP) questionnaire & nocturnal pulse oximetry
Key Question(s)	1 (Dx Misc), 2 (Staged Testing)			Index test 5	nocturnal pulse oximetry
Extractor	DM			Comments	**REJECTED FOR KQ1 DUE TO VERIFICATION BIAS. PROVISIONALLY ACCEPTED FOR KQ2 (STAGED TESTING).**

B. Study description

Sampling population [A]	Recruitment method [B]	Multicenter?	Enrollment Years	Country	Funding source	Index Test Readers BLIND to Reference Test Results?
Commercial drivers	Consecutive	no	nd	USA	Industry & Govt (Trucking Research Institute, Nellcor, Inc., and Ohmeda, Inc.,and Federal Highway Administration) NIH	Yes
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	Prospective vs retrospective (exclude case control studies)	Inclusion criteria	Exclusion criteria
Cross-sectional	Prospective	Respondents from a pool of 4,286 randomly selected commercial driver's license holders in Pennsylvania, within Philadelphia and its 50-mile radius.	Dx of OSA or obesity-hypoventilation syndrome or if using supplemental oxygen
Comments	Study design in fig 1 below		

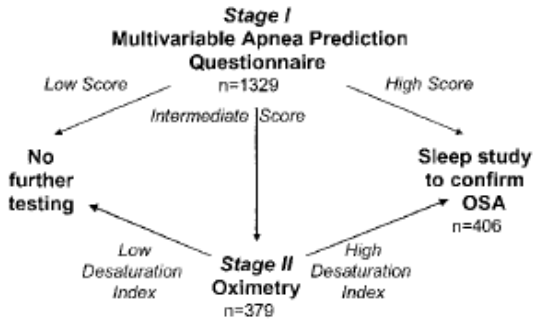


Figure 1. The two-stage strategy for prediction of apnea, which combines use of a multivariable prediction index and oximetry. Stage I consists of administering the symptom questionnaire and calculating the multivariable apnea prediction on the basis of a symptom score, body mass index (BMI), age, and sex. On the basis of the multivariable apnea prediction, drivers undergo a sleep study if the score is high, or no further testing if the score is low. The intermediate group undergoes oximetry, with subsequent overnight sleep study if the desaturation index is high, and no further testing if the desaturation index is low.

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
nd	nd	sleep lab	manual	Rechtschaffen & Kales	Total sleep time
Definition of Apnea:			AASM, 1999		
Definition of Hypopnea:			AASM, 1999		
Thresholds used:			**Definitions:**		
≥ 5, ≥ 30					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
IV	nd	nd	• Oximetry	N	Sleep lab	Simultaneous with PSG	Manual	the number of desaturations ≥ 3% magnitude divided by test duration in hours	Total recording time	ODI
Definition of Apnea:				nd						
Definition of Hypopnea:				nd						
Thresholds used:				**Definitions:**						
≥ 3%										
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used			
Name *	Multivariable Apnea Prediction (MAP) questionnaire	**Description of Test (only if not on our list)**	Included a symptom frequency score for apnea (range, 0–4) with BMI, age & sex *Score range*: 0 = lowest risk to 1= highest risk of apnea.
Thresholds Used (Cut-Offs included)	*For MAP alone:* 0.55; *For Map & Oximetry to identify severe apnea:* Upper limit of MAP: 0.9 Lower limit of MAP: 0.3 ODI: 10/hr		
Comments:			

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
1329 (1329, 406 for lab studies)	93.5%	44	White: 85% African-Americans: 12.5% Hispanics: 1.9%	28.4 ± 4.9	For lab subjects: Systolic: 132 ± 0.92 * Diastolic: 77.9 ± 0.58 *	nd	nd
NIDDM, %	**Smokers, % (Currently smoking: Smoked at least one cigarette during the preceding month)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	31% *	nd	nd	nd	nd	nd	Yes (commercial truck drivers)

* Weighted average across MAP score risk groups (high risk and low risk) = (0.415 X higher risk mean) + (0.585 x lower risk mean), weighted standard error (SE) = $\sqrt{(0.415)^2 \text{x (higher risk SE)}^2 + (0.585)^2 \text{ x (lower risk SE)}^2}$.

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.

‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	Mean multivariable apnea prediction score	Other characteristics (specify)
nd	nd	nd	nd	nd	0.49 ± 0.21	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI ≥5 n/N (%)	AHI ≥10 n/N (%)	AHI ≥15 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
nd	28.1% *				4.7% *	

* Weighted average across MAP score risk groups (high risk and low risk) = (0.415 X higher risk mean) + (0.585 x lower risk mean)

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (95% CI)	Other
			TP	FN	TN	FP						
Symptoms vs PSG	0.7	≥ 5					0.516	(0.431,0.599)	0.686	(0.621,0.747)	0.618 (0.554,0.679)	
	0.7	≥ 30					0.613	(0.460,0.842)	0.62	(0.581,0.689)	0.662 (0.517,0.763)	
BMI vs PSG	29.8	≥ 5					0.702	(0.641,0.781)	0.609	(0.542,0.657)	0.757 (0.690,0.791)	
	32.7	≥ 30					0.769	(0.533,0.875)	0.705	(0.678,0.769)	0.802 (0.682,0.857)	
Multivariable prediction vs PSG	0.5	≥ 5					0.724	(0.655,0.792)	0.756	(0.651,0.764)	0.798 (0.737,0.823)	
	0.55	≥ 30					0.808	(0.516,0.905)	0.728	(0.719,0.802)	0.841 (0.707,0.872)	

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (95% CI)	Other
			TP	FN	TN	FP						
Multivariable prediction + oximetry vs PSG	Upper limit MAP score: 0.9, Lower limit MAP score: 0.2, ODI: 5/hr	≥ 5					0.744	(0.609,0.765)	0.892	(0.869,0.937)	0.881 (0.869,0.887)	
	Upper limit MAP score: 0.9, Lower limit MAP score: 0.3, ODI: 10/hr	≥ 30					0.909	(0.719,0.969)	0.906	(0.845,0.910)	0.937 (0.936,0.939)	
Oximetry vs PSG	4.95	≥ 5					0.742	(0.667,0.822)	0.893	(0.846,0.926)	0.907 (0.867,0.936)	
	14.9	≥ 30					0.885	(0.738,1.000)	0.946	(0.897,0.951)	0.971 (0.945,0.992)	

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	Only done on 406/1329 subjects. Selection bias

H. Subgroup Analysis (If present)
If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons

J. Methodological Quality

Prospective or Retrospective?	Prospective
Verification bias? (Yes/No; if yes describe)	Yes
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	Yes (selection bias)
Adequate description of tests (Yes/No, if no describe)	yes
Clear description of population studied (Yes/No, if no describe)	Yes
Data loss / not analyzed (%)	0% (if we consider that 100% of the population was assessed for symptoms, BMI and MAP score)
Overall Quality (A/B/C)	C

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

Key Question 3
Preoperative Screening

A. Source and Extractor

Author, Year	Chung 2008			**Reference test**	PSG
PMID	18431117	**RefID**	7172	**Index test 1**	STOP Questionnaire
Key Question(s)	1 (Dx Misc), 3 (Predictor of post-op complications)			**Index test 2**	Berlin Questionnaire
				Index test 2	American Society of Anesthesiologists (ASA) Surgical checklist
Extractor	DM			**Comments**	(i) Sensitivity, Specificity and AUC of STOP Questionnaire vs PSG is extracted in Chung 2008 (PMID: 18431116); that data is not re-extracted here. STOP has been included to answer KQ3. (ii) All extracted study elements are same as in Chung 2008 (PMID: 18431116), except for the results. **(iii) For KQ3, the outcomes and results tables from the Tx form has been used.**

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Preoperative patients	Case series	Yes	nd	Canada	Foundation and Hospital funds	Yes
Comments	Selection bias is evident, as only 211/2721 (8%) of the patients invited for PSG actually were assessed by that method.					

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Prospective	≥ 18 yr; ASA physical status of I-IV; scheduled to undergo elective procedures in general surgery, gynecology, orthopedics, urology, plastic surgery, ophthalmology, or neurosurgery	Unwilling or unable to give informed consent; diagnosed with OSA or sleep breathing disorder; expected to have abnormal electroencephalographic findings (e.g., brain tumor, epilepsy surgery, patients with deep brain stimulator)
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
nd	nd	sleep lab	manual	standard scoring criteria	Total sleep time
Definition of Apnea:			AASM, 1999		
Definition of Hypopnea:			AASM, 1999		
Thresholds used:			**Definitions:**		
>5, >15, >30					
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
			•							
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used			
Name *	6)STOP Questionnaire 7)Berlin Questionnaire 8)American Society of Anesthesiologists (ASA) Screening Checklist for OSA in Surgical Patients	**Description of Test (only if not on our list)**	STOP - *S*noring, *T*iredness during daytime, *O*bserved apnea, and high blood *P*ressure (STOP). Berlin -
Thresholds Used (Cut-Offs included)	High risk of OSA vs Low Risk of OSA		
Comments:	**Berlin is not validated in surgical patients, and ASA checklist is not validated in any population**		

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
2127 (177)	50%	55 ± 13	nd	30 ± 6	41% (nd)	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Asthma, % (specify)**	**Is this a Special Population? (which?)**
18%	nd	32%	nd	nd	6%	14%	Yes (pre-op patients)

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	ASA Physical Status, % (specify)	Other characteristics (specify)
nd	nd	nd	nd	nd	I-6% II-57% III-36% IV- 1%	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI > 5 n/N (%)	AHI > 15 n/N (%)	AHI > 30 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
20 ± 6	122/177 (68.9)	70/177 (39.5)	39/177 (22.03)	nd	nd	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						
Berlin vs PSG	High vs low	>5	84	38	31	24	68.9	59.8, 76.9	56.4	42.3, 69.7	0.690	
		>15	55	15	54	53	78.6	67.1, 87.5	50.5	40.6, 62.3	0.672	
		>30	34	5	64	74	87.2	72.6, 95.7	46.4	37.9, 55.1	0.668	
ASA Checklist vs PSG	High vs low	>5	88	34	21	34	72.1	63.3, 79.9	38.2	25.4, 52.3	0.783	
		>15	55	15	40	67	78.6	67.1, 87.5	37.4	28.2, 47.3	0.730	
		>30	34	5	50	88	87.2	72.6, 95.7	36.2	28.2, 44.8	0.617	

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)

If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons
0/177	0%	Only because the validation study was conducted on patients who had data from both the questionnaire as well as the PSG; Otherwise, dropout was 91.4% if we consider all patients who were given the STOP questionnaire. If we only consider the people who consented to the PSG but did not turn up, the drop out was 211/416 (49.3%)

J. KQ4:

BASELINE CHARACTERISTICS OF SURGICAL PATIENTS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx	**211 (211)**	50%	56 ± 13		30.3 ± 6	43.6%		
Cx	**205 (205)**	52%	54 ± 13		29.7± 7	37.1%		
Total	**416 (416)**	51%	55 ± 13	nd	30.1 ± 10	39.8%	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	18%	14.7%	30.8%					
Cx	15.6%	26.8%	23.4%					
Total	16%	20.9%	27.2%	nd	nd	nd	nd	No
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

INTERVENTION / TEST *

	Test †	Brand Name or Equivalent	Description
1	PSG		
2			
3			
Control	No PSG		

K. SURGICAL OUTCOMES MEASURED (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Surgical Complications	All complications	After surgery	All recorded complications
2	Surgical Complications	Respiratory complication	After surgery	These included total desaturation, Mild desaturation (SaO2 90–95%), Severe desaturation (SaO2 ≤ 90%)
3	Surgical Complications	Cardiac complication	After surgery	These included bradycardia, tachycardia, dysrhythmia, and ischemia
4	Surgical Complications	Neurologic complications	After surgery	These include confusion, agitation, and excessive drowsiness.
5	Surgical Complications	Prolonged oxygen therapy	After surgery	
6	Surgical Complications	Additional monitoring	After surgery	
7	Surgical Complications	ICU admission	After surgery	these included Planned ICU admission, Unplanned ICU admission, ICU admission related OSA
8	Surgical Complications	Hospital stay after surgery	After surgery	
9	Surgical Complications	Readmission within 30 days	After surgery	
10	Surgical Complications	ED visit within 30 days	After surgery	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

K. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Percentage *	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Chung 2008 Canada 18431117	Total complications	**Tx**	PSG	30 days	48	211	22.8			0.03				
		Cx	no PSG		30	205	14.6							
	Respiratory complication	**Tx**	PSG	30 days	39	211	18.5			0.08				
		Cx	no PSG		25	205	12.2							
	Cardiac complication	**Tx**	PSG	30 days	12	211	5.7			0.11				
		Cx	no PSG		6	205	2.9							
	Neurologic complication	**Tx**	PSG	30 days	2	211	0.95			0.68				
		Cx	no PSG		3	205	1.5							
	Prolonged oxygen therapy	**Tx**	PSG	30 days	24	211	11.4			0.22				
		Cx	no PSG		16	205	7.8							
	Additional monitoring	**Tx**	PSG	30 days	9	211	4.3			0.46				
		Cx	no PSG		6	205	2.9							
	ICU Admission	**Tx**	PSG	30 days	13	211	6.1			0.028				
		Cx	no PSG		4	205	2.0							
	Readmission within 30 days	**Tx**	PSG	30 days	4	211	1.9			0.75				
		Cx	no PSG		5	205	2.4							
	ED Visit within 30 days	**Tx**	PSG	30 days	1	211	0.5			0.21				
		Cx	no PSG		4	205	2.0							

* RR, OR, HR, RD

L. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Median	range *	Value	SD/SE*	P	Value	SD/SE*	P
Chung 2008 Canada 18431117	Hospital stay after surgery	hours	**Tx**			211			44.8	(0.2–352.8)				+15.5		0.73
			Cx			205			29.3	(0.1–299.8)						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

Methodological Quality

Prospective or Retrospective?	Prospective/ KQ4: Retrospective
Verification bias? (Yes/No; if yes describe)	No
Blinding? (Yes/No)	Yes
Analytic problem? (Yes/No, if yes describe) *	Yes (Selection bias; only 211/2467 patients came for PSG)
Adequate description of tests (Yes/No, if no describe)	Yes
Clear description of population studied (Yes/No, if no describe)	Yes
Data loss / not analyzed (%)	0% (Only because the validation study was conducted on patients who had data from both the questionnaire as well as the PSG-see above)
Overall Quality (A/B/C)	C

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).
Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

A. Source and Extractor

Author, Year	Hallowell 200717950355			**Reference test**	PSG
PMID	17950355	**RefID**	7364	**Index test 1**	PSG after a positive Epworth sleepiness score, loud snoring, daytime sleepiness, or clinical suspicion by the surgeon or pulmonologist.
Key Question(s)	3 (Predictor of post-op complications)			**Index test 2**	
				Index test 2	
Extractor	DM			**Comments**	retrospective chart review of post op complications among 2 groups – one that had selective sleep studies based on clinical characteristics versus those that had mandatory PSG.

B. Study description

Sampling population [A]	**Recruitment method** [B]	**Multicenter?**	**Enrollment Years**	**Country**	**Funding source**	**Index Test Readers BLIND to Reference Test Results?**
Patients who have undergone bariatric surgery	Consecutive	No	1998 - 2005	USA	nd	NA
Comments						

[A] Patients representative of the general population? Patients referred to a specialized center? [However defined] high-risk patients?
[B] Consecutive patients, random sampling, case series/convenience sample

C. Participant characteristics and baseline "severity/risk"

Study design	**Prospective vs retrospective (exclude case control studies)**	**Inclusion criteria**	**Exclusion criteria**
Cross-sectional	Retrospective	All cases who have undergone bariatric surgery including patients undergoing CPAP	none
Comments			

D. Description of facility-based polysomnography and portable device monitoring (whatever is applicable)

D1. PSG

Equipment	Manufacturer (Location)	Setting (eg, Sleep lab)	Scoring (manual, automated, automated with manual review)	Standard scoring system used? If not, describe criteria used	Denominator*
Definition of Apnea:					
Definition of Hypopnea:					
Thresholds used:			**Definitions:**		
Comments:					

* Total sleep time (AHI) versus Total recording time (RDI)

D2. Other Devices

Type	Name (equipment)	Manufacturer (Location)	Channels[A]	Actigraphy (Y/N)	Setting[B]	Timing[C]	Scoring (manual, automated, automated with manual review)	Scoring system, if not identical that for PSG	Denominator [D]	RDI or AHI (only with Type II devices)
			•							
Definition of Apnea:										
Definition of Hypopnea:										
Thresholds used:				**Definitions:**						
Comments:										

A Describe Flow and Effort channels / indicate nd if not described in the study
B Setting: sleep lab/ hospital/community center, etc,
C Timing: Simultaneous with PSG/ Different day; If different, how many days between PSG and device measurement
D Total sleep time (AHI) versus Total recording time (RDI)

D2.1 (Type definitions)

Type	Portability	Indicative Nchannels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep / wake	AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	(may have EEG), HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3**	[All monitors not qualifying for type III]	No	No***	No

AHI: Apnea-Hypopnea index; ECG: electrocardiogram; EEG: Electroencephalogram; EMG: electromyography; EOG: Electro-oculogram; HR: heart rate; SaO2: arterial O2 saturation; * Heart rate is allowed instead of EEG in type II monitors. Essentially, many type II monitors gather the same signals as type I monitors. ** May have more than three channels, provided that criteria for type III are not met; ***May include monitors that measure signals that are in principle able to identify arousals from sleep.

D3. Questionnaire

Description of Test Used	
Name *	**Description of Test (only if not on our list)**
Thresholds Used (Cut-Offs included)	
Comments: **Berlin is not validated in surgical patients, and ASA checklist is not validated in any population**	

* Epworth / STOP-BANG/ Stanford / Berlin/ Pittsburgh Scale/ Friedman surgical or staging

E.1 Baseline Characteristics.

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Asthma, % (specify)**	**Is this a Special Population? (which?)**

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

E.2 Baseline Characteristics.

Habitual Snoring *	Bed partner, %	Craniofacial abnormalities/ congenital abnormalities	Epworth	MSLT	, % ()	Other characteristics (specify)

* Mean±SD. If median, SE, range, IQR, or other, specify these.

F. PSG: Polysomnography (facility-based) Results.

Mean AHI (Range)	AHI > 5 n/N (%)	AHI > 15 n/N (%)	AHI > 30 n/N (%)	AHI ≥20 n/N (%)	AHI ≥30 n/N (%)	
nd	nd	nd	nd	nd	nd	

AHI: Apnea-hypopnea index; RDI: respiratory distress index

G1. Results: Concordance [agreement between measurements – assume no gold standard]

Comparison		N Enrolled	N Analyzed	Concordance Metric*	Value (95% CI or LOA)	Other Text Description (eg, of bias)
Index	Ref					

* Bland Altman plot; LOA, Limits of Agreement (±2SD); NOT correlation coefficients and OLS regression

G2. Results: Diagnostic performances

Comparison (Index v Ref)	Index cutoff	Reference standard cutoff	Sn data		Sp data		Sens	(95% CI)	Spec	(95% CI)	ROC AUC (Q*)	Other
			TP	FN	TN	FP						

TP, Index + / Ref +
FN, Index – / Ref +
FP, Index + / Ref –
TN, Index – / Ref –

Comments on Results:	

H. Subgroup Analysis (If present)

If sub-group analysis is presented, copy the relevant tables (6 or 7) for presenting each sub-group separately. Record only those studies that have assessed an interaction test for the groups

I. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE or LACK OF ANALYSIS

n/N	% Dropout or analysis failure	Reasons

J. KQ4:

BASELINE CHARACTERISTICS OF SURGICAL PATIENTS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
1 (Selective OSA testing)	572 (572) Table 2 reports n=576		43 ± 1	nd	51.9 ± 0.3			
2 (Mandatory OSA testing)	318 (318)		44 ± 1	nd	49.3 ± 0.5			
Total		13%	43		51	nd	nd	nd
	NIDDM, %	Smokers, % (define)	GERD, %	MVA ‡ etc, %	Cognitive Function **	Depression, %	American Society of Anesthesiologists (ASA) score, (nd)	Is this a Special Population? (which?)
1 (Selective OSA testing)							2.8 ± 0.1	
2 (Mandatory OSA testing)							2.9 ± 0.1	
Total	nd	nd	nd	nd	nd	nd		yes (Morbidly obese patients who underwent bypass surgery)
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

INTERVENTION / TEST *

	Test †	Brand Name or Equivalent	Description
1	Selective OSA testing based on clinical characteristics		
2			
3			
Control	Mandatory OSA testing		

K. SURGICAL OUTCOMES MEASURED (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Harms	ICU admission	Post-operative	Combination of respiratory related ICU admission (shortness of breath or desaturation) and non-respiratory related ICU admission ((anastomotic leak, bleed, or pulmonary embolus))
2	Harms	Respiratory related ICU admission	Post-operative	If patients were transferred to the ICU for shortness of breath or desaturation
3	Harms	Duration of stay	Post-operative	nd (units not given)
4	Harms	Mortality	Post-operative	Death due to any cause

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

K. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Percentage *	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Hallowell 2007 USA 17950355	ICU admission		**1 (Selective OSA testing)**	post operative	32	576	6%							
			2 (Mandatory OSA testing)	post operative	11	318	4%							
			Total		43	890	5%							
Hallowell 2007 USA 17950355	Respiratory related ICU admission		**1 (Selective OSA testing)**	post operative	11	576	2%							
			2 (Mandatory OSA testing)	post operative	1	318	0.3%							
			Total											
Hallowell 2007 USA 17950355	Mortality		**1 (Selective OSA testing)**	90 days										
			2 (Mandatory OSA testing)											
			Total		3	890		0.3%						

* RR, OR, HR, RD

L. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Mean	sd *	Value	SD/SE*	P	Value	SD/SE*	P
Hallowell 2007 USA 17950355	Duration of stay	nd (?days)		**1 (Selective OSA testing)**	postoperative	576			3.5	0.2				0.4		
				2 (Mandatory OSA testing)	postoperative	318			3.1	0.1						
				Total												

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

Comments on Results:	Serious discrepancies in results presentation in total N, in outcome of duration of stay (different results in the table and in the text)

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

Methodological Quality

Prospective or Retrospective?	Retrospective
Verification bias? (Yes/No; if yes describe)	Yes (in Gp 1 who had selective PSG)
Blinding? (Yes/No)	No
Analytic problem? (Yes/No, if yes describe) *	Yes (selection bias in comparing those who had selective PSG versus those who had mandatory PSG)
Adequate description of tests (Yes/No, if no describe)	No
Clear description of population studied (Yes/No, if no describe)	No (discrepancy in N in the flow chart (n=890), table (n=894) and in the text (both n=894 and n=890 in different sections)
Data loss / not analyzed (%)	0%
Overall Quality (A/B/C)	C

* e.g., improper accounting for multiple measurements in same patient (should do clustered analysis).

Quality: Grade A (good) studies fulfill most commonly held concepts of high quality, including the following: blinding of assessors to results of the other test, blinding to clinical information, enrollment of consecutive patients, random order of measurements or simultaneous measurements with the compared methods, clear description of the evaluated population, setting, and measurement methods; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; not excessive data loss (<20%); and no obvious bias. Grade B (moderate) studies may be susceptible to some bias, but not sufficient to invalidate the results. Such studies do not meet the criteria described in category A. They have some deficiencies but none likely to cause major bias. Study may be missing information making assessment of the limitations and potential problems difficult. Grade C (poor) studies are subject to significant bias that may invalidate the results. Such studies may have serious errors in design, analysis or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

K. OTHER COMMENTS CONCERNING THE STUDY

Comments

Key Question 4
AHI as an Outcome Predictor

A. Source and Extractor

Author, Year	Arzt, 2005			**Outcomes**	Stroke
PMID	16141444	**RefID**	15025		
Key Question(s)	KQ 2			**Design †**	Prospective cohort
Extractor	EMB			**Comments**	Wisconsin Sleep Cohort Study

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Study Years**	**Multicenter?**	**Prospective vs retrospective**	**Country**	**Funding source**
State employees 30-60 y	Pregnancy, Unstable cardiopulmonary disease, Airway cancer, Recent upper airway surgery Inadequate PSG History of stroke	≥5	1988 (first enrollment)	No	Prospective	US	Gov't

C. BASELINE CHARACTERISTICS:

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
1475 (1475)	55%	47	nd	30	32%	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
3%	18%	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" & TREATMENT AT BASELINE

All had Sleep Study?	**Which?**	**AHI***	**Epworth***	**MSLT* †**	**Habitual Snoring ***	**Bed partner, %**	**Time Since Diagnosis**	**Other (specify)**
Yes	PSG	<5: 76% 5-20: 17% ≥20: 7%	nd	nd	nd	nd	NA	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
No						nd		
Timing of Baseline (OSA Dx, Time of survey, Other):		Time of survey						
Treatments Being Used:		Allowed (follow-up suggested if AHI≥15 or sleepiness symptoms						

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Other
PSG	≥5 (SBD)		nd	nd		

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

F. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	GEE to account for multiple 4 year periods (repeated measures)
Multivariate	Multivariate logistic regression with GEE

G. PREDICTORS TESTED

	Category	Predictor	Definition	Time Point Measured	Strata	Tested in Univariable Analysis?	Tested in Multivariable Analysis?	Comment
1	Sleep measure	AHI		Baseline	<5 ≥5 - <20 ≥20			
2	Demographic	Age						
3	Demographic	Sex						
4	Habitus	BMI						
5								
6								
	Criteria Used to Test Predictors in Multivariable Analysis							

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome	How Ascertained?
1	CVD	Stroke	4, 8, 12 y	Self-reported, physician diagnosed	Confirmation of consistency of details of stroke.
2					
3					
4					

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor				Follow-up	n Event	N Total	Pct	/1000 person-yr	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Unit	Base	Final						Metric*	Result	95% CI	P	Metric*	Result	95% CI	P	Adjusted for:
Arzt, 2005 US 16141444	Stroke	AHI		Total		4, 8, 12 y	14	1475	0.9%	1.33									
				<5			9	1121	0.8%	1.33	OR	Ref			OR	Ref			Age, Sex, BM
				5 - 20			1	255	0.4%	0.54		0.40	0.05-3.18	NS		0.29	0.04-2.36	NS	
				≥20			4	99	4.0%	5.75		4.31	1.31-14	0.02		3.08	0.74-13	NS	

* RR, OR, HR, RD

J. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	

Comments on Results	

K. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons

L. QUALITY

Questionable ascertainment of stroke. Not by medical records.
No obvious selection bias
Adequate analyses, though finer AHI categories might have been more useful.

Quality: B

A. Source and Extractor

Author, Year	Botros, 2009			**Outcomes**	T2DM
PMID	19958890	**RefID**	77		
Key Question(s)	KQ 2			**Design †**	Prospective cohort
Extractor	EMB			**Comments**	

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Study Years**	**Multicenter?**	**Prospective vs retrospective**	**Country**	**Funding source**
Nondiabetic patients at VA Referred to sleep clinic for SDB	FG≥126 mg/dL PSG only for titration	nd	2000-2005 (enrolled) July 31, 2006 final	No	Prospective	US	Gov't

C. BASELINE CHARACTERISTICS:

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
593 (potentially eligible) (544)	93%	62	79% white	33.2	65%	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
0 FG 98.3 mg/dL	nd	nd	nd	nd	nd	no	VA population

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" & TREATMENT AT BASELINE

All had Sleep Study?	**Which?**	**AHI***	**Epworth***	**MSLT* †**	**Habitual Snoring ***	**Bed partner, %**	**Time Since Diagnosis**	**Other (specify)**
Yes	PSG	31.4	8.0	nd	nd	nd	0	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		No
Timing of Baseline (OSA Dx, Time of survey, Other):					Time of diagnostic PSG			
Treatments Being Used:					CPAP and other treatments			

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Other
PSG	nd		nd	nd		

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

F. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	Kaplan Meier
Multivariate	Cox proportional hazards

G. PREDICTORS TESTED

	Category	Predictor	Definition	Time Point Measured	Strata	Tested in Univariable Analysis?	Tested in Multivariable Analysis?	Comment
1	Sleep measure	AHI		Baseline	Q1: <8 Q2: ≥8 - ≤20 Q3: ≤21 - ≥45 Q4: ≥46			
2	Demographic	Age						
3	Demographic	Sex						
4	Demographic	Race						
5	Habitus	BMI		Baseline				
6	Habitus	ΔBMI		Over follow-up period				
	Laboratory	FG		Baseline				
	Criteria Used to Test Predictors in Multivariable Analysis							

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome	How Ascertained?
1	Diabetes	T2DM incidence		Physician diagnosis and FG≥126 mg/dL	Blinded physician reviewing medical records
2					
3					
4					

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor				Follow-up	n Event	N Total	Pct	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Unit	Base	Final					Metric*	Result	95% CI	P	Metric*	Result	95% CI	P	Adjusted for:
Botros, 2009 US 19958890	T2DM, incident	AHI<8		2.9		2.7 y	6	142 (544 total)	4% (1.8/100 person-y)									
		8≥AHI≥20		13.7				136										
		21≥AHI≥45		32.6				132										
		AHI≥46		78.2				134										
		AHI≥8		41.5			55	402	14% (5.5/100 p-y)	HR	1.53	1.21-1.94	<0.001	HR	1.43	1.10-1.86	0.008	Age, Sex, Race, FG, BMI, Δ BMI
		Age													1.00		NS	
		Male													0.43		NS	
		Non-white													1.13		NS	
		FG	per mg/dL (implied)												1.04		<0.001	
		BMI	per kg/m2 (implied)												0.99		NS	
		Δ BMI	same												0.76		<0.001	

* RR, OR, HR, RD

J. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	

Comments on Results	

K. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons
49/593	8%	Incomplete PSG data

L. QUALITY

No obvious ascertainment bias
Fairly complete analysis of dataset.
Only substantial issue is that they analyzed by quartiles (top 3 v reference).

Quality: A

A. Source and Extractor

Author, Year	Lavie, 1995			Outcomes	Death
PMID	7610310	RefID	18042		
Key Question(s)	KQ 2			Design †	Retrospective cohort
Extractor	EMB			Comments	

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	Exclusion	AHI Criteria to Dx OSA	Study Years	Multicenter?	Prospective vs retrospective	Country	Funding source
Evaluated for SAS, generally for symptoms suggestive of SAS AI ≥10	"Predominantly hypopneas" Women excluded from multivariate analysis (too few) Unknown Age or BMI excluded from multivariate analysis	AI≥10 (hypopneas not included)	1976-1988	No	Retrospective	Israel	nd

C. BASELINE CHARACTERISTICS:

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
1620 (1140 in multivariate)	90% (100% in analysis)	48±11, median 49	nd	nd	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" & TREATMENT AT BASELINE

All had Sleep Study?	Which?	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Yes	PSG	nd	nd	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		

Timing of Baseline (OSA Dx, Time of survey, Other):	OSA Dx
Treatments Being Used:	~50% were treated after diagnosis, mostly by weight reduction, surgery, CNS or breathing stimulants 5 tracheostomy 25/~1215 (~2%) (CPAP introduced in the late 1980s)

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Other
PSG	AI>10		No airflow ≥10 sec	(Some data pre-O2 sat monitor, so hypopnea not included)	Loud and disturbing snoring, excessive daytime sleepiness, morning fatigue	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

F. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	t test / chi-square
Multivariate	Cox proportional hazards

G. PREDICTORS TESTED

	Category	Predictor	Definition	Time Point Measured	Strata	Tested in Univariable Analysis?	Tested in Multivariable Analysis?	Comment
1	Demographic	Age at diagnosis		Diagnosis				
2	Demographic	BMI (and weight, height)		Latest available				
3	Sleep measure	AI		Latest available				
4	Sleep measure	Mean apnea duration		Latest available				
5	Sleep measure	Apnea type	Obstructive, Mixed, Central	Latest available				
6	Comorbidities	Specific diseases	Heart, Lung, Diabetes, Hormonal, Other, HTN	Latest available				
	Criteria Used to Test Predictors in Multivariable Analysis					Key variables forced in (based on univariate and literature): Age, BMI, HTN, AI Unclear how decided whether to maintain others.		

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome	How Ascertained?
1	Death	All-cause	Dec 31, 1990		Questionnaire, Telephone, Computerized files Death certificates for cause of death
2					
3					
4					

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor				Follow-up	n Event	N Total	Pct	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Unit	Base	Final					Metric*	Result	95% CI	P	Metric*	Result	95% CI	P	Adjusted for:
Lavie, 1995 Israel 7610310	Death	AI	per unit			2-14 y	51	1140	4.5%				<0.10	OR [exp(coef)]	1.012	1.001, 1.024	0.04	Age, BMI, HTN
		Age	per year										<0.10		1.07	1.03, 1.10	0.0001	AI, BMI, HTN
		BMI	per unit										<0.10		1.07	1.02, 1.12	0.006	AI, Age, HTN
		HTN	dichot										<0.10		1.85	1.14, 3.02	0.009	AI, Age, BMI
		Heart Dz	dichot										<0.10		1.73	1.02, 2.92	<0.04	Top 4
		Lung Dz	dichot										<0.10		3.60	1.91, 6.78	<0.01	Top 4
		DM	dichot										<0.10		1.77	0.84,3.75	NS	Top 4
		Apnea duration	dichot										<0.10		1.01	0.99, 1.03	NS	Top 4
		Apnea type	categ										<0.10		nd			
	Heart or Lung Death	AI	per unit			2-14 y	25	1140	2.2%						1.01	0.99, 1.03	NS	Age, BMI, HTN
		Age	per year												1.11	1.03, 1.16	0.001	AI, BMI, HTN
		BMI	per unit												2.68	2.56, 2.82	0.001	AI, Age, HTN
		HTN	dichot												1.46	0.78, 2.75	NS	AI, Age, BMI
		Heart Dz	dichot												1.97	0.97, 3.99	0.06	Top 4
		Lung Dz	dichot												3.15	1.31, 7.55	0.01	Top 4
		DM	dichot												1.39	0.54, 3.57	NS	Top 4
		Apnea duration	dichot												1.03	1.00, 1.05	0.06	Top 4

* RR, OR, HR, RD

J. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	

Comments on Results	63 (3.9%) whose status could not be ascertained were assumed to be alive (and included in the analysis).

K. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons
302/1442 men	21%	Missing age or BMI

L. QUALITY

Appropriate analyses
No evidence of sampling or ascertainment biases.

Quality: A

A. Source and Extractor

Author, Year	Lavie, 2005			Outcomes	Mortality
PMID	4	RefID	664		
Key Question(s)	KQ 2			Design †	Retrospective cohort
Extractor	EMB			Comments	

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	Exclusion	AHI Criteria to Dx OSA	Study Years	Multicenter?	Prospective vs retrospective	Country	Funding source
Males >20 yo PSG for Sx of SA or RDI>10	Underweight (BMI<20.7) (few women, so excluded)	>10	1991-2000	No (but 4 clinics)	Retrospective	Israel	nd

C. BASELINE CHARACTERISTICS:

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
~16200 (13853)	100%	48.4±12.3 (20-93, range)	nd	28.8±4.8 (21-64)	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	Males only

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" & TREATMENT AT BASELINE

All had Sleep Study?	Which?	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Yes	PSG	25.7±21.4 (median 20)	nd	nd	nd	nd	~0	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
						nd		
Timing of Baseline (OSA Dx, Time of survey, Other):					OSA Diagnosis			
Treatments Being Used:					nd			

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Other
PSG	>10		nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

F. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	Crude mortality (/1000 pt-y) of BMIxRDI groups
Multivariate	Cox proportional hazards

G. PREDICTORS TESTED

	Category	Predictor	Definition	Time Point Measured	Strata	Tested in Univariable Analysis?	Tested in Multivariable Analysis?	Comment
1	Sleep measure	RDI	(AHI) A-H/hr	At diagnosis	Non-OSA ≤10 Mild 11-20 Mild-Mod 21-30 Moderate 31-40 Severe >40	Yes	a priori	
2	Characteristic	BMI		At diagnosis (implied)	Rec wt 20.7-27.7 Overwt 27.8-31.0 Obese ≥31.0	Yes	a priori	
3	Characteristic	Age			20-29 … 60-69 ≥70		a priori	
4								
5								
6								
	Criteria Used to Test Predictors in Multivariable Analysis							

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome	How Ascertained?
1	Death	All-cause mortality	Median±SD 4.6±2.2 y IQR 3-6.3 y Mean 4.7 y Total 65,014 pt-y of f/up		National records
2					
3					
4					

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor			Follow-up	n Event	N Total	Pct	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Base	Final					Metric*	Result	95% CI	P trend	Metric*	Result	95% CI	P	Adjusted for:
Lavie, 2005	Mortality	Total			Mean 4.7 y	363	13853	2.6	Crude mortality rate / 1000 pt-y	5.55							
Israel																	
15738297		RDI	≤10	--		34	3227	1.1		2.19		0.009	HR	Ref		0.0001	Age, BMI
			11-20			88	4154	2.1		4.52				1.52	NS		
			21-30			65	2601	2.5		5.10				1.34	NS		
			31-40			50	1204	4.1		8.57				2.13	1.36-3.34		
			>40			126	2667	4.7		10.22				2.59	1.73-3.87		
		BMI	20.7-27.7							4.77						0.001	
			27.8-31.0							4.79							
			>31.0							7.64							

* RR, OR, HR, RD
Data also reported for RDI x BMI subgroups

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor			Follow-up	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Base	Final		Metric*	Result	95% CI	P	Metric*	Result	95% CI	P	Adjusted for:
	Outcome (Unit)													
	Base													
	Final													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	

Comments on Results	Mean age at death 62.4±13.1 y; Mean age at diagnosis of those who died 61.0±12.5 Sensitivity analysis excluding 428 followed for <1 y (of whome 65 died) (to reduce influence of chronic illness) had “near identical results”. Also some data comparing studied population to population cohorts (by age)

	No interaction between RDI and BMI.

L. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons
~1620/16200	10%	National ID numbers unavailable or incorrect
736/14589	5%	RDI and/or BMI unknown

M. QUALITY
Appropriate analyses.
No evidence of sampling bias or ascertainment bias.
Some data reporting was opaque and/or difficult to interpret.

Quality: A

A. Source and Extractor

Author, Year	Marin, 2005			**Outcomes**	CVD events, Fatal; CVD events, Non-fatal
PMID	15781100	**RefID**	4540		
Key Question(s)	KQ 2			**Design †**	Prospective cohorts (similar to prospective case control)
Extractor	EMB			**Comments**	

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Study Years**	**Multicenter?**	**Prospective vs retrospective**	**Country**	**Funding source**
Men		5-30 with symptoms >30 (regardless of Sx)	1992-1994	No	Prospective	Spain	Government
Sleep disordered breathing group: OSAH or simple snorer (from sleep unit)	Non-compliant with prescribed CPAP						
Healthy controls: From population based study on sleep apnea prevalence (1991-1992) Age within 3 y and BMI within 2 kg/m^2 of severe untreated OSAH cases (AHI>30)	Excessive daytime somnolence Snoring						

C. BASELINE CHARACTERISTICS:

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
1465 [SDB] + 277 [healthy, matched] (1387 + 264)	100%	50	nd	28.7	25% 123/77	nd	5.5%
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
DM: 9%	Current 24%	nd	nd	nd	nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" & TREATMENT AT BASELINE

All had Sleep Study?	**Which?**	**AHI***	**Epworth***	**MSLT* †**	**Habitual Snoring ***	**Bed partner, %**	**Time Since Diagnosis**	**Other (specify)**
Yes	PSG	21	nd	nd	~100% (non-healthy)	nd	New	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		

Timing of Baseline (OSA Dx, Time of survey, Other):	Time of PSG (diagnosis)
Treatments Being Used:	nCPAP offered if AHI >30 or 5-30 with complaint of severe daytime sleepiness interfering with daily activities or polycythemia or cardiac failure All: Conservative advice: weight loss, avoid EtOH and sedatives, stop smoking, avoid sleep deprivation, restriction of sleep position

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Other
PSG	>5 w/symptoms (implied) >30		Cessation x 10 sec	Discernible reduction in airflow or thracoabdominal excursion x 10 sec with 4% desat	complaint of severe daytime sleepiness interfering with daily activities or polycythemia or cardiac failure	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

F. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	Chi-squared test, ANOVA, Kaplan Meier with log-rank
Multivariate	Cox proportional hazard regression

G. PREDICTORS TESTED

	Category	Predictor	Definition	Time Point Measured	Strata	Tested in Univariable Analysis?	Tested in Multivariable Analysis?	Comment
1		Age		Baseline (implied)		Yes	Yes	
2		BMI				Yes	No	Apparently NS univariate
3		CVD existing	IHD (hospital admission for MI, unstable angina, CABG or PCI), CHF, Cerebrovascular disease			Yes	Yes	
4		HTN	≥140/90 or treatment			Yes	Yes	
5		DM	clinical history			Yes	Yes	
6		Hyperlipidemia	>upper limit of normal or treatment			Yes	Yes	
		Current Smoking	any smoked tobacco			Yes	Yes	
		EtOH use	≥1 unit ≥3x/wk			Yes	Yes	
		SBP & DBP				Yes	Yes	
		FBG				Yes	Yes	
		Lipids	TC, Tg			Yes	Yes	
		Antihypertensive				Yes	Yes	
		Lipid lowering agent				Yes	Yes	
		Antidiabetic agent				Yes	Yes	
		SBD category			• Treated with CPAP • Severe (AHI>30) untreated • Mild-Moderate (AHI 5-30) untreated • Simple snorer (AHI<5) • Healthy	Yes	Yes	
	Criteria Used to Test Predictors in Multivariable Analysis					SBD category forced in Others: Significant unadjusted association with CV events (P threshold in Cox = 0.10)		

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome	How Ascertained?
1	CVD Death	Fatal cardiovascular event	Last quarter 2003	Death from MI or stroke	Medical records, death certificates, local physicians, relatives, Social Security Death Index
2	CVD event	Non-fatal CVD event		non-fatal MI, stroke, acute coronary insufficiency requiring CABG or PCI	Medical records, WHO criteria
3					
4					

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor				Follow-up	n Event	N Total	Pct	Unadjusted (reported)					Adjusted (reported)				
		Predictor	Unit	Base	Final					Per 100 person-yr	P	OR	95% CI	P	Metric*	Result	95% CI	P	Adjusted for:
Marin, 2005 Spain 15781100	CVD, Non-fatal	Healthy				10 y	12	264	4.5%	0.45	Ref	Ref			or	Ref			See Table G
		Simple snorers (AHI<5)					22	377	5.8%	0.58	NS	1.04	0.51, 1.34	NS		1.03	0.31, 1.84	NS	
		AHI 5-30, untreated					36	403	8.9%	0.89	NS	1.19	0.74, 1.89	0.09		1.15	0.34, 2.69	NS	
		AHI ≥30, untreated					50	235	21%	2.13	<0.0001	3.98	1.74, 6.13	0.003		2.87	1.17, 7.51	0.025	
		CPAP					24	372	6.5%	0.64	NS	1.06	0.55, 1.91	NS		1.05	0.39, 2.21	NS	
		Age	per yr									1.09	1.06, 1.11	<0.0001		1.09	1.04, 1.12	0.001	
		CVD	dichot									3.66	1.98, 4.07	<0.0001		2.54	1.31, 4.99	0.005	
	CVD Death	Healthy					8	264	3.0%	0.30	Ref	Ref				Ref			See Table G
		Simple snorers (AHI<5)					13	377	3.4%	0.34	NS	1.52	0.88, 2.11	NS		1.32	0.64, 3.01	NS	
		AHI 5-30, untreated					22	403	5.5%	0.55	NS	1.77	0.91, 2.76	0.07		1.57	0.62, 3.16	NS	
		AHI ≥30, untreated					25	235	11%	1.06	0.001	5.65	1.92, 6.52	<0.001		3.17	1.12, 7.52	0.001	
		CPAP					13	372	3.5%	0.35	NS	1.44	0.61, 2.80	NS		1.42	0.52, 3.40	NS	
		Age	y									1.11	1.07, 1.14	<0.0001		1.09	1.05, 1.13	0.001	
		CVD	dichot									2.68	1.13, 2.57	<0.0001		1.77	1.03, 3.09	0.02	
		SBP	per mm Hg									1.83	1.24, 5.52	0.003		1.57	1.04, 4.09	0.04	
		Current smoker	dichot									1.97	1.42, 6.71	0.002		1.51	1.02, 5.88	0.04	

* RR, OR, HR, RD

J. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	

Comments on Results	

K. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons
78/1465	5% (SBD)	No CPAP compliance (52) Lost to follow-up (26)
13/277	5% (healthy)	AHI≥5 (9) Lost to follow-up (4)

L. QUALITY

Possible selection bias by excluding those non-compliant with CPAP (who mostly got some other treatment).
Those on CPAP had more intensive follow-up.
Possible selection bias related to matching of healthy controls (similar to a case-control study).
No obvious ascertainment bias.
Good statistical analysis.

Quality: A

A. Source and Extractor

Author, Year	O'Connor, 2009			**Outcomes**	HTN
PMID	19264976	**RefID**	11605		
Key Question(s)	KQ 2			**Design †**	Prospective Cohort
Extractor	EMB			**Comments**	SHHS

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Study Years**	**Multicenter?**	**Prospective vs retrospective**	**Country**	**Funding source**
Ongoing epidemiological study ≥40 y	CPAP, tracheostomy, O2 (NYC study due to poor PSGs) Baseline HTN	NA	1995-1998	Yes	Prospective	US	Gov't

C. BASELINE CHARACTERISTICS:

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
6441 (SHHS) 2812 (met criteria) 2470 (analyzed)	45%	60	White 78% Black 4% AmInd 18%	27.9	0 (≥140/90; excluded) BP nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	Never 45% Former 42% Current 143%	nd	nd	nd	nd	No	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" & TREATMENT AT BASELINE

All had Sleep Study?	**Which?**	**AHI***	**Epworth***	**MSLT* †**	**Habitual Snoring ***	**Bed partner, %**	**Time Since Diagnosis**	**Other (specify)**
Yes	Portable	Median (IQR) 3.2 (1.0-8.7) <5: 61% 5-14.9: 25% 15-29.9: 9% ≥30: 4%	nd	nd	nd	nd	NA	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
No						nd		
Timing of Baseline (OSA Dx, Time of survey, Other):					Time of survey			
Treatments Being Used:					None			

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Other
Compumedics Portable PS-2 System	nd		Complete or almost complete cessation of airflow ≥10 sec ≥4% desaturation	≥25% lower flow or volume ≥10 sec (not apnea) ≥4% desaturation	NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

F. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	nd
Multivariate	General estimating equations

G. PREDICTORS TESTED

	Category	Predictor	Definition	Time Point Measured	Strata	Tested in Univariable Analysis?	Tested in Multivariable Analysis?	Comment
1	Sleep measure	AHI		Baseline	<5 5-14.9 15-29.9 ≥30	No	Yes	
2		BMI		Baseline		No	Yes	
3								
4								
5								
6								
	Criteria Used to Test Predictors in Multivariable Analysis							

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome	How Ascertained?
1	CV	HTN	2.0 y (range 0.4-3.6 y), 5.2 y (4.6-7.2 y)	≥140/≥90 or current treatment with antihypertensive medication	Seated blood pressure, medication recording
2					
3					
4					

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor				Follow-up	n Event	N Total	Pct	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Unit	Base	Final					Metric *	Result	95 % CI	P	Metric *	Result	95% CI	P	Adjusted for:
O'Connor, 2009 US 19264976	Incident HTN	AHI	0-4.9			2, 5 y	296	1510	20%					OR	Ref			Age, sex, race, BMI, time
			5-14.9				156	629	25%						0.92	0.72-1.17	NS	
			15-29.9				77	234	33%						1.12	0.80-1.56	NS	
			≥30				33	97	34%						1.51	0.93-2.47	NS	
							562 (total)	2470	23% (total)									

* RR, OR, HR, RD

J. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor				Follow-up	n Event	N Total	Pct	Adjusted (reported)				
		Predictor	Unit	Base	Final					Metric*	Result	95% CI	P	Adjusted for:
O'Connor, 2009 US 19264976	Incident HTN **Subgp BMI≤27.3**	AHI	0-4.9			5 y		887		OR	Ref			Age, sex, race, time
			5-14.9					213			0.89	0.59-1.34	NS	
			15-29.9					58			0.93	0.46-1.90	NS	
			≥30					21			2.71	1.24-5.93		
	Incident HTN **Subgp BMI>27.3**	AHI	0-4.9			5 y		541			Ref			
			5-14.9					378			0.92	0.67-1.27	NS	
			15-29.9					164			1.13	0.76-1.68	NS	
			≥30					65			1.18	0.64-2.19	NS	

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	
O'Connor, 2009 US 19264976	Incident HTN	AHI	5 y		

Comments on Results	

K. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons
342/2470	14%	No f/up data

L. QUALITY

No ascertainment bias
No obvious selection bias
Complete (multivariate) analyses

Quality: A

A. Source and Extractor

Author, Year	Peppard, 2000			**Outcomes**	HTN
PMID	10805822	**RefID**	1029		
Key Question(s)	KQ 2			**Design †**	Prospective Cohort
Extractor	EMB			**Comments**	Wisconsin Sleep Cohort Study

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Study Years**	**Multicenter?**	**Prospective vs retrospective**	**Country**	**Funding source**
Employees of Wisconsin state agencies Baseline and 4 y PSG	Pregnancy, Unstable or decompensated cardiopulmonary disease; Airway cancer, Upper respiratory tract surgery, Stroke, Cardiovascular disease Inadequate PSG Treatment for sleep disordered breathing	NA	1989~1995	No	Prospective	US	Gov't

C. BASELINE CHARACTERISTICS:

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
1189 (baseline PSG) **957 (invited for f/up PSG)** **709 (4 y PSG): data** **184 (8 y PSG)**	46%	47±8	nd	29±6	>140/90: 28% >160/100: 13% 125/82 Antihypertensive Rx: 10%	nd	0
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	Curernt 17%	nd	nd	nd	nd	EtOH 4±6 drinks/wk	No People with HTN at baseline included (and adjusted for)

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" & TREATMENT AT BASELINE

All had Sleep Study?	**Which?**	**AHI***	**Epworth***	**MSLT* †**	**Habitual Snoring ***	**Bed partner, %**	**Time Since Diagnosis**	**Other (specify)**
Yes	PSG	4±9	nd	nd	nd	nd	NA	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
No						nd		nd
Timing of Baseline (OSA Dx, Time of survey, Other):					Time of survey			
Treatments Being Used:					None			

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Other
PSG			Airflow cessation ≥10 sec	No chest wall movement ≥10 sec with ≥4% desat		

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

F. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	
Multivariate	Logistic regression and GEE

G. PREDICTORS TESTED

	Category	Predictor	Definition	Time Point Measured	Strata	Tested in Univariable Analysis?	Tested in Multivariable Analysis?	Comment
1	Sleep measure	AHI		Baseline	0 0.1-4.9 5.0-19.9 ≥15			
2	Demographic	Age						
3	Habitus	BMI						
4	Habitus	Neck circumference, Waist circumference, Waist to hip ratio, Skin fold measurements						
5	Lifestyle	Tobacco			Current Former No Hx No. pk-y Current pack/wk			
6	Lifestyle	Alcohol	Weekly consumption					
	Lifestyle	Exercise	h/wk					
	Demographic	Menopausal status						
	Criteria Used to Test Predictors in Multivariable Analysis					"Substantially altered regression coefficients for baseline AHI"		

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome	How Ascertained?
1	Hypertension	HTN	4 y, 8 y	>140/90 or antihypertensive medication	In clinic
2					
3					
4					

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor				Follow-up	n Event	N Total *	Pct	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Unit	Base	Final					Metric	Result	95% CI	P	Metric *	Result	95% CI	P	Adjusted for:
Peppard, 2000 US 10805822	HTN	AHI 0		0	2±4	4, 8 y	32 (34 base)	187	17% (18%)					OR	Ref		0.02 trend	Baseline HTN Age, Sex, BMI, Waist & Neck circumference, EtOH, Cigarettes
		0.1-4.9		2±1	4±6		142 (121)	507	28% (24%)						1.42	1.13-1.78		
		5.0-14.9		9±3	12±15		64 (59)	132	48% (45%)						2.03	1.29-3.17		
		≥15		31±16	27±22		40 (40)	67	60% (60%)						2.89	1.46-5.64		

* Includes double counting with 184 with data at both 4 and 8 y

J. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	

Comments on Results	Results similar restricting to 4 y data.

K. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons
480/1189	40%	No f/up PSG

L. QUALITY

No ascertainment bias
High lack of followup but those included were similar to those without data (per authors).
Difficult to interpret analysis of hypertension when those with HTN at baseline (28%) were not excluded.
Complete analyses

Quality: B

A. Source and Extractor

Author, Year	Punjabi, 2009			**Outcomes**	Death
PMID	19688045	**RefID**	214		
Key Question(s)	KQ 2			**Design †**	Prospective Cohort
Extractor	EMB			**Comments**	Sleep Heart Health Study

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Study Years**	**Multicenter?**	**Prospective vs retrospective**	**Country**	**Funding source**
In national prospective cohorts (eg, Framingham Offspring Study) ≥40 y Completed baseline examination	Treated for sleep disordered breathing with CPAP, oral appliance, oxygen or tracheostomy (n=147, ~2%) Sensitivity analysis with these patients were "materially unchanged".		1995-1998 (recruitment)	Yes	Prospective	US	Gov't

C. BASELINE CHARACTERISTICS:

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
6441 (6441)	46.7%	63±11	White 77% AA 8% NatAm 9.5% Hispanic 4% Other 1%	28.4±5.3	52%		18% Angina, heart failure, MI, stroke, coronary revascularization
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
DM 11%	Never 46% Former 43% Current 11%						No (untreated)

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" & TREATMENT AT BASELINE

All had Sleep Study?	**Which?**	**AHI***	**Epworth***	**MSLT* †**	**Habitual Snoring ***	**Bed partner, %**	**Time Since Diagnosis**	**Other (specify)**
Yes	Portable							
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

Timing of Baseline (OSA Dx, Time of survey, Other):	Time of survey
Treatments Being Used:	None (excluded)

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Other
Portable P-Series, Compumedics	≥5		Absent or nearly absent ≥10 s with 4% desat	≥30% reduction in airflow or thoracoabdominal movement ≥10 sec with 4% desat		

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

F. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	Kaplan Meier (proportional hazards) Regression spline
Multivariate	Stratified models (with cross-product terms)

G. PREDICTORS TESTED

	Category	Predictor	Definition	Time Point Measured	Strata	Tested in Univariable Analysis?	Tested in Multivariable Analysis?	Comment
1	Sleep measure	AHI			Normal <5 Mild 5.0-14.9 Moderate 15.0-29.9 Severe ≥30			Also other sleep measures tested
2								
3								
4								
5								
6								
	Criteria Used to Test Predictors in Multivariable Analysis							

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome	How Ascertained?
1	Death	All-cause mortality	To 4/1/2006 Mean 8.2 y 51,523 person-yr		F/up interviews, annual questionnaires, telephone contacts, local hospital and obituaries surveillance, SSA Death Master File
2					
3					
4					

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor			Follow-up	n Event	N Total	Pct	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Base	Final					Metric*	Result	95% CI	P	Metric*	Result	95% CI	P	Adjusted for:
	Death	Total			8.2 y	1047	6294	16.6%	Crude	20.3/1000 person-yr	19.1-21.6						
		AHI	<5	--	8.2 y	477	3429	13.9%		16.8	15.4-18.4		HR	Ref		<0.05 (implied)	Age, sex, race, BMI, smoking, prevalent HTN, DM,CVD, and BP
			5-15			320	1797	17.8%		21.7	19.4-24.2			0.93	0.80-1.08		
			15-30			165	727	22.7%		28.3	24.3-33.0			1.17	0.97-1.42		
			≥30			86	341	25.2%		32.2	26.0-39.8			1.46	1.14-1.86		
		Sex-Age											2 way interaction between AHI and Age was statistically significant (P<0.005) Interaction with sex was implied				
		Men≤70 y	<5			91	985			11.1				Ref		<0.05 (implied)	
			5-15			82	694			14.4				1.24	0.90-1.71		
			15-30			47	322			17.9				1.45	0.98-2.14		
			≥30			28	168			20.7				2.09	1.31-3.33		
		Men>70 y	<5			125	277			60.8				Ref		NS	
			5-15			111	282			51.0				0.92	0.70-1.20		
			15-30			67	140			65.1				1.23	0.90-1.68		
			≥30			36	75			69.6				1.27	0.86-1.86		
		Women (all ages)	<5			261	2167			14.5				Ref		NS	
			5-15			126	821			18.5				0.83	0.66-1.04		
			15-30			51	265			1.01				1.01	0.73-1.38		
			≥30			22	99			1.34				1.40	0.89-2.22		

* RR, OR, HR, RD

Also data for all men, and women divided <>70 y

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Predictor			Follow-up	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Base	Final		Metric*	Result	95% CI	P	Metric*	Result	95% CI	P	Adjusted for:
	Outcome (Unit)													
	Base													
	Final													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	

Comments on Results	

J. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons
	Implied 0% not analyzed	

I. QUALITY
No evidence of sampling or ascertainment bias.
Multivariable analytic method sub-par

Quality B

A. Source and Extractor

Author, Year	Reichmuth, 2005			**Outcomes**	T2DM
PMID	16192452	**RefID**	11703		
Key Question(s)	KQ 2			**Design †**	Prospective cohort
Extractor	EMB			**Comments**	Wisconsin Sleep Cohort

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Study Years**	**Multicenter?**	**Prospective vs retrospective**	**Country**	**Funding source**
30-60 y Random sample invited for PSG	DM at baseline Single visit only	NA	1988	No	Prospective	US	Gov't

C. BASELINE CHARACTERISTICS:

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
1546 (1387) 978 analyzed longitudinally	56%	49±8	nd	28.9 (IQR 25.5-33.3)	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
4% (excluded from longitudinal analysis)	Current ~17%	nd	nd	nd	nd		No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" & TREATMENT AT BASELINE

All had Sleep Study?	**Which?**	**AHI***	**Epworth***	**MSLT* †**	**Habitual Snoring ***	**Bed partner, %**	**Time Since Diagnosis**	**Other (specify)**
Yes	PSG	>5: 23%	nd	nd	nd	nd	NA	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
No						nd		

Timing of Baseline (OSA Dx, Time of survey, Other):	Time of survey
Treatments Being Used:	37 began CPAP

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Other
PSG			Cessation ≥10 sec	Discernible reduction in breathing and desat ≥4%		

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

F. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	
Multivariate	Multiple logistic regression GEE to account for large degree of double counting (978 subjects, 1857 follow-up periods (4 & 8 y)

G. PREDICTORS TESTED

	Category	Predictor	Definition	Time Point Measured	Strata	Tested in Univariable Analysis?	Tested in Multivariable Analysis?	Comment
1	Sleep measure	AHI		Baseline	<5 5-15 ≥15 ≥30			
2	Demographic	Sex						
3	Demographic	Age						
4	Habitus	Waist girth						Found to be more strongly correlated than BMI
5								
6								
	Criteria Used to Test Predictors in Multivariable Analysis							

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome	How Ascertained?
1	Diabetes	T2 DM incidence	4 y, 8 y	Physician diagnosis or FG≥126 mg/dL T2DM using oral hypoglycemic agent or lifestyle modification (Not T1DM: Age <30 y or BMI <25 and insulin treatment alone)	
2					
3					
4					

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor				Follow-up	n Event	N Total	Pct	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Unit	Base	Final					Metric *	Result	95 % CI	P	Metric *	Result	95% CI	P	Adjusted for:
Reichmuth, 2005 US 16192452	T2DM	AHI<5				4, 8 y		978 (1857 observations)						OR	Ref			
		AHI 5-15													1.56	0.80-3.02	NS	Age, Sex, Waist circumference
		AHI ≥15													1.62	0.67-3.65	NS	

* RR, OR, HR, RD

J. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	

Comments on Results	

K. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons
568/1546	37%	No follow-up data (or excluded for other reasons)

L. QUALITY

No obvious ascertainment bias
Apparently appropriate modeling for multiple time points, though reporting unclear (baseline means of observations instead of means of participants reported).
Unclear and incomplete reporting on those included in the longitudinal analysis.

Quality: B

A. Source and Extractor

Author, Year	Silva, 2009			**Outcomes**	QoL
PMID	19725256	**RefID**	11789		
Key Question(s)	KQ 2			**Design †**	Prospective Cohort
Extractor	EMB			**Comments**	SHHS

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Study Years**	**Multicenter?**	**Prospective vs retrospective**	**Country**	**Funding source**
In existing major prospective cohort study PSG at baseline and followup	(NYC site excluded because of poor PSG quality)	NA	1995 f/up 2000-2003	Yes	Prospective	US	Gov't

C. BASELINE CHARACTERISTICS:

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
6441 (SHHS total) **4586 (repeat PSG)** **(3078 evaluable)**	45%	62 (67 at f/up)	White 75% Native Am 14% Afr Am 6% Hisp/Mex Am 4% Asian/Pac Is 1%	28.7 (base) 29.3 (f/up)	nd	nd	CHD 15% (base) 20% (f/up)
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	Ex 46% Current 12% Never 42% (baseline)	nd	nd	nd	nd	Respiratory disease 9% (base) 12% (f/up)	No (Native Americans and Hispanic/Mexican Americans over-represented

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" & TREATMENT AT BASELINE

All had Sleep Study?	Which?	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Yes	Portable	8.1±11 <5: 54% 5-<15: 29% 15-<30 11% ≥30 5%	>11 25%					Difficulty initiating or maintaining sleep (DIMS) Yes: 29%
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		
Timing of Baseline (OSA Dx, Time of survey, Other):					Time of survey			
Treatments Being Used:					Sleeping pills 20% (nd re: CPAP etc)			

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Other
Compumedics Portable PS-2 System	nd		Complete or almost complete cessation of airflow ≥10 sec ≥4% desaturation	≥25% lower flow or volume ≥10 sec (not apnea) ≥4% desaturation	NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

F. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	Chi-squared, ANOVA (t test)
Multivariate	Linear regression

G. PREDICTORS TESTED

	Category	Predictor	Definition	Time Point Measured	Strata	Tested in Univariable Analysis?	Tested in Multivariable Analysis?	Comment
1	Demographic	Race		NA	Caucasian v other	Yes (NS)	No	
2	Lifestyle	Smoking	self-reported	Baseline & f/up	Never, Current, Ex			
3	Demographic	Education			<9, 9-12, >12-16, >16 years	Yes (NS)	No	
4		BMI		nd	<30, ≥30 kg/m2			analyzed both categorical and continuous
5	Comorbidity	CHD	self-reported	Baseline	Yes/No			
	Comorbidity	Respiratory diseases	self-reported	Baseline	Yes/No			
	Medication	Sleeping pill use		nd	Yes (any) / No			
	Sleep measure	RDI		Baseline	≤5, >5-15, >15-<30, ≥30			analyzed both categorical and continuous
6	Demographic	Sex				Yes (NS)	Yes	
	Demographic	Marital status				Yes (NS)	No	
	Criteria Used to Test Predictors in Multivariable Analysis					nd		

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome	How Ascertained?
1	QoL	SF-36	Baseline, 5 y (mean)		
2					
3					
4					

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor				Follow-up	n Event	N Total	Pct	Unadjusted (reported)					Adjusted (reported)				
		Predictor	Unit	Base	Final					Metric*	Base	Final	95% CI	P	Metric*	Result	95% CI	P	Adj
Silva, 2009 US 19725256	PCS	RDI<5	%	54	44	5 y				Mean PCS	49±9	48±10		<0.0001 (baseline & final) ANOVA					
		RDI 5-<15	%	29	33						48±9	46±10							
		RDI 15-<30	%	11	15						47±9	45±11							
		RDI ≥30	%	5	8						45±10	44±11							
		RDI	per hr	8.1±11	10.9±14					PCS	48.5±9	46.3±10			RR[1]	1.008		NS	A B C Re sm s sle
		Age	per y	62.0±10												0.94		<0.001	
		BMI	per unit	28.7±5												0.96		NS	
		CHD	categ	15%												0.81		NS	
		Resp Dz	categ	9%												0.84		NS	
		Smoking	categ	Ex 46% Cur 12%												0.84		NS	
		Male	categ	45%												1.57		NS	
		Sleeping pills	categ	20%												0.23		0.003	
	MCS	RDI<5	%	54	44	5 y				Mean MCS	54±8	55±7		NS (baseline & final) ANOVA					
		RDI 5-<15	%	29	33						54±8	55±8							
		RDI 15-<30	%	11	15						55±8	54±8							
		RDI ≥30	%	5	8						55±8	56±7							

[1] Regression coefficient reported. RR = exp(coefficient)

		RDI	per hr	8.1±11	10.9±14					MCS	54.1±8	54.8±8			RR[2]	0.98		NS	A B Sm T s t
		Age	per y	62.0±10												1.03		NS	
		BMI	per unit	28.7±5												1.03		NS	
		CHD	categ	15%												1.32		NS	
		Resp Dz	categ	9%												1.46		NS	
		Smoking	categ	Ex 46% Cur 12%												0.17		0.02	
		Male	categ	45%												0.70		NS	
		Sleeping pills	categ	20%															

* RR, OR, HR, RD

J. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	

Comments on Results	Also analyses of change in RDI over time as predictors of QoL. Not extracted

K. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons
0	Restricted to those with available data	

L. QUALITY

No obvious selection bias (beyond being limited to those willing to have 2 PSGs). Due to underlying studies, some minorities over-represented.
Reasonable statistical analysis.

Quality: A

[2] Regression coefficient reported. RR = exp(coefficient)

A. Source and Extractor

Author, Year	Young, 2008			**Outcomes**	Death, CVD Death
PMID	18714778	**RefID**	11976		
Key Question(s)	KQ 2			**Design †**	Prospective cohort
Extractor	EMB			**Comments**	Wisconsin Sleep Cohort Study

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Study Years**	**Multicenter?**	**Prospective vs retrospective**	**Country**	**Funding source**
30-60 y Random sample invited for PSG	Death w/in 1 year of baseline study (n=2) Inadequate PSG (22)	OSA not diagnosed	1988-	No	Prospective	US	Government

C. BASELINE CHARACTERISTICS:

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
1546 (1522)	55%	48	nd	28.6	33% (self reported)	nd	4% (self-reported)
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
3% (self-reported)	18% (current)	nd	nd	nd	nd	Stroke 0.5% Very good or excellent health 69%	No (general population)

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" & TREATMENT AT BASELINE

All had Sleep Study?	**Which?**	**AHI***	**Epworth***	**MSLT* †**	**Habitual Snoring ***	**Bed partner, %**	**Time Since Diagnosis**	**Other (specify)**
Yes	PSG		nd	nd	nd	nd	NA	"Excessive daytime sleepiness" 25%
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
No						nd		
Timing of Baseline (OSA Dx, Time of survey, Other):					Time of PSG			
Treatments Being Used:					None specified (informed of PSG results and if AHI>15 told to talk to physician)			

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Other
PSG	≥15		Cessation ≥10 sec	Discernible reduction in breathing and desat ≥4%	no	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

F. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	Kaplan-Meier and log-rank test
Multivariate	Cox proportional hazards

G. PREDICTORS TESTED

	Category	Predictor	Definition	Time Point Measured	Strata	Tested in Univariable Analysis?	Tested in Multivariable Analysis?	Comment
	Sleep measures	AHI		Baseline	AHI<5		Yes	
					5 to <15			
					15 to <30			
					≥30			
	Lifestyle	Alcohol use	drinks/wk				(sensitivity analysis)	
	Lifestyle	Cigarette use	current		Dichot		(sensitivity analysis)	
	Demographic	Education			6 categories		(sensitivity analysis)	
	Comorbidity	CVD	self report		Dichot		(mediating factor)	
	Comorbidity	Stroke	self report		Dichot		(mediating factor)	
	Comorbidity	Diabetes	self report		Dichot		(mediating factor)	
	Comorbidity	HTN	3 measurements or treatment		Dichot		(mediating factor)	
	Comorbidity	General health	self report		5 categories		(sensitivity analysis)	
	Treatment	CPAP use	≥4 noc/wk	Baseline or followup	Dichot		(sensitivity analysis)	
	Sleepiness	Excessive sleepiness	Interferes with daily living		Dichot		(sensitivity analysis)	
	Sleepiness	Frequency			5 categories		(sensitivity analysis)	
	Sleep measure	Sleep duration			Continuous?		(sensitivity analysis)	
	Body measure	BMI			Continuous		Yes	
	Body measure	Neck girth			Continuous		(sensitivity analysis)	
	Body measure	Waist-hip ratio			Continuous		(sensitivity analysis)	
	Laboratory	Total cholesterol			Continuous		(sensitivity analysis)	
	Demographic	Sex					Yes	
	Demographic	Age		Baseline	Continuous		Yes	
	Criteria Used to Test Predictors in Multivariable Analysis					nd		

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome	How Ascertained?
1	Death	All cause	Up to 3/1/2008		US Social Security Death Index, Wisconsin vital records Including cause of death (100% accuracy in 30 records compared to death certificates)
2	Death	CVD or stroke death			AMI, Acute ischemic heart disease, Heart failure with underlying chronic IHD, Stroke, AFib or Aflutter, Sudden cardiac arrest, Cardiac dysrhythmias with underlying chronic IHD, Cardiomyopathy, Pulmonary HTN
3					
4					

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor				Follow-up	n Event	N Total	Pct	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Unit	Base	Final					Metric*	Result	95% CI	P	Metric*	Result	95% CI	P	Adjusted for:
Young, 2008 US 18714778	Death, All cause	(total)				13.8 y (1.5-18.7)	80	1522	5.3%									
		AHI 0-5					46	1157	4.0%	/1000 person-y	2.85		<0.001 (log-rank)	HR	Ref		0.008 trend	Age, Age^2, Sex, BMI, BMI^2
		AHI 5-15					16	220	7.3%		5.54				1.6	0.9, 2.8		
		AHI 15-30					6	82	7.3		5.42				1.4	0.6, 3.3		
		AHI ≥30					12	63	19.1%		14.6				3.0	1.4, 6.3		
	Death, CVD or stroke	(total)					25	1522	1.6%									
		AHI 0-5					12	1157	1.0%		0.74			HR	Ref		0.12 trend	Age, Age^2, Sex, BMI, BMI^2
		AHI 5-15					6	220	2.7%		2.08				1.8	0.7, 4.9		
		AHI 15-30					2	82	2.4%		1.81				1.2	0.3, 5.8		
		AHI ≥30					5	63	7.9%		6.07				2.9	0.8, 10		

* RR, OR, HR, RD

J. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	

Comments on Results	Also, in subset without CPAP treatment, greater death rates with higher AHI compared to complete sample. Results not affected by addition of other predictor variables. Sample is biased due to healthy volunteer bias. Those who participated (had a PSG) were healthier, less HTN, lower death rate than non-participants

K. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons
24/5146	1.6%	Died within 1 year (2), Inadequate PSG (22)

L. QUALITY

Good statistical analysis
No ascertainment bias
Evidence of sampling bias (this sample healthier than population surveyed).

Quality: A

Key Question 5
PAP v Control

A.

Author, Year	Arias, 2005			**Intervention 1**	Auto CPAP
PMID*	16009798	**RefID**	4029	**Intervention 2**	
Key Question(s)	5- CPAP vs Cx			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	Sham nCPAP
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
AHI ≥10; ESS≥10; no current drug or mechanical treatment for OSAS	-Unwillingness or inability to perform the testing procedure -obstructive or restrictive lung disease demonstrated on pulmonary function testing -current use of cardioactive drugs Cardiac rhythm disturbances, including sinus bradycardia and sinus tachycardia -known hypertension, or 24-hour mean blood pressure of 135 and/or 85 mm Hg or more -left ventricular ejection fraction <50% ischemic or valvular heart disease -hypertrophic, restrictive, or infiltrative cardiomyopathy; pericardial disease or stroke by history or physical examination, ECG, chest radiography, conventional stress testing, and echocardiography -diabetes mellitus, by history or 2 random blood glucose levels □126 mg/dL -morbid obesity (body mass index >40 kg/m2) -daytime hypoxemia (PaO2 <70 mm Hg) or hypercapnia (PaCO2 >45 mm Hg)	Nd	nd	n	spain	Fondo de Investigación Sanitaria	n	y	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx	**27**							
Cx	**27**							
Total	**27**	100%	52	Nd	30.5	Daytime BP = 126/79; nighttime BP = 118/70	Nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	36	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	27							
Control:	27							
Total:	27	44.0	nd	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Nd	Nd	nd	Cessation of oronasal airflow lasting >10 seconds	Decrease of 50% in oronasal airflow lasting >10 seconds, associated with a fall in arterial oxygen saturation >4% of the preceding baseline level.	nd	separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	nCPAP	nd	nd
2				
3				
Control	PAP	Sham nCPAP	nd	conventional nCPAP device in which the area of the exhalation port is amplified, thereby nearly cancelling nasal pressure, and an orifice resistor is connected between the tubing and the nCPAP unit that loads the blower with the same airflow resistance as in effective nCPAP
For CPAP:		**How was the Pressure selected?**	Automated pressure-setting device	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Physical scale	Daytime BP	Baseline, 12 wks	8am to 11pm, measured by ambulatory blood pressure
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P
Arias, 2005 Spain 16009798	Daytime BP	mm Hg	Tx	nCPAP	12 wk	25	127/79	10/5	127/78	8/5	0/-1	-2/0	Nd	0/0	-4/-1	NS
			Cx	Sham nCPAP	12 wk	25	127/79	10/5	127/78	12/6	0/-1	2/1	nd			NS

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Both	7.4	Average nightly usage of nCPAP of <3.5 hrs

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Y	Nd	Nd	Y	Y	y	n	y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Y	N	Y	Y	Y	Y	N			n
Reasons for drop-outs:	Lack of compliance (nightly hours using CPAP)									
Other Issues:										
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Ballester, 1999			**Intervention 1**	Conservative treatment measures (CT) + CPAP
PMID*	9927363	**RefID**	5038	**Intervention 2**	
Key Question(s)	KQ 5 (CT+CPAP vs. CT)			**Intervention 3**	
Design †	RCT			**Control**	Conservative measures
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
-Severe symptoms with AHI > 15 -Mild/ moderate symptoms with AHI > 30	-severe/unstable CVD -hazardous job	15	nd	no	Spain	Government -Fondo de Investigaciones Sanitarias(FIS) de la Seguridad Social - the Commissionat per a Universitats i Recerca (1995 SGR00446) from the Generalitat de Catalunya	no	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y SE**	**Race**	**BMI*, SE**	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	68	88	53 ± 1.3	nd	32 ± 0.6	nd	nd	nd
Cx	37	87	54 ± 1.5	nd	34 ± 1.2	nd	nd	nd
Total	105	88	53 ± 10(SD)	nd	32.7			
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population (which?)**
Tx	nd	nd	nd	nd	nd	nd	nd	nd
Cx	nd	nd	nd	nd	nd	nd	nd	nd
Total	nd	nd	nd	nd	nd	nd	nd	nd
	Treatments used (prior to trial, including surgery)							
Tx	nd							
Cx	nd							
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*, SE	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	**68**	55 ± 2.7	12.1 ± 0.6	nd	nd	nd	nd	
Control:	**37**	58 ± 3	11.4 ± 1.0	nd	nd	nd	nd	
Total:	**105**	56 ± 20 (SD)	12 ± 5 (SD)	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Densa Pneumograph	>15		Air flow cessation lasting ≥10 s	≥ 10 s of discernable airflow reduction associated with cyclical Sao2 dip of 3%		separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Auto-titrating CPAP	CT + CPAP	Rescare AutoSet System	The AutoSet system is a computer-based CPAP machine that performs an automatic pressure titration in response to snoring, inspiratory airflow contour morphology, or the presence of apneas or hypopneas.
2				
3				
Control	CT			Enough hours of sleep, Sleep on side, Avoid sedatives and alcohol, Weight loss
For CPAP:		**How was the Pressure selected?**	Automatic titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	Spent full day in the sleep unit for titration and practice. Out-patient follow up at 4, 8, 12 weeks and weekly phone calls.

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	ESS	3 mo	
2	Miscellaneous	SAHS-related symptoms questionnaire	3 mo	15 items re: symptoms Snoring Breathing pauses Nocturia Dry mouth Morning headache & others Score 15 (absence) – 16 (max)
3	QoL	Nottingham Health Profile	3 mo	38 items – 6 domains Energy Pain Sleep Emotional reactions Social isolation Physical mobility "yes" or "no" answer to each item and the scores are calculated as follows: total number of affirmative answers to the items in one dimension divided by the total number of items in that dimension multiplied by 100. Scores 0 (absence of distress in each dimension) - 100 (maximal distress). Hunt 1981
4	Compliance		3 mo	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Ballester, 1999 Spain 9927363	Compliance, >4.5 h/night	**Tx**	CPAP	3 mo	50	68	%	73%						
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SD/SE*	P	Value	SD/SE*	P
Ballester, 1999 Spain 9927363	ESS	Units on a scale	**Tx**	CT + CPAP	3 mo	68	12.1	0.6	5.6	0.5	-6..5			-5.7		< 0.001
			Cx	CT	3 mo	37	11.4	1.0	10.6	1.0	-0.8					
	SAHS-related symptoms questionnaire	Units on a scale	**Tx**	CT + CPAP	3 mo	68	43.4	0.8	26.5	1.4	-16.9			-12.3		< 0.001
			Cx	CT	3 mo	37	41.8	1.1	37.2	1.9	-4.6					
	NHP – Emotional reactions	Units on a scale	**Tx**	CT + CPAP	3 mo	68	28.4	3.3	17.0	3.0	-11.4			-8.4		0.08
			Cx	CT	3 mo	37	29.4	5.0	26.4	4.5	-3.0					
	NHP - Sleep	Units on a scale	**Tx**	CT + CPAP	3 mo	68	30.1	3.3	18.1	3.0	-12.0			-4.9		0.183
			Cx	CT	3 mo	37	23.1	3.8	16.0	4.0	-7.1					
	NHP - Physical	Units on a scale	**Tx**	CT + CPAP	3 mo	68	24.2	2.6	15.1	2.1	-9.1			-5.2		0.09
			Cx	CT	3 mo	37	25.0	3.6	21.1	3.2	-3.9					
	NHP – Social isolation	Units on a scale	**Tx**	CT + CPAP	3 mo	68	14.2	2.3	8.5	1.79	-5.7			-3.7		0.03
			Cx	CT	3 mo	37	13.2	3.0	11.2	3.4	-2.0					
	NHP – Pain	Units on a scale	**Tx**	CT + CPAP	3 mo	68	20.5	3.3	14.8	3.1	-5.7			-0.2		0.94
			Cx	CT	3 mo	37	20.6	4.0	15.1	3.9	-5.5					
	NHP - Energy	Units on a scale	**Tx**	CT + CPAP	3 mo	68	34.3	4.7	12.7	3.3	-21.6			-20.6		< 0.005
			Cx	CT	3 mo	37	23.2	4.6	22.2	5.0	-1.0					

Number analyzed is presumed to be 68 & 37.

* Delete or correct the incorrect value/item. If change, highlight yellow.

** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
Ballester, 1999 Spain 9927363	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	nd	nd	y	y	NA	nd	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	Y				
Reasons for drop-outs:	Nd									
Other Issues:	No power calculation									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Barbe, 2001			**Intervention 1**	nCPAP
PMID*	11388814	**RefID**	5044	**Intervention 2**	
Key Question(s)	KQ 5 (CPAP vs Cx)			**Intervention 3**	
Design †	RCT			**Control**	Sham CPAP
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
AHI ≥30, ESS ≤10	Cognitive deterioration of any cause, chr dis, affecting QoL, severe cardiac dis, <8 yrs of formal education, alcohol/ drug abuse	≥30	Aug 1999 – Mar 2000	Yes (6)	Spain	Gov	Yes (SF-36) 25 in each grp	Yes	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**29 (29)**	26 (90%)	54±2		29±1			
Cx	**26 (25)**	23 (92%)	52±2		29±0.4			
Total	**55 (54)**	49 (91%)		nd	29		Implies 0%	Implies 0%
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd				Non sleepy pts
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI* SE	Epworth* SE	MSLT SE* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	29	54±3	7±0.4	12±1				
Control:	25	57±3	7±0.4	10±1				
Total:					nd	nd		
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥30		Cessation of respi flow >10s	Significant reduction in air flow followed by an arousal or an episode of SaO2 >4%	No or mild daytime sleepiness	Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	Nasal CPAP	Respironics	
2				
3				
Control	Placebo	Sham CPAP		No pressure added
For CPAP:		**How was the Pressure selected?**	Full night PSG titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
none		
For CPAP:	**Describe the frequency of the initial education follow-up**	Initial edu & then telephonic access

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	QoL	SF-36	6 weeks	
2	QoL	FOSQ	6 weeks	
3	Sleepiness measures	ESS	6 weeks	
4	Sleepiness measures	MSLT	6 weeks	
5	BP		6 weeks	

6	Psychological tests	WMS- mental control	6 weeks	Wechsler Memory Scale (Wechsler 1981 (24))
7	Psychological tests	WMS- verbal paired associated	6 weeks	Wechsler Memory Scale (Wechsler 1981 (24))
8	Psychological tests	Trial Making A test	6 weeks	
9	Psychological tests	Trial Making B test	6 weeks	
10	Psychological tests	WAIS- Digital symbols	6 weeks	Wechsler Adult Intelligence Scale (Wechsler 1998 (23))
11	Psychological tests	WAIS- block design	6 weeks	
12	Psychological tests	WAIS- digit span	6 weeks	
13	Psychological tests	Hits on steer clear test	6 weeks	
14	Psychological tests	PASAT 1	6 weeks	Paced Auditory Serial Addition Test (Lezack 1995 (25))
15	Psychological tests	PASAT 2	6 weeks	
16	Psychological tests	PASAT 3	6 weeks	
17	Psychological tests	PASAT 4	6 weeks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	**Outcome**		**Intervention**	**Follow-up**	**n Event**	**N Total**	**Unadjusted (reported)**				**Adjusted (reported)**			
							Metric*	**Result**	**95% CI**	**P btw**	**Result**	**95% CI**	**P btw**	**Adjusted for:**
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SD/SE*	P
Barbe, 2001 Spain 11388814	ESS	Score	**Tx**	nCPAP	6 weeks	29	7	0.4	8	0.6	+1	1		+1		0.2
			Cx	Sham CPAP		25	7	0.4	8	1	0	1				
	MSLT	min	**Tx**	nCPAP	6 weeks	29	12	1	13	1	+1	1		0		>0.2
			Cx	Sham CPAP		25	10	1	11	1	+1	1				
	FOSQ	Score	**Tx**	nCPAP	6 weeks	29	102	3	108	2	+7	2		+4		>0.2
			Cx	Sham CPAP		25	107	3	110	2	+3	3				
	SF-36 physical component summary	Score	**Tx**	nCPAP	6 weeks	29	49	1	51	1	+2	1		+1		>0.2
			Cx	Sham CPAP		25	48	1	50	1	+1	1				
	SF-36 mental component summary	Score	**Tx**	nCPAP	6 weeks	29	51	2	51	2	-1	2		-2		>0.2
			Cx	Sham CPAP		25	50	2	52	2	+1	1				
	Diurnal Systolic BP	mm Hg	**Tx**	nCPAP	6 weeks	29	130	2	127	2	-3	2		-2		>0.2
			Cx	Sham CPAP		25	127	2	124	3	-1	2				
	Diurnal Diastolic BP	mm Hg	**Tx**	nCPAP	6 weeks	29	82	1	81	1	-1	1		-1		>0.2
			Cx	Sham CPAP		25	80	2	80	2	0	1				

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Barbe, 2001 Spain 11388814	Memory	WMS-mental control	6 weeks	nCPAP	29	Sham CPAP	25	0					
	Memory	WMS-verbal paired associated	6 weeks	nCPAP	29	Sham CPAP	25	0					
	Cognition	Trial Making A test	6 weeks	nCPAP	29	Sham CPAP	25	0					
	Cognition	Trial Making B test	6 weeks	nCPAP	29	Sham CPAP	25	0					
	Cognition	WAIS-Digital symbols	6 weeks	nCPAP	29	Sham CPAP	25	0					
	Cognition	WAIS-block design	6 weeks	nCPAP	29	Sham CPAP	25	0					
	Cognition	WAIS-digit span	6 weeks	nCPAP	29	Sham CPAP	25	0					
		Hits on steer clear test	6 weeks	nCPAP	29	Sham CPAP	25	0					
		PASAT 1	6 weeks	nCPAP	29	Sham CPAP	25	0					
		PASAT 2	6 weeks	nCPAP	29	Sham CPAP	25	0	Net diff	+2			
		PASAT 3	6 weeks	nCPAP	29	Sham CPAP	25	0					
		PASAT 4	6 weeks	nCPAP	29	Sham CPAP	25	0					

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Sham CPAP	1/26 (4%)	Change of residence-1

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	NA	Yes
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Yes	No	Yes	Yes	No	Yes	NA			NA
Reasons for drop-outs:	Change of residence-1									
Other Issues:	N <30									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Barnes, 2002			**Intervention 1**	nCPAP
PMID*	11897643	**RefID**	4055	**Intervention 2**	
Key Question(s)	KQ 5 (CPAP vs. Cx)			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	Placebo tablet
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
>18 yrs, AHI: 5-30	Min SaO2<75% in REM & 80% in NREM, comorbidities (DM, unstable IHD), h/o falling asleep while driving or working or some other unsafe situation, fluency in English,cerebrovascular dis, closed head injury with loss of consciousness >15 min, psychiatric illness, alcohol/drug abuse	5-30	nd	Yes (2)	Australia	Gov	Yes 17 (all)	No	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y, SD**	**Race**	**BMI* SD**	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**42 (28)**					>140/90		
Cx	**42 (28)**							
Total	**42 (28)**	24 (86%)	45.5±10.7	nd	30.9±4.9	7 (25%)	Implies 0%	Implies 0%
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	Implies 0%	nd	Implies 0%	Implies 0%	See results		Implies 0%	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	None							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	28	12.9±5.8	11.3±5.0	12.3±5.1	nd	nd	Probably new	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	5-30		<20% airflow for ≥ 10s	>50% reduction in at least 2 of airflow, thoracic mov, abd mov lasting for ≥10s			

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	nCPAP	Sullivan Elite; ResMed, Aus	
2				
3				
Control	Placebo	Placebo tablet		
For CPAP:		**How was the Pressure selected?**	nd	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
none		
For CPAP:	**Describe the frequency of the initial education follow-up**	Follow up visit at 2 wks & then 2 phone calls of encouragement

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	BP		8 weeks	
2	Sleepiness measures	ESS	8 weeks	
3	Sleepiness measures	MSLT	8 weeks	
4	QoL	SF-36	8 weeks	
5	QoL	FOSQ	8 weeks	

6	Compliance		8 weeks	
7	Neurobehavioral test	Memory- Word pair memory recall	8 weeks	Neuropsychological assessment battery; Dinges 1985 (30)
8	Neurobehavioral test	Memory- WMS-R visual reproduction	8 weeks	
9	Neurobehavioral test	Cognition Trial A & B	8 weeks	
10	Neurobehavioral test	Cognition- Digital symbol substitution test	8 weeks	Neuropsychological assessment battery; Dinges 1985 (30)
11	Neurobehavioral test	Cognition- Controlled oral word association test	8 weeks	
12	Neurobehavioral test	Vigilance & divided attention- Psychomotor vigilance task	8 weeks	Neuropsychological assessment battery; Dinges 1985 (30)
13	Neurobehavioral test	Vigilance & divided attention- Stroop color association test	8 weeks	
14	Neurobehavioral test	Mood- POMS (Profile of Moods States)	8 weeks	Neuropsychological assessment battery; Dinges 1985 (30)
15	Neurobehavioral test	Mood- Beck depression inventory	8 weeks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	**Outcome**		**Intervention**	**Follow-up**	**n Event**	**N Total**	**Unadjusted (reported)**				**Adjusted (reported)**			
							Metric*	**Result**	**95% CI**	**P btw**	**Result**	**95% CI**	**P btw**	**Adjusted for:**
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD/SE*	Value	SD*	P	Value	SD/SE*	P
Barnes, 2002 Australia 11897643	ESS	Score	**Tx**	nCPAP	8 weeks	28	11.2	5.0			-2.7		≤0.01	-0.6		NS
			Cx	Placebo tablet		28	11.2	5.0			-2.1		≤0.01			
	MSLT	min	**Tx**	nCPAP	8 weeks	28	12.5	4.8			-1.8			-1.0		NS
			Cx	Placebo tablet		28	12.5	4.8			-0.8					
	FOSQ	Score	**Tx**	nCPAP	8 weeks	28	0.8	0.1			+0.07		≤0.005	+0.01		NS
			Cx	Placebo tablet		28	0.8	0.1			+0.06		≤0.005			
	SF-36 physical functioning	Score	**Tx**	nCPAP	8 weeks	28	78.1	22.4			+4.2			-1.3		NS
			Cx	Placebo tablet		28	78.1	22.4			+5.5		≤0.05			
	SF-36 mental health	Score	**Tx**	nCPAP	8 weeks	28	72.5	19.1			+6.4		≤0.05	+0.1		NS
			Cx	Placebo tablet		28	72.5	19.1			+6.3		≤0.05			
	Day Systolic BP	mm Hg	**Tx**	nCPAP	8 weeks	28	132.0	11.0			-0.7	25.6		-2.9		NS
			Cx	Placebo tablet		28	132.0	11.0			+2.2	9.8				
	Day Diastolic BP	mm Hg	**Tx**	nCPAP	8 weeks	28	84.0	7.8			-0.5	25.6		-2.6		NS
			Cx	Placebo tablet		28	84.0	7.8			+2.1	9.8				
	Compliance	h/nt	**Tx**	nCPAP	8 weeks	23			3.53	2.13						
		%	**Cx**	Placebo tablet		28			93%							

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Barnes, 2002 Australia 11897643	Memory	Word pair memory recall	8 weeks	nCPAP	28	Placebo tablet	28	0					
	Memory	WMS-R visual reproduction	8 weeks	nCPAP	28	Placebo tablet	28	0					
	Cognition	Trial Making A test	8 weeks	nCPAP	28	Placebo tablet	28	0					
	Cognition	Trial Making B test	8 weeks	nCPAP	28	Placebo tablet	28	0					
	Cognition	Digital symbol substitution test	8 weeks	nCPAP	28	Placebo tablet	28	0					
	Cognition	Controlled oral word association test	8 weeks	nCPAP	28	Placebo tablet	28	nCPAP	Net diff	+2.7			0.02
	Vigilance & divided attention	Psychomotor vigilance task	8 weeks	nCPAP	28	Placebo tablet	28	0					
	Vigilance & divided attention	Stroop color association test	8 weeks	nCPAP	28	Placebo tablet	28	0					
	Mood	POMS	8 weeks	nCPAP	28	Placebo tablet	28	0					
	Mood	Mood- Beck depression inventory	8 weeks	nCPAP	28	Placebo tablet	28	0					

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
	14 (33%)	Work commitments- 6; CPAP intolerance- 5; unrelated surgery- 1; subsequent diagnosis of periodic limb movement syn- 1; loss of interest- 1

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	No	No	No	Yes	No	Yes	nd	NA	Yes
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Yes	No	No	Yes	Yes	nd	Yes			No
Reasons for drop-outs:	14 (33%) Work commitments- 6; CPAP intolerance- 5; unrelated surgery- 1; subsequent diagnosis of periodic limb movement syn- 1; loss of interest- 1									
Other Issues:										
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Becker, 2003			**Intervention 1**	Nasal CPAP
PMID*	12515745	**RefID**	4059	**Intervention 2**	
Key Question(s)	KQ5 (CPAP vs Cx)			**Intervention 3**	
Design †	RCT			**Control**	Sub therapeutic nasal CPAP
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
AHI≥5, ESS≥10	Central sleep apnea, respi fail, heart failure (NYHA III/ IV), MI (within 3 months), cardiac arrhythmia (2nd& 3rd degree block or premature ventricular contractions in Lown class IV/ V), Professional drivers	≥5	nd	No	Germany	Industry (ResMed)	No	No	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y, SD**	**Race**	**BMI*, SD**	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**30(16)**	15 (94%)	54.4±8.9		33.3±5.1	8 (50%) nd	0	0
Cx	**30(16)**	14 (88%)	52.3±8.4		33.5±6.0	13 (81)	0	0
Total	**60(32)**	29 (91%)	53.3	nd	33.4	21 (66%)	0	0
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								2/3rd were hypertensives
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	16	62.5±17.8	14.4±2.5					
Control:	16	65.0±26.7	14.1±3.2					
Total:	32			nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥5		nd	nd		Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	Nasal CPAP	Sullivan IV (ResMed) or Aria (Respironics)	9.1±2.3 cm H2O
2				
3				
Control	Placebo	Sub therapeutic nasal CPAP	Sullivan IV (ResMed) or Aria (Respironics)	3 / 4 cm H2O
For CPAP:		**How was the Pressure selected?**	Manual titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	2 nights of adaptation

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	BP		9 weeks	
2	Sleep quality	AHI	9 weeks	
3	Sleep quality	Min SaO2	9 weeks	
4	Sleep quality	NREM III/ IV	9 weeks	
5	Sleep quality	REM Sleep	9 weeks	
6	Sleep quality	Arousal	9 weeks	
7	Sleepiness measures	ESS	9 weeks	
8	Compliance		9 weeks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value	95% CI*	P
Becker, 2003 Germany 12515745	Daytime mean BP	mm Hg	**Tx**	nCPAP	9 weeks	16	103.6	16.1	93.6	11.3	-10.0	12.1		-11.3	-19.7, -2.7	0.01
			Cx	Sub therapeutic nCPAP		16	103.5	12.1	104.8	10.6	+1.3					
	Daytime Systolic BP	mm Hg	**Tx**	nCPAP	9 weeks	16	140.1	17.6	132.1	15.7	-8.0			-10.3	-20.6, +0.1	0.05
			Cx	Sub therapeutic nCPAP		16	141.0	13.8	143.2	11.2	+2.2					
	Daytime Diastolic BP	mm Hg	**Tx**	nCPAP	9 weeks	16	86.4	16.1	75.8	11.6	-10.6			-11.2	-19.5, -2.8	0.01
			Cx	Sub therapeutic nCPAP		16	85.4	12.3	85.9	10.6	+0.5					
	ESS	score	**Tx**	nCPAP	9 weeks	16	14.4	2.5	5.1	3.8	-9.3			-4.1		0.009
			Cx	Sub therapeutic nCPAP		16	14.1	3.2	8.9	5.0	-5.2					
	AHI	Events/hr	**Tx**	nCPAP	9 weeks	16	62.5	17.8	3.4	3.1	-59.1			-27.5		0.001
			Cx	Sub therapeutic nCPAP		16	65.0	26.7	33.4	29.2	-31.6					
	Min SpO2	%	**Tx**	nCPAP	9 weeks	16	64.1	14.7	80.5	16.8	+16.4			+5.6		NS
			Cx	Sub therapeutic nCPAP		16	61.2	14.9	72.0	15.7	+10.8					
	NREM III/ IV sleep	%TST	**Tx**	nCPAP	9 weeks	16	6.2	7.2	15.2	7.1	+9.0			+3.4		NS
			Cx	Sub therapeutic nCPAP		16	6.0	8.4	11.6	6.7	+5.6					
	REM Sleep	%TST	**Tx**	nCPAP	9 weeks	16	11.4	6.8	22.3	5.7	+10.9			+4.1		NS
			Cx	Sub therapeutic nCPAP		16	14.3	6.3	21.1	8.8	+6.8					
	Compliance		**Tx**	nCPAP	9 weeks	16			5.5	2.0				+0.1		NS
			Cx	Sub therapeutic nCPAP		16			5.4	2.2						
	Arousals	n/h	**Tx**	nCPAP	9 weeks	16	58.7	21.9	24.1	9.8	-34.6			-13.8		

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value	95% CI*	P
			Cx	Sub therapeutic nCPAP		16	62.0	28.0	41.2	27.2	-20.8					

TST = Total Sleep Time
* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
nCPAP	14/30 (47%)	Refused to continue-3; technical defect-6; medication changed-3; other-2
Sub therapeutic nCPAP	14/30 (47%)	Refused to continue-2; technical defect-5; medication changed-4; other-3

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	No	No	No	Yes	No	Yes	NA	NA	Yes

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	Yes	No	No	Yes	Yes	Yes	NA	NA

Reasons for drop-outs:	Refused to continue-5; technical defect-11; medication changed-7; other-5
Other Issues:	No power calculation, No allocation concealment, High dropout rate
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Campos-Rodriguez, 2006			**Intervention 1**	CPAP
PMID*	16778262	**RefID**	3131	**Intervention 2**	
Key Question(s)	KQ 5 (CPAP v Cx)			**Intervention 3**	
Design †	RCT			**Control**	Sham CPAP
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
- Age: 30-70 - AHI≥10 - HTN (>140/90) on Rx with ≥ 1 drug for ≥ 3 months	- central apnea >30% - Respiratory failure - Heart failure (NYHA-III/IV) - IHD, arrhythmia - Neoplastic / systemic diseases - Secondary HTN - Professional drivers	≥ 10	nd	No	Spain	nd	Yes (24hMBP)	Yes	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**36 (34)**	56	55.3±9.6	nd	35.7±5.6	100 (>140/90)	0	0
Cx	**36 (34)**	65	58.0±7.0	nd	33.8±6.3	100	0	0
Total	**72 (68)**	60	57	nd	34.8	100	0	0
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	44							
Cx	38							
Total	41	16	nd	nd	nd	nd	nd	30-70 yrs with primary HTN and on treatment
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	No CPAP							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	34	58.3±24.6	15.0±3.9		nd	nd	new	
Control:	34	59.5±21.7	13.6±3.6					
Total:	68	58.9	14.3					
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥10		Airflow cessation >10s	Reduction of ≥ 50% in airflow for >10s followed by ≥4% decrease in SaO2 or an arousal		Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Respironics, PA	
2				
3				
Control	Placebo	Sham CPAP		CPAP pressure <2 cm H2O
For CPAP:		**How was the Pressure selected?**	Full night PSG titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	Telephonic advice if needed

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	h/d	4 weeks	
2	BP	BP (sys, dia, 24h mean)	4 weeks	
3	Sleepiness	ESS	4 weeks	
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD	Value	SD/SE*	P	Value	95% CI*	P
Campos-Rodriguez, 2006 Spain 16778262	Compliance	h/d	Tx	CPAP	4 weeks	34			5.0	1.4						0.13 (btw grp final values)
			Cx	Sham CPAP		34			4.4	1.9						
	ESS	score	Tx	CPAP	4 weeks	34	15.0	3.9	11.2	3.0	-3.8		<0.001	-2.4		
			Cx	Sham CPAP		34	13.6	3.6	12.2	2.2	-1.4		0.12			
	24hMBP	mm Hg	Tx	CPAP	4 weeks	34	97.7	10.7	96.5	9.5	-1.2			-0.8	-2.7, 4.3	0.65
			Cx	Sham CPAP		34	96.2	10.1	95.9	10.8	-0.3					
	SBP	mm Hg	Tx	CPAP	4 weeks	34	132.9	13.5	131.3	12.1	-1.6			-0.9	-3.9, 5.9	0.69
			Cx	Sham CPAP		34	130.4	15.9	129.8	16.3	-0.6					
	DBP	mm Hg	Tx	CPAP	4 weeks	34	78.4	10.3	76.9	9.3	1.5			-0.7	-2.1, 3.6	0.61
			Cx	Sham CPAP		34	77.6	8.7	76.8	9.0	0.8					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	(2/36) 6%	Changed Rx-1; lost to f/up-1
Sham CPAP	(2/36) 6%	Changed Rx-1; intolerance-1

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
HTN uncontrolled on Rx	Campos-Rodriguez, 2006 Spain 16778262	24hMBP	mm Hg	**Tx**	CPAP	4 weeks	12					-2.3	6.2	0.78	-0.7		
				Cx	Sham CPAP							-1.6	6.0				
		SBP	mm Hg	**Tx**	CPAP	4 weeks	12					-3.0	9.6	0.54	-1.0		
				Cx	Sham CPAP							-2.0	8.7				
		DBP	mm Hg	**Tx**	CPAP	4 weeks	12					-2.5	7.4	0.73	-1.1		
				Cx	Sham CPAP							-1.4	3.3				

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	Yes	Yes	Yes	Yes	No	Yes	NA	NA	No
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Yes	No	Yes	Yes	Yes	Yes				
Reasons for drop-outs:	(4/72) Changed Rx-2; lost to f/up-1; intolerance-1									
Other Issues:	Unclear randomization									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Chakravorty, 2002			**Intervention 1**	CPAP
PMID*	12449179	**RefID**	4132	**Intervention 2**	
Key Question(s)	KQ 5 (CPAP vs. Cx)			**Intervention 3**	
Design †	RCT			**Control**	Lifestyle intervention
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
h/o snoring & excessive daytime sleepiness	Neuromuscular disorders, Hypothyroidism, respi dis,	≥15	June 1998 – Oct 1999	No	UK	nd	nd	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y, SD**	**Race**	**BMI* SD**	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**37 (32)**		49±11		40±14.5			
Cx	**34 (21)**		52±9.6		32.3±5.5			
Total	**71 (53)**	nd	50±11	nd	37±12	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	32	55±28.7	16±5.6					
Control:	21	35±19.1	14±4.2					
Total:	53	49±28	14±5		Implies 100%	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥15		AASM recommendations; sleep 1999 (15)			separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Autoset II CPAP (ResMed Plc, UK)	
2				
3				
Control		Lifestyle intervention		Sleep hygiene, quit smoking, reduce alcohol, stress control, weight reducing diet, reg exercise
For CPAP:		**How was the Pressure selected?**	Home based automatic titration before the study began	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	Appropriate mask fitting, demo followed by 30 min in lab trial & then direct access to the techs during the trial

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	QoL	QALY	3 months	
2	QoL	EuroQol	3 months	
3	QoL	Standard gamble	3 months	Gafni 1994 (11)
4	Sleep quality	AHI	3 months	
5	Sleep quality	Sleep efficiency	3 months	
6	Sleep quality	Stage III& IV	3 months	
7	Sleep quality	REM Sleep	3 months	
8	Sleep quality	Arousal index	3 months	
9	Sleepiness measures	ESS	3 months	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value	SD*	P
Chakravorty, 2002 UK 12449179	ESS	score	**Tx**	CPAP	3 months	32	16	5.6	8	6.4	-8		<0.001	-5		
			Cx	Lifestyle intervention		21	14	4.2	11	5	-3		<0.05			
	AHI	events/hr	**Tx**	CPAP	3 months	32	55	28.7	8	28	-47		<0.001	-46		
			Cx	Lifestyle intervention		21	35	19.1	34	21	-1					
	Sleep efficiency	%	**Tx**	CPAP	3 months	32	67.7	18.2	67.5	15.7	-0.2			-3.0		
			Cx	Lifestyle intervention		21	71.6	12.8	74.4	11.1	+2.8					
	Stage III& IV	min	**Tx**	CPAP	3 months	32	64.7	50.2	69.5	50.1	+4.8			0.7		
			Cx	Lifestyle intervention		21	81.2	52.5	85.3	46.6	+4.1					
	Stage III& IV	%TST	**Tx**	CPAP	3 months	32	16.6		21							
			Cx	Lifestyle intervention		21	18.7		22							
	REM Sleep	min	**Tx**	CPAP	3 months	32	80.6	39.3	81.9	35.8	+1.3			-4.1		
			Cx	Lifestyle intervention		21	87.1	40.5	92.5	47.8	+5.4					
	REM Sleep	%TST	**Tx**	CPAP	3 months	32	20.7		24.9							
			Cx	Lifestyle intervention		21	20.1		23.9							
	Arousal index	n/h	**Tx**	CPAP	3 months	32	64	28	38.9	28.6	-25.1		<0.001	-9.8		
			Cx	Lifestyle intervention		21	52.2	28.5	36.9	21.5	-15.3		<0.05			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Chakravorty, 2002 UK 12449179	QALY	EuroQoL	3 months	CPAP	32	Lifestyle intervention	21	CPAP	Net difference	+1.13			
	QALY	Standard gamble utility	3 months	CPAP	32	Lifestyle intervention	21	CPAP	Net difference	+3.5			

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	32/37 (87%)	CPAP intolerance -4; Pituitary tumor surgery -1
Lifestyle intervention	21/34 (62%)	Health reasons (acute abd, chest infection, visual impairment) – 5; Surgery – 2; dropped out -6

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	nd	No	nd	nd	No	Yes	NA	NA	Yes

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	Yes	No	Yes	Yes	No	Yes	NA	NA

Reasons for drop-outs:	CPAP intolerance -4; Pituitary tumor surgery -1; Health reasons (acute abd, chest infection, visual impairment) – 5; Surgery – 2; dropped out -6
Other Issues:	No power calculation
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Comondore, 2009			**Intervention 1**	CPAP
PMID*	18795367	**RefID**	3186	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	no tx
Extractor	si			**Comments**	

* or Cochrane number
† RCT; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
medically stable; OSA with AHI ≥15	believe they could not tolerate CPAP; complained of substantial hypersomnolence	≥15	nd	no	Canada	non profit	no	no	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**13 (presumed 13)**	69%	56	nd	31.1			
Cx	**13 (presumed 13)**	69%	56	nd	31.1			
Total	**13 (presumed 13)**	69%	56	nd	31.1	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	13	27.9	6.8	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥15	nd	nd	nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	AutoSet Spirit (ResMed)	fixed at 95th %tile
2				
3				
Control	no tx			
For CPAP:		**How was the Pressure selected?**	auto titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	CVD markers		baseline, 4 wk	
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	95%CI*	P
Comondore, 2009 Canada 18795367	fasting plasma glucose	mmol/L	Tx	CPAP	4 wk	13	5.43		5.45		0.02			0.03	-0.22 to 0.28	0.89
			Cx	no tx	4 wk	13	5.45		5.44		-0.01					
Comondore, 2009 Canada 18795367	HbA1C	%	Tx	CPAP	4 wk	13	5.91		5.94		0.03			0.04	-0.27 to 0.34	0.90
			Cx	no tx	4 wk	13	5.85		5.85		-0.01					
Comondore, 2009 Canada 18795367	HOMA	mmol/L	Tx	CPAP	4 wk	13	3.76		3.22		-0.54			-1.11	-2.19 to -0.04	0.58
			Cx	no tx	4 wk	13	3.36		3.93		0.57					
Comondore, 2009 Canada 18795367	SBP	mm Hg	Tx	CPAP	4 wk	13	139.3		131.9		-7.4			-3.6	-18.45 to 11.25	0.50
			Cx	no tx	4 wk	13	137.4		133.6		-3.8					
Comondore, 2009 Canada 18795367	DBP	mm Hg	Tx	CPAP	4 wk	13	82.7		79		-3.7			-0.7	-8.53 to 7.13	0.84
			Cx	no tx	4 wk	13	84.8		81.8		-3					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	n	nd	nd	y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	y	small sample size			4 wk (unclear if it is adequate for HbA1C)
Reasons for drop-outs:										
Other Issues:	multiple comparisons in a small pilot study									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Coughlin, 2007			**Intervention 1**	autoCPAP
PMID*	17251237	**RefID**	3194	**Intervention 2**	
Key Question(s)	KQ 5 (CPAP v Cx)			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	Sham CPAP
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
- Confirmed OSA - Naïve to CPAP - No known other medical conditions - Not on any medications	- Abnormal baseline ECG - DM, Renal, liver, cardiac disease - Peripheral neuropathy BP ≥ 180/110	>15	nd	No	UK	No interests declared	Yes (Metabolic syndrome) Min N=31 (pairs)	Yes	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx						British HTN Society		
Cx						Definition of HTN		
Total	**35 (34)**	100%	49±8.3	nd	36.1±7.6	79% (140/90)	0	0
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	0	35%	nd	nd	nd	nd	0	Healthy obese males
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	No CPAP							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	34	39.7±8.7	13.8±4.9	nd	100%	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>15		Airflow cessation ≥10 sec and ≥4% desaturation	50% reduction in airflow and ≥4% desaturation and reduced chest wall movement (EEG arousals not required)	Snoring, excessive daytime sleepiness (ESS≥10) or two other typical symptoms (impaired concentration, unrefreshing sleep, choking during sleep, witnessed apneas, restless sleep, irritability or personality change, nocturia, decreased libido)	Split	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Aria LX, Respironics	
2				
3				
Control	Placebo	Sham CPAP	Aria LX, Respironics	CPAP pressure <1 cm H2O
For CPAP:		**How was the Pressure selected?**	Automatic titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	Advice and support given through out the study

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	h/night	6 weeks	Machine running time using a smart card. Adequate ≥ 3.5h/night
2	BP	BP (sys, dia, mean arterial)	6 weeks	Waking BP, supine, mean of 3 measurements taken at 1-min intervals, HTN > 140/90
3	Sleepiness	ESS	6 weeks	
4	Metabolic syndrome	Fasting glucose		
3	Metabolic syndrome	HOMA insulin resistance		Homeostasis model assessment (Matthews 1985, Ref 25)
4	Metabolic syndrome	Metabolic syndrome diagnosis		National Cholesterol Education Programm guidelines: (≥3 of: Waist circumference >102 cm; Triglycerides ≥1.7 mmol/L; HDL cholesterol <1.04 mmol/L; BP≥130/85; Fasting glu ≥6.1 mmol/L)

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Coughlin, 2007 UK 17251237	Metabolic Syndrome	**Tx**	CPAP	6 wk	27	34	Difference in proportions		-0.08, 0.20	0.63				
		Cx	Sham CPAP	6 wk	29	34								

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SE*	Value	SD/SE*	P	Value	95% CI*	P
Coughlin, 2007 UK 17251237	Compliance	h/night	**Tx**	CPAP	6 wk	34			3.9	Range 0-7.4				+1.3		<0.01
			Cx	Sham CPAP	6 wk	34			2.6	0-7.5						
	Compliance[1]	h/night	**Tx**	CPAP	6 wk	17			3.9	0-6.2				+2.0		<0.01
			Cx	Sham CPAP	6 wk	17			1.9	0-5.5						
	Compliance[2]	h/night	**Tx**	CPAP	6 wk	17			4	0-7.4				+0.7		0.22
			Cx	Sham CPAP	6 wk	17			3.3	0-7.5						
	ESS	score	**Tx**	CPAP	6 wk	34	13.8	4.9	9.4	0.9				-3.1	-4.5, -1.7	<0.01
			Cx	Sham CPAP	6 wk	34										
	SBP	mm Hg	**Tx**	CPAP	6 wk	34			135.7	2.0				-6.7	-10.1, -1.7	<0.01
			Cx	Sham CPAP	6 wk	34			142.4	2.4						
	DBP	mm Hg	**Tx**	CPAP	6 wk	34			86.8	0.15 (Note: this is probably a typo in the article)				-4.9	-8.0, -1.8	<0.01
			Cx	Sham CPAP	6 wk	34			91.7	1.6						
	Mean arterial	mm Hg	**Tx**	CPAP	6 wk	34			103.1	1.5				-5.5	-8.2, -2.8	<0.01
			Cx	Sham CPAP	6 wk	34			108.6	1.7						
	Fasting glucose	mmol/L	**Tx**	CPAP	6 wk	34			4.7	0.1				-0.1	-0.3, 0.03	0.11
			Cx	Sham CPAP	6 wk	34			4.8	0.1						
	HOMA insulin resistance		**Tx**	CPAP	6 wk	34			3.3	0.4				-0.6	-1.3, 0.1	0.08
			Cx	Sham CPAP	6 wk	34			3.9	0.5						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper
[1] First phase, prior to cross; [2] Second phase, after to cross

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	3% (1/35)	With drew due to personal reasons, & lost to follow up

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Adequate compliance (≥3.5 h/night)	Coughlin, 2007 UK 17251237	Metabolic Syndrome	Tx	CPAP	6 wk	16	23	Difference in paired proportions		-0.04, 0.30	0.25				
			Cx	Sham CPAP	6 wk	19	23								

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SE*	Value	SD/SE*	P	Value	95% CI*	P
Adequate compliance (≥3.5 h/night)	Coughlin, 2007 UK 17251237	ESS	unit	**Tx**	CPAP	6 wk	23			9.2	1.2				-3.9	-5.7, -2.1	<0.01
				Cx	Sham CPAP	6 wk	23			13.1	1.0						
		SBP	mm Hg	**Tx**	CPAP	6 wk	23			133.7	2.5				-8.5	-12.7, -4.3	<0.01
				Cx	Sham CPAP	6 wk	23			142.2	2.8						
		DBP	mm Hg	**Tx**	CPAP	6 wk	23			86.6	1.9				-6.7	-10.9, -2.5	<0.01
				Cx	Sham CPAP	6 wk	23			93.3	1.7						
		MAP	mm Hg	**Tx**	CPAP	6 wk	23			102.3	1.9				-7.3	-10.8, -3.8	<0.01
				Cx	Sham CPAP	6 wk	23			109.6	2.0						
		FG	mmol/L	**Tx**	CPAP	6 wk	23			4.6	0.1				-0.1	-0.3, 0.1	0.31
				Cx	Sham CPAP	6 wk	23			4.7	0.1						
		HOMA IR		**Tx**	CPAP	6 wk	23			2.8	0.3				-0.4	-1.1, 0.3	0.22
				Cx	Sham CPAP	6 wk	23			3.2	0.5						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
Coughlin, 2007 UK 17251237	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	nd	Yes	Yes	Yes	Yes	Yes	NA	NA	Yes

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	Yes	No	No (mask used?)	Yes	Yes	Yes	NA	nd
Reasons for drop-outs:	Lost to follow up							
Other Issues:								
Overall Quality (A, B, C)	**A**							

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Cross, 2008			**Intervention 1**	Auto PAP
PMID*	18390635	**RefID**	3198	**Intervention 2**	
Key Question(s)	5 (CPAP)			**Intervention 3**	
Design †	Cross over			**Control**	Sham CPAP
Extractor	No			**Comments**	There were two studies. Study one in patients with mild OSAHS. Only results of study 2 (Cross over study) are extracted. Total sample size study 1 and 2 =51, n study 2 alone = 31(27 analyzed)

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSAHS ESS>10 34-62yrs	Atherosclerotic disease Asthma Reparatory failure Inter-current illness	>15/hr	nd	n	UK	Foundation	n	y	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**31(27)**	96	48(2) mean(SEM)	nd	37(1) mean(SEM)	Systolic 143.2(3.3) Diastolic 80.4(2.02) mean(SEM)	nd	Hypercholesterolemia 25%
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	3%(1/27)	22	nd	nd	nd	nd	nd	22% on either aspirin, statins or beta blockers
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	All patients received either of three vasodilators (acetycholidne 5, 10 and 20ug/min, substance P at 2, 4 and 8 pmol/min and sodium nitropruside at 2,4 ,8 ug/min) separated by 20min saline infusion							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	27	63(5) mean(SEM)	nd	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>15/hr			3% or 4% decline in O_2 saturation	ESS>10	separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	ResMed	
2				
3				
Control	Palcebo	Sham CPAP		
For CPAP:		**How was the Pressure selected?**	autotitrated	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
	All patients were asked to abstain from alcohol for 24hrs and from food, tobacco and caffeinated drinks 4 hrs before each vascular assessment.	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Intermediate or surrogate outcomes	Systolic blood pressure	6 weeks	
2	Intermediate or surrogate outcomes	Diastolic blood pressure	6 weeks	
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SD/SE*	P	Value	SD/SE*	P
Cross ,2008 UK 18390635	Systolic blood pressure	MmHg	Tx	CPAP	6 weeks	27	143	3.3	141	3.1	-2			-3.8		0.07
			Cx	Sham CPAP	6 weeks	27	143	3.3	144.8	3.7	1.8					
	Diastolic blood pressure	MmHg	Tx	CPAP	6 weeks	27	80.4	2.02	82.3	1.9	1.9			0		0.84
			Cx	Sham CPAP	6 weeks	27	80.4	2.02	82.3	1.7	1.9					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	na	y	y	y	y	y	na	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y		y	n	y

Reasons for drop-outs:	
Other Issues:	
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Drager 2007			**Intervention 1**	CPAP with C-flex
PMID*	17556718	**RefID**	3240	**Intervention 2**	
Key Question(s)	5 (CPAP vs Cx)			**Intervention 3**	
Design †	RCT			**Control**	No treatment
Extractor	DM			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
all male adults with a sleep study within 1 month; AHI > 30 ; Naive to treatment	> 60 years age; BMI > 35 kg/m^2; diabetes mellitus; hypertension, cerebrovascular disease, valvular heart disease, renal failure; current or past smoking history, and chronic use of any medication.	> 30	Jan 2004 – Jan 2006	No	Brazil	Government, Foundation, Industry (Devices provided by Respironics, Inc)	No	No	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race (White in %)**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	12 (12)		44 ± 7	84	29.9 ± 3.0			
Cx	12 (12)		47 ± 6	92	29.7 ± 2.9			
Total	24 (24)	100				nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	Yes (Severe OSA patients free of co-morbidities)
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	12	56 ± 22	14 ± 4					
Control:	12	62 ± 22	13 ± 5					
Total:				nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		nd

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	> 30	nd	Apnea was defined as complete cessation of airflow for at least 10 seconds, associated with oxygen desaturation of 3%	Hypopnea was defined as a significant reduction (.50%) in respiratory signals for at least 10 seconds associated with oxygen desaturation of 3%.	nd	Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP with C-Flex	REMStar Pro with C-Flex	CPAP (Fixed) - Respironics, Inc., Murrysville, PA
2				
3				
Control	No treatment	No treatment		
For CPAP:		**How was the Pressure selected?**	The ideal CPAP was determined for all participants by an overnight sleep study titration, during which the pressure was adjusted to abolish apnea and hypopnea.	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	AHI	4 months	
2	Sleepiness measures	Epworth Sleeping Scale Score	4 months	
3	Other	Daytime systolic blood pressure	4 months	From 24-h Blood pressure monitoring in mmHg
4	Other	Daytime diastolic blood pressure	4 months	From 24-h Blood pressure monitoring in mmHg
5	Other	Nighttime systolic blood pressure	4 months	From 24-h Blood pressure monitoring in mmHg
6	Other	Nighttime diastolic blood pressure	4 months	From 24-h Blood pressure monitoring in mmHg

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx	CPAP (Fixed) with C-Flex											
		Cx	No Intervention											

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
Drager 2007 Brazil 17556718	AHI	events / hour	**Tx**	CPAP with C-Flex	4 months	12	56	22	4.5	1.9	-51.5					
			Cx	No Treatment	nd	12	62	22	nd	nd	nd					
Drager 2007 Brazil 17556718	Epworth Sleeping Scale Score	Units on a scale	**Tx**	CPAP with C-Flex	4 months	12	14	4	7	2	-7		<0.001	-7		
			Cx	No Treatment	4 months	12	13	5	13	4	0					
Drager 2007 Brazil 17556718	Daytime systolic blood pressure	mmHg	**Tx**	CPAP with C-Flex	4 months	12	122	5	119	9	-3		NS	-1		
			Cx	No Treatment	4 months	12	124	11	122	9	-2		NS			
Drager 2007 Brazil 17556718	Daytime diastolic blood pressure	mmHg	**Tx**	CPAP with C-Flex	4 months	12	79	4	75	7	-4		0.007	-1		0.56
			Cx	No Treatment	4 months	12	78	9	75	6	-3		NS			
Drager 2007 Brazil 17556718	Nighttime systolic blood pressure	mmHg	**Tx**	CPAP with C-Flex	4 months	12	108	9	105	10	-3		NS	-4		
			Cx	No Treatment	4 months	12	112	10	113	9	1		NS			
Drager 2007 Brazil 17556718	Nighttime diastolic blood pressure	mmHg	**Tx**	CPAP with C-Flex	4 months	12	67	8	63	8	-4		0.001	-1		0.44
			Cx	No Treatment	4 months	12	69	7	66	10	-3		NS			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	Yes	Yes	No	nd	nd	Yes	NA	Yes	No (AHI was nor reported for control group)
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Yes	No	Yes	Yes	Yes	Yes	NA			NA
Reasons for drop-outs:	No dropouts									
Other Issues:										
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Egea 2008			**Intervention 1**	CPAP
PMID*	17904420	**RefID**	3250	**Intervention 2**	
Key Question(s)	5 (CPAP vs Cx)			**Intervention 3**	
Design †	RCT			**Control**	Placebo (Sham-CPAP)
Extractor	DM			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Cardiac failure patients with SUSPECTED left ventricular ejection fraction < 45%, optimally treated and stable for atleast 1 month prior to inclusion; AHI >10	Previously diagnosed with or without CPAP Rx; uncontrolled arterial hypertension; valvular or congenital cardiopathy, unstable angina, acute myocardial infarction or cardiac surgery in the 3 months prior to enrollment; severe sleepiness in situations of activity; present or past medical history of clinically significant renal, liver or pulmonary disease; untreated hypothyroidism; clinically ignificant kyphoscoliosis; morbid obesity BMI > 41 kg/m2 ; concomitant use of morphine, hypnotics and sedatives, theophylline, acetazolamide or home oxygen therapy.	> 10	nd	Yes	Spain	Hospital	nd	Yes	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?)	AFib/AFlutter, %	CVD †, % (specify)
Tx	**35(28)**	96	**64 ± 0.9**		**31.7 ± 2.4**			
Cx	**38(32)**	91	**63 ± 1.6**		**30.5 ± 1.6**			
Total	**73(60)**			nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	Yes (Stable heart failure patients with Sleep apnea)
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring (Daily snoring in % / Snoring 3 or more times/week in %)*	Bed partner, %	Time Since Diagnosis	Other (Minimum SaO2 in %)
Treatment:	27	43.7 ± 4.4	8.0 ± 0.7		83 / 88			76.9 ± 2.0
Control:	29	35.3 ± 3.1	7.3 ± 0.8		69 / 76			77.4 ± 2.1
Total:		(AHI data extracted is from table 2; AHI in table 1 is reported differently)		nd		nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		nd

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	> 10		Air flow cessation of >10secs with thoracoabominal motion	3% decline in 0_2 sat		Split night	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP (Fixed)		CPAP pressure was the pressure that abolished snoring, apneas, hypopneas and episodes of flow limitation.
2				
3				
Control	No Treatment	Sham CPAP		Applied pressure remained at atmospheric pressure
For CPAP:		**How was the Pressure selected?**	Pressure increased until symptoms were abolished	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	AHI	3 months	
2	Sleep study measures	REM	3 months	
3	Sleep study measures	Stage 3 and 4	3 months	
4	Sleepiness measures;	ESS	3 months	
5	QoL	SF-36 – physical component summary	3 months	
6	QoL	SF-36 – mental component summary	3 months	
7	QoL	6 min walking test	3 months	in meters
8	Other	Systolic blood pressure	3 months	in mmHg
9	Other	Diastolic blood pressure	3 months	in mmHg

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ * (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P
Egea 2008 Spain 17904420	AHI	events / hour	**Tx**	CPAP (Fixed)	3 months	27	43.7	4.4	10.8	2.2	-32.9		<0.001	-25.6		
			Cx	Sham - CPAP	3 months	29	35.3	3.1	28	4.6	-7.3		0.12			
Egea 2008 Spain 17904420	REM	%	**Tx**	CPAP (Fixed)	3 months	27	15.7	1.9	12.2	1.2	-3.5		0.12	-2.8		
			Cx	Sham - CPAP	3 months	29	12.9	1.3	12.2	1.3	-0.7		0.57			
Egea 2008 Spain 17904420	Stage 3 and 4	%	**Tx**	CPAP (Fixed)	3 months	27	7.9	1.6	7.2	2	-0.7		0.74	3.2		
			Cx	Sham - CPAP	3 months	29	9.7	1.9	5.8	1.8	-3.9		0.03			
Egea 2008 Spain 17904420	ESS	Units on a scale	**Tx**	CPAP (Fixed)	3 months	20	8.6	0.8	5	0.8	-3.6		0.001	-1.9		
			Cx	Sham - CPAP	3 months	25	6.9	0.8	5.2	0.8	-1.7		0.009			
Egea 2008 Spain 17904420	SF-36 – physical component summary	Units on a scale	**Tx**	CPAP (Fixed)	3 months	20	41.4	2	44.9	1.8	3.5		0.1	4.8		
			Cx	Sham - CPAP	3 months	25	42	2.1	40.7	2.1	-1.3		0.4			
Egea 2008 Spain 17904420	SF-36 – mental component summary	Units on a scale	**Tx**	CPAP (Fixed)	3 months	20	46.4	3	48.8	2.3	2.4		0.4	-0.5		
			Cx	Sham - CPAP	3 months	25	45.8	2.7	48.7	2.2	2.9		0.27			
Egea 2008 Spain 17904420	6 min walking test	meters	**Tx**	CPAP (Fixed)	3 months	20	403	21	406	21	3		0.76	-9		
			Cx	Sham - CPAP	3 months	25	381	23	393	24	12		0.27			

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ * (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P
Egea 2008 Spain 17904420	Systolic blood pressure	mmHg	**Tx**	CPAP (Fixed)	3 months	20	124.3	4.2	124.3	4.9	0		1.0	1.6		
			Cx	Sham - CPAP	3 months	25	125	2.7	123.4	2.8	-1.6		0.46			
Egea 2008 Spain 17904420	Diastolic blood pressure	mmHg	**Tx**	CPAP (Fixed)	3 months	**20**	75.6	2.3	76	2.8	0.4		0.86	-0.8		
			Cx	Sham - CPAP	3 months	25	75.8	2.4	77	3.7	1.2		0.63			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP Fixed	20%	nd
Sham-CPAP	15.8%	nd

Intervention	% Dropout	Reasons
CPAP	2/35	Refused for personal reasons
CPAP	5/35	CPAP intolerable
Sham CPAP	1/38	died
Sham CPAP	1/38	Angina
Sham CPAP	4/38	Sham CPAP Intolerable

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	nd	Yes (exactly 20% in intervention group)	Yes	nd	No	Yes	No	Yes	No (Discrepancy in AHI reported in table 1 and 2, no explanation given)

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	Yes	No	Yes	No (Citations included to more information)	NA	No	NA	NA

Reasons for drop-outs:	No reason provided
Other Issues:	PSG results included 17% Central sleep apnea subjects, but sleepiness and QoL measures only included OSA subjects
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Engelman, 1996			**Intervention 1**	CPAP
PMID*	8843528	**RefID**	4236	**Intervention 2**	
Key Question(s)	KQ 5 (CPAP vs Cx)			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	Oral Placebo Tx
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
At least 2 symptoms of SAHS; AHI≥5	nd	≥5	nd	No	UK	Industry (Glaxo supplied placebo tablets)	Post-hoc analysis (BP)	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y SE**	**Race**	**BMI* SE**	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**16 (13)**	11 (85%)	51±3	nd	36.0±2.6	5 (13%) >134/84	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI* SE	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	13	49±9	nd	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥5		nd	nd	nd	Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	APD-1 CPAP unit (ResCare, UK)	
2				
3				
Control	Placebo	Oral Placebo Tx		
For CPAP:		**How was the Pressure selected?**	Titration study	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	Contacted at 2 weeks

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	BP		3 weeks	
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SE*	Value	SD/SE*	P	Value	SD/SE*	P
Engelman, 2006 UK 8843528	Daytime Systolic BP	mm Hg	Tx	CPAP	3 weeks	13			138	4						
			Cx	Oral Placebo Tx		13			139	3						
	Daytime Diastolic BP	mm Hg	Tx	CPAP	3 weeks	13			84	3						
			Cx	Oral Placebo Tx		13			86	3						
	Daytime MAP	mm Hg	Tx	CPAP	3 weeks	13			102	3						
			Cx	Oral Placebo Tx		13			103	3						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
	3/16 (20%)	Equipment unavailability-1; poor ABP quality-1; pt nonattendance-1

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	nd	Yes	nd	nd	No	Yes	NA	NA	Yes
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Yes	No	No	Yes	Yes	Yes	No			No
Reasons for drop-outs:	3/16 (20%): Equipment unavailability-1; poor ABP quality-1; pt nonattendance-1									
Other Issues:	No power calculation									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Engleman 1994			**Intervention 1**	CPAP
PMID*	7906330	**RefID**	5238	**Intervention 2**	
Key Question(s)	5(CPAP)			**Intervention 3**	
Design †	Cross over			**Control**	Placebo
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
At least 2 symptoms of SAHS; AHI 5-15.9	nd	≥5	nd	n	UK	Industry (Glaxo supplied placebo tablets)	nd	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**?(17)**							
Cx	**?(15)**							
Total	**35(32)**	74	49(S.E1.5)	nd	33(1.6)	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SE. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	32	Median (range) 28(7-129)	nd	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥5		10secs	50% reduction in respiratory movement >10secs		Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Sullivan APD-1 CPAP unit (ResCare, UK)	
2				
3				
Control	Placebo	Oral Placebo		Ranitidine 300 mg homologue, Glaxo, Green ford, UK in a dose of two tablets at bedtime
For CPAP:		**How was the Pressure selected?**	Assumed manual	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	MSLT	4 weeks	
2	Cognitive scale	IQ decrement score	4 weeks	
3	Cognitive scale	Trailmaking B	4 weeks	
4	Cognitive scale	PASAT	4 weeks	
5	Psych scale	HADs anxiety score	4 weeks	
6	Psych scale	HADS depression score	4 weeks	
7	QoL	GHQ 28 total score	4 weeks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P
Engleman 1994 7906330 UK	MSLT		Tx	CPAP	4 weeks	32			7.2	0.7						0.03
			Cx	Placebo	4 weeks	32			6.1	0.7						
	IQ decrement score		Tx	CPAP	4 weeks	32			4.0	2.1						0.04
			Cx	Placebo	4 weeks	32			7.2	2.0						
	Trailmaking B		Tx	CPAP	4 weeks	32			66	5						0.02
			Cx	Placebo	4 weeks	32			75	5						
	PASAT		Tx	CPAP	4 weeks	32			nd	nd						0.11
			Cx	Placebo	4 weeks	32			nd	nd						
	HADs anxiety score		Tx	CPAP	4 weeks	32			4.5	0.6						0.02
			Cx	Placebo	4 weeks	32			5.7	0.8						
	HADS depression score		Tx	CPAP	4 weeks	32			3.3	0.5						0.002
			Cx	Placebo	4 weeks	32			5.2	0.7						
	GHQ 28 total score		Tx	CPAP	4 weeks	32			1.8	0.7						0.003
			Cx	Placebo	4 weeks	32			5.2	0.9						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
both	3/35	Pressure at work, relocation, reluctance to use CPAP (I patient)

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	nd	nd	n	y	na	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	y	y	n	No washout period between treatments

Reasons for drop-outs:	
Other Issues:	Baseline data not reported, no wash out period between treatments, nd on blinding
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Engleman 1997			**Intervention 1**	CPAP
PMID*	9059469	**RefID**	5237	**Intervention 2**	
Key Question(s)	5(CPAP)			**Intervention 3**	
Design †	Cross over			**Control**	Placebo
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
At least 2 symptoms of SAHS; AHI 5-15.9	nd	≥5	nd	n	UK	Industry (Glaxo supplied placebo tablets)	nd	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**?(8)**							
Cx	**?(8)**							
Total	**18(16)**	85	52(2)	nd	29.8(1.8)	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	16	11(1)	nd	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥5		10secs	50% reduction in respiratory movement >10secs		Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Sullivan APD-1 CPAP unit (ResCare, UK)	
2				
3				
Control	Placebo	Oral Placebo		Ranitidine 300 mg homologue, Glaxo, Green ford, UK in a dose of two tablets at bedtime
For CPAP:		**How was the Pressure selected?**	Assumed manual because they spent three full days in sleep lab	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	MSLT	4 weeks	
2	Sleepiness measures	ESS	4 weeks	
3	Cognitive scale	IQ decrement score	4 weeks	
4	Cognitive scale	Trailmaking B	4 weeks	
5	Cognitive scale	PASAT	4 weeks	
6	Cognitive scale	Verbal fluency total words	4 weeks	
7	Psych scale	HADs anxiety score	4 weeks	
8	Psych scale	HADS depression score	4 weeks	
9	QoL	GHQ 28 total score	4 weeks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P
Engleman 1997 9059469 UK	MSLT		**Tx**	CPAP	4 weeks	16			10.0	1.2						NS
			Cx	Placebo	4 weeks	16			9.9	1.5						
	ESS		**Tx**	CPAP	4 weeks	16			10.1	1.4						NS
			Cx	Placebo	4 weeks	16			10.0	1.2						
	IQ decrement score		**Tx**	CPAP	4 weeks	16			7.0	3.1						NS
			Cx	Placebo	4 weeks	16			5.3	3.5						
	Trailmaking B		**Tx**	CPAP	4 weeks	16			64.1	5.5						0.02
			Cx	Placebo	4 weeks	16			77.7	9.2						
	PASAT		**Tx**	CPAP	4 weeks	16			37.8	3.3						NS
			Cx	Placebo	4 weeks	16			35.3	2.8						
	Verbal fluency total words		**Tx**	CPAP	4 weeks	16			38.5	3.5						NS
			Cx	Placebo	4 weeks	16			39.2	3.1						
	HADs anxiety score		**Tx**	CPAP	4 weeks	16			4.5	1.2						NS
			Cx	Placebo	4 weeks	16			5.1	1.1						
	HADS depression score		**Tx**	CPAP	4 weeks	16			3.4	0.9						0.03
			Cx	Placebo	4 weeks	16			5.0	1.0						
	GHQ 28 total score		**Tx**	CPAP	4 weeks	16			1.4	0.6						NS
			Cx	Placebo	4 weeks	16			3.2	1.3						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	nd	nd	n	y	na	y	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	y	y	n			No washout period between treatments
Reasons for drop-outs:										
Other Issues:	Baseline data not reported, no wash out period between treatments, nd on blinding									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Engleman, 1998			**Intervention 1**	CPAP
PMID*	9708223	**RefID**	5235	**Intervention 2**	
Key Question(s)	5- CPAP v Cx			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	Oral placebo
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
AHI ≥15; ≥2 symptoms of sleep apnea	lung disease, neurological disorders, and coexisting sleep disorders, live more than 50 miles from the Scottish National Sleep Centre	nd	nd	n	UK	British lung foundation	no	N	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**23(23)**							
Cx	**23(23)**							
Total	**23(23)**	91%	47	Nd	30	Nd	Nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	Nd	Nd	Nd	Nd	Nd	Nd	Nd	no
	Treatments used (prior to trial, including surgery)							
Tx	Nd							
Cx	Nd							
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	23							
Control:	23							
Total:	23	43	12.0	Nd	Nd	Nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	Nd	Nd	Nd	Nd	Nd	separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Sullivan APD-1 units, ResCare Ltd, Abingdon, UK	nd
2				
3				
Control	Other	Oral placebo	Glaxo	nd
For CPAP:		**How was the Pressure selected?**	Overnight titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Mean sleep onset latency	4 wk	
2	Sleepiness measures	ESS	4 wk	
3	Sleepiness measures	UMACL Energetic Arousal Score	4 wk	University of Wales Institute of Science and Technology adjective checklist
4	Cognitive scale	SteerClear	4 wk	Vigilance task
5	Cognitive scale	Trailmaking B	4 wk	Attention test
6	Cognitive scale	Digit symbol substitution	4 wk	IQ subtest
7	Cognitive scale	Block Design	4 wk	IQ subtest
8	Cognitive scale	Performance IQ decrement	4 wk	IQ test
9	Cognitive scale	RVIP (correct)	4 wk	Rapid Visual Information Processing
10	Psych scale	PASAT 2-s	4 wk	Paced Auditory Serial Addition Test; measure of cognitive function
12	Psych scale	HADS Anxiety and Depression Score	4 wk	Hospital Anxiety and Depression Scale
13	General symptom scale	GHQ-28	4 wk	General Health Questionnaire
14	General symptom scale	NHP Part 2 score	4 wk	Nottingham health profile part 2; measures quality of life

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	95%CI	P
Engleman, 1998 UK 9708223	Mean sleep onset latency	Min	Tx	CPAP	4 wk	23	Nd	Nd	9.2	3.9	Nd	nd	nd	2.4	(0.8 to 4.0)	<0.001
			Cx	Oral placebo	4 wk	23	Nd	Nd	6.8	4.3	nd	Nd	nd			
	ESS	Number	Tx	CPAP	4 wk	22	12.0	4	6	3	-6	Nd	nd	-6	nd	0.001
			Cx	Oral placebo	4 wk	22	12.0	4	12	4	0	nd	Nd			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Engleman, 1998 UK 9708223	UMACL Energetic Arousal Score	NA	4 wk	CPAP	23	Placebo	23	0					
	SteerClear	NA	4 wk	CPAP	22	Placebo	22	0					
	Trailmaking B	NA	4 wk	CPAP	23	Placebo	23	0					
	Digit symbol substitution	NA	4 wk	CPAP	23	Placebo	23	0					
	Block Design	NA	4 wk	CPAP	23	Placebo	23	0					
	Performance IQ decrement	NA	4 wk	CPAP	23	Placebo	23	0					
	RVIP (correct)	NA	4 wk	CPAP	23	Placebo	23						
	PASAT 2-s	NA	4 wk	CPAP	23	Placebo	23	0					
	HADS Anxiety Score	NA	4 wk	CPAP	23	Placebo	23	0					
	HADS Depression Score	NA	4 wk	CPAP	23	Placebo	23	0					
	GHQ-28	NA	4 wk	CPAP	23	Placebo	23	0					
	NHP Part 2 score	NA	4 wk	CPAP	23	Placebo	23	0					

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
nd		

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
nd						

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	Nd	Nd	Y	N	Y	Y	Y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Y	N	Y	N	N	Y	N			y
Reasons for drop-outs:	NA									
Other Issues:	No adverse event data									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Engleman 1999			**Intervention 1**	CPAP
PMID*	9927358	**RefID**	5234	**Intervention 2**	
Key Question(s)	5- CPAP v Cx			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	Oral placebo
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
≥2 OSA symptoms including ESS ≥8, admitted sleepiness while driving, AHI 5.0-14.9	Those residing more than 50 miles from the laboratory, shift workers, and those with other coexisting sleep disorders, neurological or lung disease were excluded	nd	Nd	no	UK	British Lung Foundation	For the sample size of 34 patients, power to show significant differences (p ≤ 0.05) between treatments for the observed differences in variables was 95% for symptoms, 25% for MWT, >99% for Epworth, 60% for PASAT, and 85% for HADS depression scores.	no	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**37(34)**							
Cx	**37(34)**							
Total	**37(34)**	62%	44	Nd	30	Nd	Nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	Nd	Nd	Nd	Nd	Nd	Nd	Nd	Mild OSA (AHI 5-15)
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	34							
Control:	34							
Total:	34	10	13	Nd	Nd	Nd	nd	Mean min O2 saturation of 89
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
			Thermistor airflow absent ≥10 sec	abdominal or thoracic respiratory movement amplitude was reduced to 50% or less of the preceding stable baseline value for 10 s or longer, during sleep	Nd	Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1			Sullivan III CPAP unit and a heated CPAP humidifier (both ResMed Ltd., Abingdon, UK)	Pts advised to use CPAP, with or without humidification, all night and every night and during any daytime naps during that treatment period.
2				
3				
Control	Oral placebo	Other	Glaxo, Greenford, UK	Two tablets at bedtime
For CPAP:		**How was the Pressure selected?**	Overnight titration study to abolish irregularities and arousals from sleep (manual)	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	MWT	4 wk	Sleep onset latency
2	Sleepiness measures	ESS	4 wk	
3	Sleepiness measures	UMACL Energetic Arousal Score	4 wk	University of Wales Institute of Science and Technology adjective checklist
4	Cognitive scale	SteerClear	4 wk	Vigilance task
5	Cognitive scale	Trailmaking A and B	4 wk	Attention tests
6	Cognitive scale	Digit symbol	4 wk	IQ subtest
7	Cognitive scale	Block Design Score	4 wk	IQ subtest
8	Cognitive scale	Performance IQ score	4 wk	IQ test
9	Psych scale	PASAT 2-s	4 wk	Paced Auditory Serial Addition Test; measure of cognitive function
10	Psych scale	HADS Anxiety and Depression Score	4 wk	Hospital Anxiety and Depression Scale
11	General symptom scale	NHP Part 2 score	4 wk	Nottingham health profile part 2; measures quality of life
12	General symptom scale	SF-36	4 wk	Vitality, role-physical, mental health

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Effect size (final difference/standard deviation of difference)		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
Engleman, 1999 UK 9927358	MWT	Min	**Tx**	CPAP	4 wk	34	Nd	Nd	16.2	10.6	Nd	nd	nd	0.19	nd	NS
			Cx	Oral placebo	4 wk	34	Nd	Nd	14.4	8.5	nd	Nd	nd			
	ESS	Number	**Tx**	CPAP	4 wk	34	13	3	8	4	-3	Nd	nd	0.75	nd	0.008
			Cx	Oral placebo	4 wk	34	13	3	11	4	-2	nd	Nd			
	SF-36 Role-physical	Number	**Tx**	CPAP	4 wk	34	58	36	81	27	23	Nd	Nd	0.55	nd	0.03
			Cx	Oral placebo	4 wk	34	58	36	64	34	6	nd	Nd			
	SF-36 mental health	Number	**Tx**	CPAP	4 wk	34	64	19	79	16	15	nd	Nd	0.29	nd	NS
			Cx	Oral placebo	4 wk	34	64	19	75	15	11	Nd	nd			
	SF-36 Vitality	number	**Tx**	CPAP	4 wk	34	33	19	58	19	25	nd	Nd	0.67	nd	0.001
			Cx	Oral placebo	4 wk	34	33	19	46	23	13	nd	Nd			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Engleman, 1999 UK 9927358	UMACL Energetic Arousal Score	NA	4 wk	CPAP	34	Placebo	34	0					
	SteerClear	NA	4 wk	CPAP	34	Placebo	34	0					
	Trailmaking A and B	NA	4 wk	CPAP	34	Placebo	34	0					
	Digit symbol	NA	4 wk	CPAP	34	Placebo	34	CPAP	Effect size (final difference/standard deviation of difference)	0.5	nd	Nd	0.004
	Block Design Score	NA	4 wk	CPAP	34	Placebo	34	0					
	Performance IQ score	NA	4 wk	CPAP	34	Placebo	34	0					
	PASAT 2-s	NA	4 wk	CPAP	34	Placebo	34	CPAP	Effect size (final difference/standard deviation of difference)	0.36	nd	Nd	0.02
	HADS Anxiety Score	NA	4 wk	CPAP	34	Placebo	34	0					
	HADS Depression Score	NA	4 wk	CPAP	34	Placebo	34	CPAP	Effect size (final difference/standard deviation of difference)	0.41	nd	nd	0.003
	NHP Part 2 score	NA	4 wk	CPAP	34	Placebo	34	0					

* If more than 2 interventions being tested in study

** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0

*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
All	8%	Unwilling to do CPAP first, failing to attend final assessment, could not handle travelling

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
Milder OSA (AHI 5-10)	Engleman, 1999 UK 9927358	SF-36 mental health	Number	Tx	CPAP	4 wk	14	nd	nd	82	13	nd	nd	nd	0.50	nd	0.05
				Cx	Oral placebo	4 wk	14	nd	nd	73	15	nd	nd	nd		nd	
		SF-36 vitality	number	Tx	CPAP	4 wk	14	nd	nd	55	20	nd	nd	nd	0.94	nd	<0.01
				Cx	Oral placebo	4 wk	14	nd	nd	39	24	nd	nd	nd		nd	

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Author, Year Country PMID	Subgroup	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
					Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Engleman, 1999 UK 9927358	Milder OSA (AHI 5-10)	SteerClear	NA	4 wk	CPAP	14	Placebo	14	CPAP	Effect size (final difference/standard deviation of difference)	0.52	nd	Nd	0.05
		PASAT 2-s	NA	4 wk	CPAP	14	Placebo	14	CPAP	Effect size (final difference/standard deviation of difference)	0.8	nd	Nd	<0.01
		HADS Depression Score	NA	4 wk	CPAP	14	Placebo	14	CPAP	Effect size (final difference/standard deviation of difference)	0.66	nd	nd	0.04

Comments on Subgroup Results	Only reported significant results

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			CPAP	Oral placebo		
Engleman, 1999 UK 9927358	Early wakenings from sleep	4 wk	11.8%	0%		
	Sleep disturbance to patient or partner caused by noise from CPAP	4 wk	23.5%	0%		
	Mask or headgear problems	4 wk	23.5%	0%		
	Dry or open mouth during use	4 wk	11.8%	0%		
	Waking with mask off	4 wk	5.9%	0%		
	Continued snoring on CPAP	4 wk	2.9%	0%		
	Inability to fall asleep with prescribed pressure	4 wk	2.9%	0%		
	Muscle tightness	4 wk	0%	2.9%		
	More frequent awakenings from sleep	4 wk	0%	2.9%		
	Paresthesia in limbs	4 wk	0%	2.9%		
	Paresthesia in throat	4 wk	0%	2.9%		
	headaches	4 wk	0%	8.8%		
	Delayed sleep onset	4 wk	0%	2.9%		
	Stomach cramps	4 wk	0%	2.9%		
	Hungover and tired sensations in the morning	4 wk	0%	8.8%		
	Chest and arm pain	4 wk	0%	2.9%		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	Y	Y	N	Nd	Y	Y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Y	N	Y	Y	Y		y			y
Reasons for drop-outs:	Unwilling to do CPAP first, failing to attend final assessment, could not handle travelling									
Other Issues:										
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Faccenda, 2001			**Intervention 1**	CPAP
PMID*	11179104	**RefID**	5243	**Intervention 2**	
Key Question(s)	KQ 5 (CPAP vs. Cx)			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	Oral Capsule
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
2 major symptoms of SAHS; AHI ≥15	Sleepiness when driving; >50 milesaway from the center; shift work; DM; on Tx for hypertension	≥15	nd	No	UK	Gov	No	No	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y median, range**	**Race**	**BMI* median, range**	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**71 (68)**	81%	50 (29-72)	nd	30 (21-53)	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	0%	nd	nd	nd	nd	nd		
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	68	35 (15-129)	15 (6-24)	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥15			≥50% reduction in thoracoabdominal mov sum signal		Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Auto Set; ResMed	
2				
3				
Control		Placebo	Oral Capsule	
For CPAP:		**How was the Pressure selected?**	Auto titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	nd

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	ESS	1 month	
2	QoL	FOSQ	1 month	
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SE*	Value	SD/SE*	P	Value	SD/SE*	P
Faccenda, 2001 UK 11179104	ESS	Score	Tx	CPAP	1 month	68			10.1	0.7						0.001
			Cx	Oral Capsule		68			12.5	0.8						
	FOSQ	Score	Tx	CPAP	1 month	68			12.4	0.5						0.01
			Cx	Oral Capsule		68			11.6	0.7						
			Tx													
			Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	2/68 (3%)	None given
Oral Capsule	1/68 (2%)	None given

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	No	Yes	No	Yes	Yes	Yes	NA	NA	Yes
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Yes	No	No	Yes	Yes	Yes	NA			No
Reasons for drop-outs:	No reasons were given									
Other Issues:	No wash out period but no measurements were made until 26 days after cross over; No power calculations reported									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Haensel, 2007			**Intervention 1**	CPAP
PMID*	17503102	**RefID**	3342	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	Placebo CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Sx of sleep apnea; 30-65 y/o; 1-2x ideal body wt;	>2x ideal body wt; heart, liver, renal disease, DM, psychosis, narcolepsy, ETOH or drug abuse, asthma, cerebrovascular disease, depression, BP >170/105, central apnea	≥15	nd	no	US	NIH	no	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**25**	80	48.2	56% white; 20% black	33.1±8.2	nd	nd	nd
Cx	**25**	80	49	64% white; 4% black	33.7±7.5	nd	nd	nd
Total	**50**	80	48.6	60% white; 12% black	33.4	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	nd	0	nd	no
Cx	nd	nd	nd	nd	nd	0	nd	no
Total	nd	nd	nd	nd	nd	0	nd	no
	nd	nd	nd	nd	nd			
	Treatments used (prior to trial, including surgery)							
Tx	nd							
Cx	nd							
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	25	63.6±29.1	nd	nd	nd	nd	nd	
Control:	25	58.4±30.4	nd	nd	nd	nd	nd	
Total:	50	61	nd	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥15		↓flow ≥90% from baseline for ≥10 s	↓flow ≥50% & <90% from baseline for ≥10 s		Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	CPAP (fixed)	CPAP	Aria LX CPAP, Respironics, PA	starts at 4 cm H_20, increased by 1-2 cm
2				
3				
Control	Placebo CPAP	mock CPAP	Aria LX CPAP, Respironics, PA	<1 cm H_20
For CPAP:		**How was the Pressure selected?**	Manual	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Psych scale	Profile of Mood States (POMS)	Day 1, Day 14	
2	Sleep study measures	AHI; %O_2 <90	Day 1, Day 14	
3	Sleepiness measures	sleep efficiency (%)	Day 1, Day 14	
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SD/SE*	P
Haensel, 2007 US 17503102	POMS total score		**Tx**	CPAP	2 wk	25	22.6	6.2	7.9	6.5						0.141
			Cx	Placebo CPAP	2 wk	25	25.8	7.3	14.8	8						
	AHI		**Tx**	CPAP	2 wk	25	65.9	28.6 (SD)	3.5	3.4 (SD)						<0.001
			Cx	Placebo CPAP	2 wk	25	57.5	32.1	53.4	32.9						
	$\%O_2$ <90		**Tx**	CPAP	2 wk	25	4.3	7.5 (SD)	0	0						0.061
			Cx	Placebo CPAP	2 wk	25	2.9	5.2	2.4	3.5						
	sleep efficiency	%	**Tx**	CPAP	2 wk	25	80.3	2.3 (SD)	87.5	1.5 (SD)						0.180
			Cx	Placebo CPAP	2 wk	25	82	1.6	85.9	1.6						
	average nighttime CPAP use	h	**Tx**	CPAP	2 wk	25			6.6	1.2						NS
			Cx	Placebo CPAP	2 wk	25			6	1.3						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
Haensel, 2007 US 17503102	POMS subscores on tension, depression, fatigue, confusion, vigor, and anger	Tx			NS diff btw groups
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	0 (presumed)	
Placebo CPAP	0 (presumed)	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
Haensel, 2007 US 17503102	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	y	y	nd	y	n	n	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	n	y		
Reasons for drop-outs:								
Other Issues:		relatively small samples, no power calculation						
Overall Quality (A, B, C)		**B**						

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Henke, 2001			**Intervention 1**	nCPAP
PMID*	11282765	**RefID**	5371	**Intervention 2**	
Key Question(s)	KQ 5 (CPAP vs.Cx)			**Intervention 3**	
Design †	RCT			**Control**	Sham nCPAP
Extractor	RB			**Comments**	We are using only part 1 of one-way cross over study

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
> 10 with daytime sleepiness; >20 with out daytime sleepiness	SpO2 <85% for >50% of TST; clinical signs of rt sided CHF; claustrophobia; nasal obstruction preventing use of nCPAP	> 10 with daytime sleepiness; >20 with out daytime sleepiness	Apr 1992 – June 1996	nd	USA	Gov	No	Yes	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**27**	52	50.2±10.4	White:18; Asian:1; Black:3 Hispanic:5	42.7±10.5			
Cx	**18**	61	50.6±9.7	White:12; Asian:2; Black:0 Hispanic:4	42.2±11.9			
Total	**45**					nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx							None had h/o drug/ alcohol abuse, MI within past 6 months, cirrhosis, COPD, unstable DM or thyroid disorder	
Cx								
Total	None	nd	nd	nd				
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	None							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	27	62.1±27.4	16.4±5.6					
Control:	18	68.1±25.2	16.0±4.8					
Total:	45							
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>10 with symptoms; >20 without symptoms		nd	nd	nd	Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	Nasal CPAP	nd	Mean pressure 10±2.4
2				
3				
Control	Placebo	Sham nCPAP		Pressure 0-1
For CPAP:		**How was the Pressure selected?**	Overnight PSG titration Manual	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
nd		
For CPAP:	**Describe the frequency of the initial education follow-up**	nd

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Psychological tests	Trial Making A test	2 weeks	
2	Psychological tests	Trial Making B test	2 weeks	
3	Psychological tests	WAIS- Digital symbols	2 weeks	Wechsler Adult Intelligence Scale (Lezak 1995 (25))
4	Psychological tests	WAIS- complex figure	2 weeks	
5	Psychological tests	WAIS- digit span	2 weeks	
6	Psychological tests	Steer clear	2 weeks	
7	Compliance		2 weeks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
Henke, 2001 USA 11282765	Compliance	h/d	Tx	nCPAP	2 weeks	27			5.9	1.8						
			Cx	Sham nCPAP		18			5.2	2.2						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Henke, 2001 USA 11282765	Cognition	Trial Making A test	2 weeks	nCPAP	27	Sham CPAP	18	0					
	Cognition	Trial Making B test	2 weeks	nCPAP	27	Sham CPAP	18	0					
	Cognition	WAIS-Digital symbols	2 weeks	nCPAP	27	Sham CPAP	18	0					
	Cognition	WAIS-complex figure	2 weeks	nCPAP	27	Sham CPAP	18	0					
	Cognition	WAIS-digit span	2 weeks	nCPAP	27	Sham CPAP	18	0					
		Hits on steer clear test	2 weeks	nCPAP	27	Sham CPAP	18	0					

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
None in the first period		

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	nd	Yes	Yes	Yes	nd	Yes	NA	NA	Yes
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Yes	No	No	Yes	Yes	Yes	NA			NA
Reasons for drop-outs:	None									
Other Issues:	No power calculation; one-way cross over									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Hui, 2006			**Intervention 1**	Auto PAP
PMID*	16928705	**RefID**	3398	**Intervention 2**	
Key Question(s)	KQ 5 (CPAP v Cx)			**Intervention 3**	
Design †	RCT			**Control**	Sham CPAP
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
20-80 yrs, AHI ≥5/hr, symptoms of OSA	Problems staying awake during driving, professional drivers, shift workers, recent MI, unstable angina, malignancy	≥ 5	nd	No	Hong Kong	University	Yes (mean BP) 50/group	Yes (not reliable)	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y, SE**	**Race**	**BMI*, SE**	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**28(23)**	19, 83%	50.2±1.7		27.4±0.7	65% (>140/90)		
Cx	**28(23)**	18, 78%	51.4±2.1		26.9±0.8	39%		
Total	**56(46)**	37, 80%	50.8±1.3	nd	27.2±0.5	52%	nd	0%
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx		9%						
Cx		9%						
Total	nd	9%	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	none							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*, SE	Epworth*, SE	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	23	31.3±3.3	10.2±1.0				New	
Control:	23	29.1±3.6	11.2±1.1				New	
Total:	46	30.2±2.4	10.7±0.7	nd	nd	nd	New	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥5/hr		Airflow cessation >10 sec	reduction in airflow ≥50% for >10s and >3% desaturation or arousal	excessive daytime sleepiness or two other symptoms (choking/gasping during sleep, recurrent awakenings, daytime fatigue, impaired concentration, unrefreshing sleep)	separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	Auto-titrating CPAP	Resmed, Australia	
2				
3				
Control	Placebo	Sham CPAP		CPAP pressure 4 cm H2O
For CPAP:		**How was the Pressure selected?**	Automatic titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	Education brochure and video

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	ESS	3 months	
2	Compliance	h/night	3 months	
3	BP	BP (sys, dia, mean arterial)	3 months	
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	95% CI*	P
Hui, 2006 Hong Kong 16928705	ESS	score	Tx	CPAP	3 months	23	10.2	1.0	7.0	1.0	-3.2	0.9		-0.04	-2.94, 2.86	0.979
			Cx	Sham CPAP		23	11.2	1.1	8.1	1.0	-3.1	1.1				
	compliance	h/night	Tx	CPAP	3 months	23			5.1	0.4						
			Cx	Sham CPAP		23			2.6	0.4						
	Wake time BP - Systolic	mm Hg	Tx	CPAP	3 months	23	129.1	3.0	126.8	3.0				-2.5	-8.2, +3.2	0.376
			Cx	Sham CPAP		23	127.7	3.0	128.0	3.4						
	Diastolic	mm Hg	Tx	CPAP	3 months	23	84.3	2.1	82.3	2.0				-1.8	-5.3, +1.8	0.317
			Cx	Sham CPAP		23	83.6	2.1	83.4	1.9						
	Mean arterial	mm Hg	Tx	CPAP	3 months	23	98.9	2.1	96.9	2.1				-2.2	-6.2, +1.9	0.293
			Cx	Sham CPAP		23	98.1	2.1	98.3	2.4						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	5/28, 18%	Defaulted -3; technical problems -2
Sham CPAP	5/28, 18%	Refused to continue due to uncomfortable Rx -5

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SE*	P	Value	95% CI*	P
HTN	Hui, 2006 Hong Kong 16928705	Daytime BP - Systolic	mm Hg	**Tx**	CPAP	3 months	15					-3.5	2.8		-4.8	-14.5, +4.7	0.304
				Cx	Sham CPAP		9					+1.3	3.8				
HTN		Diastolic	mm Hg	**Tx**	CPAP	3 months	15					-2.9	1.6		-2.4	-8.0, +3.2	0.383
				Cx	Sham CPAP		9					-0.5	2.2				
HTN		Mean arterial	mm Hg	**Tx**	CPAP	3 months	15					-3.0	1.8		-3.1	-9.5, 3.4	0.338
				Cx	Sham CPAP		9					0.1	2.8				

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	NA	NA	Yes

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	Yes	Yes	Yes	Yes	Yes	Yes	NA	NA

Reasons for drop-outs:	Defaulted -3; technical problems -2; Refused to continue due to uncomfortable Rx -5
Other Issues:	Underpowered; Non-ITT analyses; likely selection bias; questionable patient blinding
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Ip, 2004			**Intervention 1**	CPAP
PMID*	14551167	**RefID**	4396	**Intervention 2**	
Key Question(s)	KQ5 CPAP vs Cx			**Intervention 3**	
Design †	RCT			**Control**	No intervention
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Sleep apnea Male	Previous OSA treatment Structural heart disease HTN, dyslipidemia, DM, other chronic illness Any medication (including CAM)	≥15	nd	No	Hong Kong	Gov't	No	No	No
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**14 (14)**							
Cx	**14 (14)**							
Total	**28**	100	43 (21-62)	(Chinese?)	29.4 (22-44)	0% (by eligibility) 122 (100-139) / 76 (50-92)	nd (probably 0, by eligibility)	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	0 (by eligibility)	11%	nd	nd	nd	nd	nd	Very healthy (for OSA)
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	None							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

DATA ALSO REPORTED BY TREATMENT GROUP. ONLY DBP SIG DIFF BETWEEN GROUPS

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	28	46.0±14.5	11.1±6.2 (0-22)	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
No						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥15		Complete cessation of airflow ≥10 sec	≥50% reduction in airflow for ≥10 sec or <50% but desat >3% or arousal	No	Unclear	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	nasal CPAP	nd	nd
2				
3				
Control		No intervention		
For CPAP:		**How was the Pressure selected?**	"at pre-titrated pressure (in-laboratory titration was done using Sullivan Autoset Flow generator II , Resmed)"	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	nd

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep Measure	AHI	4 wk	
2	Compliance	hours of use		Measured by device
3	Sleep Measure	Minimum SaO2		
4	Sleep Measure	Arousal index		

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference Final (F test – F control)*		
							Value	SD	Value	SD	Value	SD/SE*	P	Value	SD/SE*	P
Ip, 2004	AHI	/hr	Tx	CPAP	4 wk	14	47.7	15.3	1.7	1.8			<0.001			<0.001
Hong Kong			Cx	No Tx		13	45.1	14.3	15.9	15.5			NS			
14551167																
	Compliance	hr/noc	Tx	CPAP	4 wk	14	--		4.3							
			Cx	No Tx		13			--							
	Min O2 sat	%	Tx	CPAP	4 wk	14	64.9	11.85	91.4	2.6			<0.001			<0.001
			Cx	No Tx		13	66.6	12.2	66.5	15.0			NS			
	Arousal ind	/hr	Tx	CPAP	4 wk	14	33.4	17.2	17.5	10.7			<0.001			<0.001
			Cx	No Tx		13	33.8	15.0	35.5	17.7			NS			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Tx	0	
Cx	7%	Patient decision to use nCPAP

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	nd	Yes	No	No	No	No (not net change)	NA	NA	Yes
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Yes	No	No (CPAP machine?)	Yes	No	Yes	NA			NA
Reasons for drop-outs:	Cx: 1 "decided to use nCPAP"									
Other Issues:										
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Jenkinson, 1999, (Hack, 2000)			**Intervention 1**	autoCPAP
PMID*	10382693, 10679542	**RefID**	5419 5345	**Intervention 2**	
Key Question(s)	5(nCAP)			**Intervention 3**	
Design †	RCT			**Control**	Subtherapeutic CPAP
Extractor	NO			**Comments**	2 studies reporting different outcomes on subsets of the same population were extracted. (Data unique to the second study are highlighted in green)

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA Excessive daytime sleepiness ESS ≥10 Men 30-75yrs	Mentally impaired Respiratory failure Job loss or inability to drive due to excessive sleepiness	nd	1997-1998	n	UK		Y(MWT,ESS,SF 36 MCS	y	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y***	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**54(52)**		50(33-71)		35.1(25.8-44.3)			
Cx	**53(49)**		48(36-68)		35.0(26.9-51.4)			
Total	**107(101)**	100		nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Median(range)
Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

Comments 48 patients from the first study and 11 new patients were included in the second study.

D. OSA "SEVERITY" AT BASELINE

	N analyzed(N analyzed)	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	52(33)		16.0(10.7-21.7)					
Control:	49(26)		17.0(10.0-23.0)					
Total:	101(59)	nd		nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

Comments 48 patients from the first study and 11 new patients were included in the second study.

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
One night sleep lab recording body movt and heart rate and sao2 and snoring. Visi-lab	nd	>4%	nd	nd	snoring	seperate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	nCPAP	Resmed	
2				
3				
Control	PAP	Subtherapeutic nCPAP		Administrating subtherapeutic pressure 1cm H2O. six 4mm holes punched in mask to allow air escape
For CPAP:		**How was the Pressure selected?**	auto	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study	MWT	4 weeks	
2	Sleepiness	ESS	4 weeks	
3	Other	Standard deviation of position on road	4 weeks	Position on the road relative to center was measured 20 times per second and standard deviation of these were calculated as an indication of the variability of steering error or wander
4	Other	Standard deviation of deterioration	4 weeks	
5	Other	Off road events	4 weeks	Off road events recorded during a three and a half hour driving simulation test
6	Other	Length of drive	4 weeks	
7	Other	Reaction time	4 weeks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value (median)	range* (5th and 95th centile)	Value	range* (5th and 95th centile)	Value	range* (5th and 95th centile)	P	Value	SD/SE*	P
Jenkinson, 1999 10382693 UK	MWT	min	Tx	nCPAP	4 weeks	52	22.5	7.6-40.0	32.9	11.6-40.0	6.75	-16.4-25.6	<0.0001			0.005
			Cx	Subtherapeutic nCPAP	4 weeks	49	20.0	3.5-40.0	23.5	7.0-40.0	0	-14.3-23.6	NS			
	ESS		Tx	nCPAP	4 weeks	52	15.5	10.0-23.0	7.0	0.7-17.0	-9.0	-19.1-1.4	<0.0001			<0.0001
			Cx	Subtherapeutic nCPAP	4 weeks	49	15.0	9.0-22.5	13.0	4.0-9.0	-2.0	-12.0-4.0	<0.0001			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	range*	Value	range *	Value	range *	P	Value	SD/SE*	P
Hack 2000 10679542 UK	Standard deviation of position on road		**Tx**	nCPAP	4 weeks	33	0.36	0.15-1.12	0.21	0.14-0.63			0.001			0.08
			Cx	Subtherapeutic nCPAP	**4 weeks**	26	0.35	0.15-1.17	0.30	0.14-1.19			0.73			
	Standard deviation of deterioration	SD/h	**Tx**	nCPAP	4 weeks	33	0.18	-1.14-30.3	0.06	-1.02-0.40			0.03			0.007
			Cx	Subtherapeutic nCPAP	**4 weeks**	26	0.18	-0.02-2.67	0.24	-0.04-2.64			0.47			
	Off road events	No/hr	**Tx**	nCPAP	4 weeks	33	17.8	0.4-149	9.0	0.0-76			0.004			0.07
			Cx	Subtherapeutic nCPAP	**4 weeks**	26	34.8	0.9-149	23.0	0-150			0.05			
	Length of drive	min	**Tx**	nCPAP	4 weeks	33	24.8	7.6-30.0	30.0	17.6-30.0			0.03			0.08
			Cx	Subtherapeutic nCPAP	**4 weeks**	26	27.6	10.9-30.0	26.9	9.1-30.0			0.29			
	Reaction time	secs	**Tx**	nCPAP	4 weeks	33	2.8	1.8-4.9	2.3	1.5-3.5			<0.001			0.04
			Cx	Subtherapeutic nCPAP	**4 weeks**	26	2.8	1.7-5.5	2.7	1.6-4.0			0.11			

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Jenkinson, 1999 10382693													

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Subtherapeutic cPAP	4/53	Did not use CPAP Failed to return at the end, 1 collapsed
nCPAP	2/54	Did not use CPAP

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	y	y	n	y	na	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	n	y	na	na
Reasons for drop-outs:								
Other Issues:								
Overall Quality (A, B, C)		**B**						

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Kajaste 2004			**Intervention 1**	Nasal CPAP
PMID*	15033131	**RefID**	4418	**Intervention 2**	
Key Question(s)	5 (CPAP vs Cx)			**Intervention 3**	
Design †	RCT			**Control**	No treatment
Extractor	DM			**Comments**	All subjects received a 2-year cognitive behavioral therapy (CBT) for weight loss and 6-week Very Low Calorie Diet (VLCD).

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
BMI > 35 kg/m^2; subjective symptoms of OSAS; Oxygen Desaturation Index per hour exceeding 4% from baseline (ODI_4) > 10.	Decompensated cardiac failure; juvenile-type diabetes; endocrine disease causing obesity, or severe psychiatric disorder	ODI_4 > 10	nd	No	Finland	Non-profit foundation	No	No	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	18 (17)		50.1 ± 7.9		42.5 ± 4.5			
Cx	15 (14)		47.9 ± 8.0		45.4 ± 6.2			
Total	33 (31)	100		?Caucasian		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	Yes (Obese male patients)
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	ODI_4*	Index of Subjective Sleepiness (ISS)*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	17	47.9 ± 33.5						
Control:	14	55.5 ± 28.5						
Total:			14.2 ± 4.1	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		nd

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	> 10				Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	Nasal CPAP (Fixed)		CPAP pressure adjusted during two nights. Nasal CPAP treatment was stopped 1 week before the 6-month follow-up assessments.
2				
3				
Control	No treatment	No treatment		
For CPAP:		**How was the Pressure selected?**	The minimum pressure level sufficient to prevent oxygen desaturations and normalize nocturnal SaO2 trace in all positions was chosen for the final pressure. The mean (range) pressure level was 13 (7.5–18.5) cmH2O.	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description
Very Low Calorie Diet (VLCD)	Initial 6-week diet using Dietta Mini® (Medifood Ltd, Finland) VLCD preparations. The daily dose contained 500 kcal energy, 50 g high-quality proteins, 65 g carbohydrates, 1 g fat, and the recommended daily allowance of vitamins and minerals. Dietta-Mini was provided free of charge by the manufacturer.
cognitive behavioral therapy (CBT)	Started after the 6-week VLCD intervention. The patients received dietary counseling including oral and written information on eating behavior, nutrition, exercise, eating related emotions and attitudes, health and weight, and principles of weight reduction. They were encouraged to monitor their eating habits, to normalize their eating patterns, and to increase exercise. The treatment program included regular individual meetings of 30–45 min with the therapist. These were held two to four times a month during the first 6 months, once a month during the next 6 months, and every second month during the second year.
For CPAP:	**Describe the frequency of the initial education follow-up**

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	ODI_4	6 months, 12 months. 24 months	ODI: average number of oxygen desaturation events per hour exceeding 4% from the baseline.
2	QoL	SCL-90R General Symptom Index (GSI)	6 months, 12 months. 24 months	semi-standardized interview questionnaire
3	Sleepiness measures	index of subjective sleepiness (ISS)	6 months, 12 months. 24 months	Based on four questions from the Basic Nordic Sleep Questionnaire measuring tiredness and sleepiness (range: 4 (none)–20 (very severe))
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
Kajaste 2004 Finland 15033131	ODI_4	events/hour	**Tx**	Nasal CPAP (fixed)	6 months	17	47.9	33.5	18.3	17.8	-29.6			-3.3		NS
			Cx	No Treatment	6 months	14	55.5	28.5	29.2	18.3	-26.3					
Kajaste 2004 Finland 15033131	SCL-90R General Symptom Index (GSI)	Units on a scale	**Tx & Cx**	Nasal CPAP (fixed) and No Treatmen Gps	6 months	31	63.7	14.0	57.7	13.0	-6		<0.001			
Kajaste 2004 Finland 15033131	index of subjective sleepiness (ISS)	Units on a scale	**Tx & Cx**	Nasal CPAP (fixed) and No Treatmen Gps	6 months	31	14.2	4.1	10.9	3.7	-3.3		<0.001			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	6	Refused to start the weight reduction program
No Treatment	7	Refused to start the weight reduction program

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	nd	Yes	No	nd	No	Yes	NA	Yes	No (6 month results for QoL and Sleepiness measures were not reported for the two groups)

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	Yes	No	Yes	No	Yes	Yes	NA	NA

Reasons for drop-outs:	Refused the common weight loss intervention
Other Issues:	Small sample size; No power calculation
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Kaneko, 2003			**Intervention 1**	CPAP + Optimal drug therapy
PMID*	12660387	**RefID**	4423	**Intervention 2**	
Key Question(s)	K5(CPAP vs Cx)			**Intervention 3**	
Design †	RCT			**Control**	Optimal drug therapy
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA, heart failure (ischemic/ nonischemic dilated cardiomyopathy) for at least 6 months, LVEF≤45% at rest, NYHA II-IV	Exacerbations of heart failure with in last 3 mo, despite optimal drug Rx, Primary valvular heart dis, pacemaker implant, unstable angina/ MI/ cardiac surgery with in 3 mo	>20	nd	No	Canada	Government & Industry	No	No	No
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y, SE**	**Race**	**BMI* SE**	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**12**	11 (92%)	55.9±2.5		30.4±1.8	7 (58%) nd		
Cx	**12**	10 (83%)	55.2±3.6		32.3±2.5	5 (42%)	2 (17%)	
Total	**24**	21 (88%)	55.6	nd	31.4	12 (50%)		100%
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								symptomatic, stable,
Cx								optimally treated CHF
Total	nd	nd	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	12	37.1±6.4	6.8±0.7		100%			
Control:	12	45.2±5.3	5.7±0.9		100%			
Total:	24			nd	100%	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥20		nd	nd	Habitual snoring	Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP + Optimal drug therapy		
2				
3				
Control		Optimal drug therapy		
For CPAP:		**How was the Pressure selected?**	Overnight titration adjusted to abolish apnea & hypopnea or highest tolerated level	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
Optimal drug therapy		
For CPAP:	**Describe the frequency of the initial education follow-up**	nd

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	BP	Daytime BP	1 month	
2	Sleep quality	AHI	1 month	
3	Sleep quality	Min SpO2	1 month	
4	Sleep quality	Stage III & IV sleep	1 month	
5	Sleep quality	REM Sleep	1 month	
6	Sleep quality	Arousals	1 month	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P
Kaneko, 2003 Canada 12660387	AHI	Events/hr	**Tx**	CPAP +Drug Rx	1 month	12	37.1	6.4	8.3	2.8	-28.8		<0.001	-28.3		0.002
			Cx	Drug Rx		12	45.2	5.3	44.7	6.8	-0.5		NS			
	Min SpO2	%	**Tx**	CPAP +Drug Rx	1 month	12	82.3	1.2	89.6	1.1	+7.3		0.004	+8.8		0.01
			Cx	Drug Rx		12	78.4	2.2	76.9	3.6	-1.5		NS			
	Stage III & IV sleep	%TST	**Tx**	CPAP +Drug Rx	1 month	12	10.0	2.6	12.7	3.3	+2.7		NS	+3.2		
			Cx	Drug Rx		12	8.5	3.0	8.0	3.5	-0.5		NS			
	REM Sleep	%TST	**Tx**	CPAP +Drug Rx	1 month	12	7.7	1.6	12.2	2.1	+4.5		NS	+5.9		
			Cx	Drug Rx		12	13.2	1.8	11.8	2.7	-1.4		NS			
	Arousals	no/hr sleep	**Tx**	CPAP +Drug Rx	1 month	12	31.4	6.1	12.8	1.7	-18.6		NS			0.003
			Cx	Drug Rx		12	42.9	5.5	42.3	6.2	-0.6					
	Daytime Systolic BP	mm Hg	**Tx**	CPAP +Drug Rx	1 month	12	126	6	116	5	-10		0.02	-16		0.008
			Cx	Drug Rx		12	128	7	134	8	+6		NS			
	Daytime Diastolic BP	mm Hg	**Tx**	CPAP +Drug Rx	1 month	12	62	4	59	2	-3		NS	-1		
			Cx	Drug Rx		12	60	4	58	3	-2		NS			

TST = Total Sleep Time

* Delete or correct the incorrect value/item. If change, highlight yellow.

** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
	no dropouts	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	No	Yes	No	No	Yes	Yes	NA	NA	Yes
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Yes	No	No	Yes	No	Yes	NA			NA
Reasons for drop-outs:	No dropouts									
Other Issues:	No power calculation									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Lojander, 1996, 1999			**Intervention 1**	nasal CPAP
PMID*	8681614, 10188139	**RefID**		**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	2 RCTs			**Control**	conservative treatment
Extractor	SI			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
mental or physical effects of OSAS and ODI findings; previously untreated; experts decided that nasal CPAP is the preferred treatment	asthma, COPD, periodic leg movement syndrome, hypothyroidism, serious concomitant disease, unable to work because of somnolence, BMI >40	nd	1987-1992	no	Finland	Ahokas and Ida Montin Foundation	yes, 12 pts per arm	no	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**21**	96	51		29 (range 24-38)	nd	nd	nd
Cx	**23**	89	51		33 (range 24-41)	nd	nd	nd
Total	**44**	93	51		31.1	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	121 (110-148, Wechsler Verbal)	nd	nd	no
Cx	nd	nd	nd	nd	111 (91-140)	nd	nd	no
Total	nd	nd	nd	nd	116	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx	none							
Cx	none							
Total	none							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	ODI4*	Epworth*	MSLT* †	Heavy Snorers#	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	21	25 (10-92)	nd	nd	19/21	nd	nd	nd
Control:	23	29 (10-96)	nd	nd	21/23	nd	nd	nd
Total:	44	27	nd	nd	91%	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

not defined ; * Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	nd				Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	nasal CPAP	Nightbird, Respironics III, or Remstar	initiated at hospital @ 2 consecutive nights, adjusted to abolish all apneas and desaturations
2				
3				
Control		Conservative treatment		
For CPAP:		**How was the Pressure selected?**	adjusted individually	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	daytime somnolence	3 mo and 12 mo	VAS (not extracted as this is not an externally validated instrument)
2	Sleep study measures	ODI4	3 mo and 12 mo	no. of desat of ≥4% per h in bed
3	Cognitive scale	Wechsler	3 mo and 12 mo	
4	Sleep study measures	ODI10	3 mo and 12 mo	no. of desat of ≥10% per h in bed

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
Lojander, 1996 Finland 8681614	ODI4		Tx	nasal CPAP	12 mo	13	25 (n=21)		0 (n=13)							<0.001
			Cx	conservative	12 mo	20	29 (n=23)		15 (n=20)							
	ODI10		Tx	nasal CPAP	12 mo	13	7 (n=21)		0 (n=13)							<0.001
			Cx	conservative	12 mo	20	7 (n=23)		1 (n=20)							
Lojander, 1999 Finland 10188139	Wechsler Verbal		Tx	nasal CPAP	12 mo	9	121 (n=10)				-7 (n=9)					NS
			Cx	conservative	12 mo	12	111 (n=17)				-6 (n=12)					
	Wechsler Performance		Tx	nasal CPAP	12 mo	9	115 (n=10)				-9 (n=9)					NS
			Cx	conservative	12 mo	12	114 (n=17)				-5 (n=12)					
	Wechsler Memory		Tx	nasal CPAP	12 mo	9	128 (n=10)				-7 (n=9)					NS
			Cx	conservative	12 mo	12	118 (n=17)				2 (n=12)					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
nasal CPAP	38%	failure to adjust, nasal problems

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			Conservative			
Lojander, 1996 Finland 8681614	death		1/23			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	n		nd	y	y	n	NA	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	n	y	y	y	y	nd				
Reasons for drop-outs:	failure to adjust to the machine, nasal problems									
Other Issues:	large drop out; expert panel decided patients would be more suitable for nasal CPAP but no objective criteria stated									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Loredo 1999, Yu 1999 ,Bardwell, 2001 Profant, 2003			**Intervention 1**	CPAP
PMID*	10593774, 10504011 11485111 12571548	**RefID**	5543, 5988, 5047, 4689	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	Sham CPAP
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
30 to 65 yrs OSA	Medication known to affect sleep CHF, symptomatic obstructive pulmonary , coronary or cerebral vascular disease, history of life threatening arrhythmias, cardiomyopathy, history of psychosis, narcolepsy or currently abused alcohol or drugs	RDI≥20	nd	n	USA	NIH grants		y	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**?(23)**	73	46.9(8.3)		33(5)	130(16)/82(8)		
Cx	**?(18)**	88	49.8(9.3)		29.1(5.6)	125(14)/79(9)		
Total	**48(41)**	75		nd			nd	0
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	**nd**	**nd**	**nd**	**nd**		nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	23							
Control:	18							
Total:	41	nd	nd	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	RDI ≥20		Decrements in airflow ≥90% for 10secs	Decrements in airflow ≥ 50% but <90% from baseline for 10secs			The number of apneas and hypopneas per hour were calculated to obtain RDI

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Respironics, Monroeville, PA	CPAP pressure of 8 ,10 or 20 cm H20 reached or snoring, apneas, hypopneas abolished with increasing pressures
2				
3				
Control	Placebo	Placebo CPAP		Same device as intervention, but mock titration. Drilled hole in mask so pressure varied from 2cm H20 at end of expiration to 1.5 cm H2 o during inspiration
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	Slow wave sleep	7 days	
2	Sleep study measure	REM sleep	7 days	
3	Sleep study measure	Sleep effieciency	7 days	
4	Sleep study measure	Arousal index	7 days	
5	Sleep study measure	RDI	7 days	The number of apneas and hypopneas per hour were calculated to obtain RDI
6	Psych scale	POMS – total mood disturbance	11days	
7	QOl	MOS sub scales	1 week	
8	Psych scale	Neuropsychological test	1 week	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value	SD*	P
Loredo 1999 US 10593774	Slow wave sleep	%	Tx	CPAP	7 days	23	7.4	8.7	12.5	10.6	5.1			-1.6		
			Cx	Sham CPAP	7 days	18	6.3	8.6	13.0	14.5	6.7					
	REM sleep	%	Tx	CPAP	7 days	23	19.0	7.9	26.2	7.0	7.2			5.7		
			Cx	Sham CPAP	7 days	18	17.7	8.0	19.2	8.3	1.5					
	Sleep efficiency	%	Tx	CPAP	7 days	23	83.7	10.7	88.1	8.6	4.4			2.9		
			Cx	Sham CPAP	7 days	18	82.2	11.8	83.7	12.9	1.5					
	Arousal index		Tx	CPAP	7 days	23	55.1	24.4	1.4	9.5	-53.7			-38.6		0.001
			Cx	Sham CPAP	7 days	18	48.6	28.2	33.5	23.2	-15.1					
	RDI		Tx	CPAP	7 days	23	56.4	24.1	3.3	3.8	-53.1			-37.2		<0.001
			Cx	Sham CPAP	7 days	18	44.2	25.3	28.3	22.7	-15.9					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Yu 1999 US 10504011	POMS- TMD		**Tx**	CPAP	11 days	20	43.2	48.5	16.3	27.0						NS
			Cx	Sham CPAP		14	36.5	28.4	18.0	24.3						

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Yu 1999 US 10504011	POMS	Tension	11 days	CPAP	20	Sham CPAP	14	0					
		Depression	11 days	CPAP	20	Sham CPAP	14	0					
		Fatigue	11 days	CPAP	20	Sham CPAP	14	0					
		Confusion	11 days	CPAP	20	Sham CPAP	14	0					
		Vigor	11 days	CPAP	20	Sham CPAP	14	0					
		Anger	11 days	CPAP	20	Sham CPAP	14	0					

* If more than 2 interventions being tested in study

** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0

*** "Net Difference" or "Final Difference"

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Profant 2003 US 12571548	MOS	Satisfaction with physical functioning	1 week	CPAP	21	Sham CPAP	18	0					
		Effects of pain	1 week	CPAP	21	Sham CPAP	18	0					
		Pain severity	1 week	CPAP	21	Sham CPAP	18	0					
		Cognitive functioning	1 week	CPAP	21	Sham CPAP	18	0					
		Mental health index I and II	1 week	CPAP	21	Sham CPAP	18	0					
		Psychological well being I and II	1 week	CPAP	21	Sham CPAP	18	0					
		Depression/behavioral emotional control	1 week	CPAP	21	Sham CPAP	18	0					
		Anxiety	1 week	CPAP	21	Sham CPAP	18	0					
		Role limitation due to emotional problems	1 week	CPAP	21	Sham CPAP	18	0					
		Physical and physiological functioning	1 week	CPAP	21	Sham CPAP	18	0					
		Positive affect II	1 week	CPAP	21	Sham CPAP	18	0					

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Bardwell, 2001 11485111	Neuropsychological test	Digit symbol	1 week	CPAP	20	Sham CPAP	16	0					
		Trial A	1 week	CPAP	20	Sham CPAP	16	0					
		Trail B	1 week	CPAP	20	Sham CPAP	16	0					
		Digit span total	1 week	CPAP	20	Sham CPAP	16	0					
		Stroop naming (No. correct)	1 week	CPAP	20	Sham CPAP	16	0					
		Stroop reading (No. correct)	1 week	CPAP	20	Sham CPAP	16	0					
		Stroop interference (no. correct)	1 week	CPAP	20	Sham CPAP	16	0					
		Word fluency (no. correct)	1 week	CPAP	20	Sham CPAP	16	0					
		Word fluency (Preservations)	1 week	CPAP	20	Sham CPAP	16	0					
		Word fluency (Intrusions)	1 week	CPAP	20	Sham CPAP	16	0					
		Word fluency (variations)	1 week	CPAP	20	Sham CPAP	16	0					

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	y	y	n	y	na	y	Y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	y	y	na			na
Reasons for drop-outs:										
Other Issues:	Small sample size									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Loredo, 2006 (von Kanel, 2006; Bardwell, 2007)			**Intervention 1**	CPAP
PMID*	16676791 (17313322; 16565866)	**RefID**	3550 (3076; 3935)	**Intervention 2**	O2
Key Question(s)	KQ 5 CPAP			**Intervention 3**	
Design †	RCT			**Control**	Sham CPAP
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	Exclusion	AHI Criteria to Dx OSA	Enrollment Years	Multicenter?	Country	Funding source	Power calculation? (specify outcome)	Blinding, patient	Blinding, outcome assessor
Chronic loud snoring 30-65 y 1-2x IBW Sleep apnea	Rx that may affect sleep CHF, COPD, coronary or cerebrovascular disease, life threatening arrhythmia, cardiomyopathy, psychosis, narcolepsy, current EtOH or drug abuse Previous OSA treatment Periodic limb movement index ≥15/hr	≥15	2000-2004	No	US	Gov't	(a posteriori) Outcomes: Slow wave sleep: 80% power for 5% points difference	Yes	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?)	AFib/AFlutter, %	CVD †, % (specify)
Tx: CPAP	**22 (22)**	82	48 (29-65)	10/2/3/2/1‡	31.8 (23.1-44.0)	135/80 (8/18)#		
Tx: O2	**22 (22)**	73	43 (30-56)	12/2/0/2/0	32.0 (23.4-52.0)	132/79 (3/16)		
Cx: Sham	**19 (19)**	84	48 (31-65)	6/1/1/0/2	31.8 (23.4-50.2)	127/77 (2/10)		
Total	**76 (76)**						nd	0 (by eligibility)
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	No
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	None							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

‡ White/Black/Hispanic/Asian/Other; from von Kanel 2006 (subset of Loredo 2006)
 # from von Kanel 2006 (subset of Loredo 2006)

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Tx: CPAP	22	65.9±28.6	11.6±4.9 (2-22)					
Tx: O2	22	64.9±33.7	12.8±4.5 (0-21)					
Cx: Sham	19	57.5±32.1	12.3±6.7 (0-23)					
Total:				nd	nd	nd	nd	

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify)	Other characteristics
No	nd	

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥15	NA	≥90% decrement ≥10 sec	≥50-90% decrement ≥10 sec	no	Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	nCPAP		heated humidifier (sham O2) (Aria 156 LX CPAP System, Respironics
2	Miscellaneous	O2 3L/min		attached to sham CPAP; FiO2 32-34% at mask
3				
Control		Sham CPAP		CPAP<1 cm H2O and sham O2; 10 ¼" holes
For CPAP:		**How was the Pressure selected?**	Manual	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	PSG done on night following titration (3rd PSG) with additional training given then

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep measure	AHI	2 wk	
2	Sleep measure	Slow wave sleep		Stage 3-4
3	Sleep measure	REM		
4	Sleep measure	Sleep efficiency		
	Sleep measure	Arousal index		sudden rise in EEG frequency to alpha or theta for ≥ 3 seconds but < 15 seconds whether or not associated with a rise in EMG activity, except for arousals during REM sleep which required also a rise in EMG activity.
	Sleepiness	Epworth SS		
	Compliance			Hours/night
	Psych scale	Brief Symptom Index (BSI) Global Severity Index		53 item from Symptom Checklist-90-Revised; each rated 0 (not at all) to 4 (extremely). Higher scores indicate greater levels of psychological distress). Measure of Level of Distress
	Psych scale	Brief Symptom Index (BSI) Depressive symptoms		Measure of level of depression

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/(SEM)	Value	SD/(SEM)	Value	SD/SE*	P	Value	P c/t Placebo	P ANOVA
Loredo, 2006	AHI	/hr	**Tx**	CPAP	2 wk	22	65.9	28.6	~3	(nd or 0)			<0.001		<0.05	<0.001
US			**Tx**	O2		22	64.9	33.7	~52.5	(~7.5)			NS		NS	
16676791			**Cx**	Sham CPAP		19	57.5	32.1	~54	(~7.5)			NS			
von Kanel, 2006	AHI	/hr	**Tx**	CPAP	2 wk	18	66.6	6.87	3.57	0.85			<0.001			<0.001
US			**Tx**	O2		16	59.5	9.28	50.0	10.2			0.003			
16565866			**Cx**	Sham CPAP		10	59.1	9.99	52.1	9.51			NS			
	Sleep eff	%	**Tx**	CPAP	2 wk	22	80.7	11.4								NS
			Tx	O2		22	83.8	11.3								
			Cx	Sham CPAP		19	83.1	7.2								
	Slow wave	%	**Tx**	CPAP	2 wk	22	5.0	6.9	7.1	6.2			NS			NS
			Tx	O2		22	5.7	7.4	6.9	9.5			NS			
			Cx	Sham CPAP		19	4.1	5.1	4.7	5.8			NS			
	REM	%	**Tx**	CPAP	2 wk	22	14.3	6.9	~22	(~1-1.5)			<0.003		<0.05	<0.001
			Tx	O2		22	15.1	4.7	~15	(~1)			NS		NS	
			Cx	Sham CPAP		19	15.3	4.8	~15.5	(~1)			NS			
	Arousal index	/hr	**Tx**	CPAP	2 wk	22	41.0	28.4	~10.5	(nd or 0)			<0.001		<0.05	<0.001
			Tx	O2		22	47.8	34.2	~40	(~7.5-8)			NS		NS	
			Cx	Sham CPAP		19	43.8	32.6	~40.5	(~7.5-8)			NS			
Bardwell, 2007	Arousal ind	/hr	**Tx**	CPAP	2 wk	12	35.9	28.9	9.8	4.8			<0.001		Final values ≤0.05 ≤0.01 (c/t O2)	
US			**Tx**	O2		14	50.7	35.4	43.6	33.1			NS		NS	
17313322			**Cx**	Sham CPAP		12	43.0	25.2	38.7	27.5			NS			
	Compliance	hr	**Tx**	CPAP	2 wk	22	--		6.61	1.19						NS
			Tx	O2		22	--		6.60	1.19						
			Cx	Sham CPAP		19	--		5.98	1.27						
	ESS		**Tx**	CPAP	2 wk	22	11.6	4.9	8.2	4.4						NS
			Tx	O2		22	12.8	4.5	10.0	4.5						

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/(SEM)	Value	SD/(SEM)	Value	SD/SE*	P	Value	P c/t Placebo	P ANOVA
			Cx	Sham CPAP		19	12.3	6.7	10.6	6.4						
Bardwell, 2007	BSI GSI		**Tx**	CPAP	2 wk	12	0.29	(~0.08)	0.17	(~0.07)			0.034		Final Values NS	0.048
US			**Tx**	O2		14	0.38	(~0.07)	0.19	(~0.07)			0.001		NS	
17313322			**Cx**	Sham CPAP		12	0.35	(~0.08)	0.37	(~0.07)			NS			
											Compared to norms for nonpsychiatric patients, these values fell short of criteria for clinically meaningful changes in distress					
	BSI Depression		**Tx**	CPAP	2 wk	12	0.29	(~0.15)	0.19	(~0.16)			NS		nd	0.019
			Tx	O2		14	0.40	(~0.15)	0.18	(~0.15)			0.012			
			Cx	Sham CPAP		12	0.42	(~0.15)	0.56	(~0.15)			NS			
											Compared to norms for nonpsychiatric patients, these values fell short of criteria for clinically meaningful changes in depression symptoms					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper
RED values were estimated from figures (using Engauge Digitizer); estimated to the nearest 0.5.

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	Compliance (and other outcomes) does not include 5 subjects excluded because intolerant of CPAP equipment

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	Yes	Yes	Yes	Yes	No	Partial (mostly ANOVA only)	NA	NA	No (incomplete reporting of results)

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	Yes	Possible, nd on which patients dropped out	Yes	Yes	Yes	Yes	NA	NA

Reasons for drop-outs:	8/71 excluded: 3 intolerant of CPAP equipment; 5 did not complete protocol
Other Issues:	Poorly reported results, with much missing data. Incomplete analyses.
Overall Quality (A, B, C)	**B: Slow Wave, ESS, BSI GSI & Depression** **C: Other outcomes**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Mansfield, 2004			**Intervention 1**	Nasal CPAP
PMID*	14597482	**RefID**	4534	**Intervention 2**	
Key Question(s)	KQ 5 (CPAP v Cx)			**Intervention 3**	
Design †	RCT			**Control**	No treatment
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
18-80 yrs; symptomatic, stable, optimally treated CHF, AHI >5 obstructive events Symptoms: snoring, witnessed apneas/nocturnal choking, excessive daytime sleepiness	Significant central sleep apnea (>20% events central type), neurological dis, renal dis with serum creat >150mmol/L, Pulm dis with FER < 70%	5-15	nd	No	Australia	Gov	No	No	No
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y, SE**	**Race**	**BMI*, SE**	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**28(19)**	19/19, 100%	55.5±2.2		33.6±1.0			100%
Cx	**27(21)**	19/21, 90%	59.6±1.5		33.3±1.2			100%
Total	**55(40)**	38/40, 95%		nd			nd	100%
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								symptomatic, stable,
Cx								optimally treated CHF
Total	nd	nd	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx	None							
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*, SE	Epworth*, SE	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	19	25.0±4.1	9.5±0.9				Implies new	
Control:	21	26.6±4.5	8.8±0.9	nd	nd	nd		
Total:	40							
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>5		nd	nd	snoring, witnessed apneas/nocturnal choking, excessive daytime sleepiness	Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	Nasal CPAP (fixed)	Autoset-T, ResMed, Aus	
2				
3				
Control	No Treatment			
For CPAP:		**How was the Pressure selected?**	Manual titration during PSG	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
Lifestyle advice	Advice on diet, alcohol consumption and exercise for pts with CHF	
For CPAP:	**Describe the frequency of the initial education follow-up**	One home visit and phone call every second week

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	BP		3 months	
2	Sleep quality	AHI	3 months	
3	Sleep quality	Min SpO2	3 months	
4	Sleep quality	SWS	3 months	
5	Sleep quality	REM Sleep	3 months	
6	Sleepiness measures	ESS	3 months	
7	QoL	SF-36	3 months	
8	QoL	Guyatt CHF Questionnaire score	3 months	Guyatt et al, 1989 (27); Disease Mastery (4-28), Dyspnea (5-35), Fatigue (4-28), Emotional function (7-49)
9		NYHA class	3 months	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P
Mansfield, 2004 Australia 14597482	ESS	score	**Tx**	Nasal CPAP	3 months	19	9.5	0.9	6.9	1.0	-3.1 (reported)	1.4		-4.2		0.01
			Cx	No treatment		21	8.8	0.9	9.9	1.0	1.1	0.8				
	AHI	Events/hr	**Tx**	Nasal CPAP	3 months	19	25.0	4.1	2.9	0.8	-21.1	3.8		-12.7		<0.001
			Cx	No treatment		21	26.6	4.5	18.2	2.8	-8.4	3.6				
	Min SpO2	%	**Tx**	Nasal CPAP	3 months	19	79.6	2.6	91.1	0.9	11.5	2.7		11.5		0.001
			Cx	No treatment		21	77.2	3.9	77.2	3.5	0	1.6				
	SWS	%SPT	**Tx**	Nasal CPAP	3 months	19	5	1	7	2	2	2		0		NS
			Cx	No treatment		21	6	1	4	1	2	1				
	REM Sleep	%SPT	**Tx**	Nasal CPAP	3 months	19	14	1	13	2	-1	2		0		NS
			Cx	No treatment		21	12	2	11	1	-1	1				
	BP	mm Hg	**Tx**	Nasal CPAP	3 months	19	99	3	100	2	1	3		7		NS
			Cx	No treatment		21	105	3	99	3	-6	3				
	NYHA Class		**Tx**	Nasal CPAP	3 months	19	2.2	0.2	2.3	0.2	0.1	0.1		0.1		NS
			Cx	No treatment		21	2.4	0.2	2.4	0.2	0	0				
	SF-36 Role-physical	score	**Tx**	Nasal CPAP	3 months	19	34	10	60	10	26			26		0.03
			Cx	No treatment		21	46	10	46	10	0					
	SF-36 Vitality	score	**Tx**	Nasal CPAP	3 months	19	44	4	63	5	19			20		0.02
			Cx	No treatment		21	55	6	54	6	-1					
	SF-36 Mental Health	score	**Tx**	Nasal CPAP	3 months	19	72	6	81	5	9			14		0.01
			Cx	No treatment		21	79	5	74	5	-5					

SWS = Slow Wave Sleep; SPT = Sleep Period Time
* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Mansfield, 2004 Australia 14597482	CHF Questionnaire score	Disease Mastery	3 months	nCPAP	19	No Rx	21	nCPAP	Net Difference		4	28	0.02
	CHF Questionnaire score	Dyspnea	3 months	nCPAP	19	No Rx	21	nCPAP	Net Difference		5	35	NS
	CHF Questionnaire score	Fatigue	3 months	nCPAP	19	No Rx	21	nCPAP	Net Difference		4	28	0.01
	CHF Questionnaire score	Emotional function	3 months	nCPAP	19	No Rx	21	nCPAP	Net Difference		7	49	0.02

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
nCPAP	9/28 (32%)	Withdrew-4; unstable-3; death-2
No Rx	6/27 (22%)	Withdrew-3; unstable-3

Unstable: CHF became worse needing change in ongoing Rx likely to impact significantly on LVEF

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	No	No	No	No	No	Yes	NA	NA	Yes

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	Yes	No	No	Yes	No	Yes	NA	NA

Reasons for drop-outs:	The baseline characteristics of the drop outs was similar to the entire cohort.
Other Issues:	No power calculation
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Marshall, 2005			**Intervention 1**	Humidified CPAP
PMID*	15860720	**RefID**	4546	**Intervention 2**	
Key Question(s)	5- CPAP vs Cx			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	Sham CPAP
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
(AHI 5-30; older than 18 years; complained of habitual snoring or nocturnal choking and at least one daytime sleepiness symptom daytime/evening napping, sleepiness while driving, never or rarely awakening refreshed) or had an Epworth Sleepiness Score >8	history of extreme somnolence requiring immediate treatment; performed shift work; chronic sleep restriction (average total sleep time (<6 hours/night); were currently taking sedatives, antidepressants, psychotropics or stimulants; had an alcohol intake of >3 standard units/24 hours or caffeine dependency (unable to forego caffeine on testing days); had undergone upper airway surgery since the diagnostic sleep study; or had any clinically significant co-existing disease or additional sleep disorders	nd	Nov 2001 – Feb 2003	n	New Zealand	Health Research Council of New Zealand (to AMN) and by a PhD stipend from Massey University	31 patients would be required to show a 2.5 point improvement between sham CPAP and CPAP in the Epworth Sleepiness Scale with 90% power, significance set at 0.05 and an intra-individual SD of 4.1 points in a crossover design	y	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx	**31(29)**							
Cx	**31(29)**							
Total	**31(29)**	76	50.5	nd	31.5	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	31(29)							
Control:	31(29)							
Total:	31(29)	21.6	12.5	nd	nd	Nd	Nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	Nd	nd	obstructive apnoea was defined as cessation of breathing for 10 seconds or more (<20% normal airflow) with ongoing respiratory effort. Without this effort a 10 second apnoea or longer was defined as a central apnoea; combinations of effort/no effort defined a mixed apnoea	>50% reduction in the amplitude of at least two of the three respiratory channels (oronasal flow, thoracic, and abdominal effort) or >50% reduction in nasal pressure for at least 10 seconds accompanied by either an arousal from sleep or >4% blood oxygen dip	nd	separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	Humidified CPAP	Fisher and Paykel HC 221; Fisher and Paykel Healthcare, Auckland, New Zealand	
2				
3				
Control	PAP	Sham CPAP		The sham CPAP created conditions that were identical to CPAP at 8 cm H2O in terms of noise, mask temperature, mask humidity, and airflow through the exhalation port
For CPAP:		**How was the Pressure selected?**	-Therapeutic CPAP was determined by manual titration to abolish apnoeas, hypopnoeas, and reduce respiratory related arousals and confirmed by a sleep physician -Sham CPAP device was set to 8 cm H_2O but actually delivered <1.0 cm H_2O due to placement of a resistor at the pump outlet and a modified mask with extra holes drilled around the exhalation port	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	ESS	3 weeks	
2	Sleepiness measures	ModMWT	3 weeks	Modified Maintenance of Wakefulness test
3	General symptom scales	FOSQ	3 weeks	Total FOSQ score
4	Psych scale	SF-36 mental health	3 weeks	
5	Physical scale	SF-36 physical functioning	3 weeks	
6	Physical scale	SF-36 vitality	3 weeks	
7	Psych scale	HADS	3 weeks	Hospital Anxiety and Depression Scale—Anxiety and Depression subscales
8	Physical scale	Psychomotor vigilance task	3 weeks	Chronometric measure of individual's readiness to detect and respond to small changes in a labile environment. 3 measures- Mean reaction time (ms), lapses (>500 ms reaction time), errors.

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference		
							Value	SE*	Value	SE*	Value	SD/SE*	P	Value	95% CI	P
Marshall, 2005 New Zealand 15860720	ESS	scale	**Tx**	Humidified CPAP	3 weeks	29	12.5	0.8	9.7	0.7	-2.8	nd	<0.001	-2.4	-4.2, -0.6	0.04
			Cx	Sham CPAP	3 weeks	29	12.5	0.8	12.0	0.7	-0.5	Nd	NS			
	ModMWT	minutes	**Tx**	Humidified CPAP	3 weeks	29	20.9	2.5	23.1	2.0	2.2	Nd	NS	5.2	-0.6, 11	0.09
			Cx	Sham CPAP	3 weeks	29	20.9	2.5	17.9	2.0	-3	Nd	NS			
	FOSQ	scale	**Tx**	Humidified CPAP	3 weeks	29	12.6	0.3	13.6	0.3	1	Nd	<0.01	0.3	-0.5, 1.1	NS
			Cx	Sham CPAP	3 weeks	29	12.6	0.3	13.3	0.3	0.7	Nd	NS			
	SF-36 mental health	Scale	**Tx**	Humidified CPAP	3 weeks	29	75	3	77	2	2	Nd	NS	-3	10, 3	NS
			Cx	Sham CPAP	3 weeks	29	75	3	80	2	5	Nd	NS			
	SF-36 physical functioning	Scale	**Tx**	Humidified CPAP	3 weeks	29	82	3	81	2	-1	Nd	NS	1	-3, 6	NS
			Cx	Sham CPAP	3 weeks	29	82	3	80	2	-2	Nd	NS			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Marshall, 2005 New Zealand 15860720	HADS	Anxiety, depression	3 weeks	Humidified CPAP	29	Sham CPAP	29	0					
	Psychomotor vigilance task	Meant reaction time (ms), lapses (>500 ms reaction time), errors	3 weeks	Humidified CPAP	29	Sham CPAP	29	0					

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Both	6.45	One patient Non-fatal MI, one CPAP intolerant

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	n	y	y	y	y	y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	y	y	N			y
Reasons for drop-outs:	One patient Non-fatal MI, one CPAP intolerant									
Other Issues:										
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	McArdle, 2001			**Intervention 1**	CPAP
PMID*	11704596	**RefID**	4555	**Intervention 2**	
Key Question(s)	KQ5 (CPAP vs Cx)			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	Oral Capsule
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
≥2 symptoms of SAHS; AHI >15; apnea & hypopneas >30 (non-EEG based)	Meds/ coexisting dis likely to disturb sleep quality; overnight shift workers; alcohol >210g/wk; driving problems due to sleepiness	>15	nd	No	Aus	San Diego Foundation	Yes 22 (Sleep architecture)	No	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**23**	20 (87%)	53±11	nd	31±5	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd		
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI* median (IQR)	Epworth* median (IQR)	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	23	40 (25-65)	14 (10-17)	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>15		Douglas et al 1992 (18)			Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Sullivan Elite (ResCare, UK)	Mean pre 10±3
2				
3				
Control	Placebo	Oral Capsule		
For CPAP:		**How was the Pressure selected?**	nd	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	nd

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep quality	Stage REM	1 month	
2	Sleep quality	Stage ¾		
3	Sleep quality	Arousal index		
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	median	IQR*	Value	SD/SE*	P	Value	SD/SE*	P
McArdle, 2001 Australia 11704596	Stage REM	min	Tx	CPAP	1 month	22			86	30						0.1
			Cx	Placebo					74	29						
	Stage 3/4	min	Tx	CPAP	1 month	22			41	30-67						0.007
			Cx	Placebo					23	12-39						
	Arousal index	ev/hr	Tx	CPAP	1 month	22			21	17-31						<0.001
			Cx	Placebo					45	32-77						

Mean±SD

* Delete or correct the incorrect value/item. If change, highlight yellow.

** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study

** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0

*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
	1 (4%)	Refuse to continue CPAP

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	Yes/No	Yes	No	Yes	No	Yes	NA	NA	Yes
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Yes	No	No	Yes	No	Yes	Yes			nd
Reasons for drop-outs:	1 (4%) Refuse to continue CPAP									
Other Issues:	Allocation concealment: yes – assessors; no - patients									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Mills 2006; Lim 2007			**Intervention 1**	Nasal CPAP
PMID*	16357087;17694727	**RefID**	3600; 3529	**Intervention 2**	Supplemental Oxygen
Key Question(s)	KQ 5 (CPAP vs. Cx)			**Intervention 3**	
Design †	RCT			**Control**	Sham CPAP
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
30-65 yrs; 1.0-2.0 times of ideal body weight; AHI >15	Any major illness; CHF; COPD; DM; liver, renal dis; narcolepsy; previous surgery for OSA; alcohol/ drug abuse; psychosis; periodic limb movement >15 on baseline PSG; BP >180/110	> 15	nd	No	USA	Gov		Yes	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y SE**	**Race**	**BMI* SE**	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx1	**17**	15(88%)	47.6±2.58		31.7±1.4	53% (no def)		
Tx2	**17**	13(76%)	43.9±2.49		30.7±1.2	71%		
Cx	**16**	13(81%)	49.0±2.56		32.2±1.7	81%		
Total	**50**						0%	0%
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx1								
Tx2								
Cx								
Total	0%	nd	nd	nd			Implies 0%	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	None							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI* SE	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Tx1:	17	65.0±8.3						
Tx2:	17	61.8±9.4						
Control:	16	61.2±8.2						
Total:			nd	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>15		Decrements in airflow ≥90% for ≥10s	Decrements in airflow ≥50% but <50% for ≥10s		Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Aria LX, Respironics	+ room air
2		Supplemental oxygen	Aria LX, Respironics	3L/min
3				
Control	Placebo	Sham CPAP	Aria LX, Respironics	0-0.5cm H2O +room air
For CPAP:		**How was the Pressure selected?**	Manual titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	instructions and then telephone calls

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	BP		2 weeks	
2	Sleep quality	AHI	2 weeks	
3	Compliance		2 weeks	
4	Wechsler Adult Intelligence Scale-Rev	Digit Symbol	2 weeks	Wechsler 1981 (23)
		Digit Span	2 weeks	
		Letter-Number Sequencing	2 weeks	
		Symbol Search	2 weeks	
5	Brief Visuospatial Memory Test-Rev		2 weeks	Benedict 1997 (24)
6	Hopkins Verbal learning Test-Rev		2 weeks	Benedict 1998 (25)

7	Trail Making A/B		2 weeks	Boll 1981(26)
8	Digit Vigilance		2 weeks	Lewis 1995 (27)
9	Stroop Color-Word		2 weeks	Golden 1978 (28)
10	Word Fluency		2 weeks	Lezak 1995 (29)

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SD/SE*	P	Value	SD/SE*	P
Mills, 2006 USA 16357087	AHI	Events/hr	**Tx1**	CPAP	2 weeks	17	65.0	8.3	2.56	0.57	-62.44		0.0	-58.54		
			Tx2	Supplemental oxygen		17	61.8	9.4	50.1	10.7	-11.7			-7.8		
			Cx	Sham CPAP		16	61.2	8.2	57.3	8.2	-3.9					
	compliance	h/night	**Tx1**	CPAP	2 weeks	17			6.78	0.38				0.8		
			Tx2	Supplemental oxygen		17			6.56	0.32				1.42		
			Cx	Sham CPAP		16			5.98	0.35						
	Systolic BP		**Tx1**	CPAP	2 weeks	17	155.2	4.5	145.1	5.1	-10.1		0.013	-8.0		
			Tx2	Supplemental oxygen		17	149.5	3.4	144.5	3.6	-5.0			-2.9		
			Cx	Sham CPAP		16	149.0	5.8	146.9	5.3	-2.1					
	Diastolic BP		**Tx1**	CPAP	2 weeks	17	84.2	2.6	79.5	3.2	-4.7		0.026	-4.0		
			Tx2	Supplemental oxygen		17	81.3	1.8	79.9	2.8	-1.4			-0.7		
			Cx	Sham CPAP		16	83.6	3.4	82.9	3.0	-0.7					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Lim, 2007 USA 17694727	Neuropsychological tests	All except the one below	2 weeks	nCPAP	17	Sham CPAP	14	0					
				Supplemental Oxygen	15	Sham CPAP	14	0					
		Digit Vigilance	2 weeks	nCPAP	17	Sham CPAP	14	nCPAP	Net Diff	-15.3			0.02
				Supplemental Oxygen	15	Sham CPAP	14	Sham CPAP	Net Dif	+16.6			

These scores were from raw data. This study also presented T-scores adjusted for age, race, sex & education. * If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
nd		

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	Yes	Yes	Yes	Yes	nd	Yes	NA	NA	Yes

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	Yes	No	Yes	Yes	Yes	Yes	NA	NA

Reasons for drop-outs:	nd
Other Issues:	No power calculation
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Monasterio, 2001			**Intervention 1**	CPAP + conservative therapy
PMID*	11587974	**RefID**	4588	**Intervention 2**	
Key Question(s)	5 (CPAP v Cx)			**Intervention 3**	
Design †	RCT			**Control**	Conservative therapy
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
-Suspicion of mild SAHS (AHA: 10-20) - absence of severe daytime sleepiness (ASDA criteria)	-apnea index > 20 -hazardous jobs (drivers or those who handle dangerous machinery) -notable CVD -conditions that may affect cognitive or QoL evaluation: severe neurological or psychiatric disease, severe chronic disease, or illiteracy	>10	nd	Yes (6)	Spain	Government	Yes (ESS) 75/group	no	Yes (cognitive function, also implied QoL, sleepiness scales) No (AHI, implied) (statisticians also blinded)
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**77(66)**	81	53	nd	29.4	126/81	nd	nd
Cx	**65(59)**	91	54	nd	29.5	132/84	nd	nd
Total	**142(125)**	86	54	nd	29		nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd		nd	nd	no
Cx	nd	nd	nd	nd		nd	nd	no
Total	nd	nd	nd	nd	See Results	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx	nd							
Cx	nd							
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	66	20±6	12.1±4.9	10±5		nd	new	nd
Control:	59	21±6	13.2±4.3	11±5		nd	new	nd
Total:	125	20±6	12.6±4.6		nd	nd	new	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		nd

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	10-20	nd	ASDA criteria 1994		no	Separate nights	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP and conservative measures	nd	nd
2				
3				
Control		Conservative therapy		Weight loss if BMI > 27; avoidance of sedatives and alcohol; avoidance of supine position; and adequate hours of sleep.
For CPAP:		**How was the Pressure selected?**	separate PSG	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	At titration PSG

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	BP	Systolic BP	3, 6 mo	
2	BP	Diastolic BP	3, 6 mo	
3	Miscellaneous	SAHS-related symptoms questionnaire (shortened)	3, 6 mo	8 items: Snoring, Breathing pauses, Nocturia, Choking, Morning headache, Nonrestorative sleep, Morning drowsiness, Concentration difficulties. Score 8 (absence) – 32 (max) Ballester 1999; Montserrat 2001
4	Sleepiness measures	Epworth Sleepiness Scale	3, 6 mo	
5	Sleepiness measures	Multiple Sleep Latency Test	6 mo	Sub-group analysis only
6	QoL	Nottingham Health profile questionnaire	3, 6 mo	Hunt 1981
7	QoL	Functional Outcomes Sleep Questionnaire	3,6 mo	
8	Sleep study	AHI	6 mo	
9	Cognitive scale	Attention - Digit symbol (WAIS) SS	3, 6 mo	Wechsler 1976
10	Cognitive scale	Attention - Digits forward and backward (WAIS) SS	3,6 mo	
11	Cognitive scale	Attention - Mental control (WMS) p	3, 6 mo	Wechsler 1974
12	Cognitive scale	Memory - Verbal paired associated (WMS) p	3,6 mo	
13	Cognitive scale	Memory - Visual memory (WMS), SS	3, 6 mo	
14	Cognitive scale	Executive function - Verbal fluency, p	3,6 mo	Pena-Casanova 1990; Lezack 1995
15	Cognitive scale	Executive function - Block design (WAIS), SS	3, 6 mo	
16	Cognitive scale	Executive function - TMT A, s	3,6 mo	
17	Cognitive scale	Executive function - TMT B, s	3, 6 mo	
18	Cognitive scale	Executive function - PASAT 4-s, correct	3,6 mo	
19	Cognitive scale	Executive function - PASAT 3-s , correct	3, 6 mo	
20	Cognitive scale	Executive function - PASAT 2-s, correct	3,6 mo	
21	Cognitive scale	Executive function - PASAT 1-s, correct	3, 6 mo	
22	Cognitive scale	Vigilance - Steer-clear, % hits	3,6 mo	Findley 1989 Will need to track down definitions
23	CPAP pressure & Compliance		6 mo	
24	Side effects		6 mo	nd

p = percentile; PASAT = paced auditory serial addition test (reduced version with 20 items for each condition); ss = scaled scores (mean 10, SD 3); TMT = trail-making test; WAIS = Wechsler Adults Intelligence Scale; WMS = Wechsler Memory Scale.

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Monasterio, 2001 Spain 11587974	Compliance, >4 h/night	**Tx**	CPAP	6 mo	42	66	%	64%						
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Monasterio, 2001 Spain 11587974	SAHS related symptoms	Score	**Tx**	CPAP + conservative therapy	6 mo	66	21	4	14	5	-7			-5		<0.001
			Cx	conservative therapy		59	21	3	19	4	-2					
	Epworth Sleepiness Scale	Score	**Tx**	CPAP + conservative therapy	6 mo	66	12.1	4.9	9.6	5.5	-2.5			-1.1		NS
			Cx	conservative therapy		59	13.2	4.3	11.8	5.2	-1.4					
	FOSQ	Score	**Tx**	CPAP + conservative therapy	6 mo	66	101	18	106	20	5			3		NS
			Cx	conservative therapy		59	100	15	102	21	2					
	NHP	Score	**Tx**	CPAP + conservative therapy	6 mo	66	21	20	15	18	-6			-1		NS
			Cx	conservative therapy		59	20	16	15	15	-5					
	AHI	Events/night	**Tx**	CPAP + conservative therapy	6 mo	66	20	6	6	8	-14			-11		<0.001
			Cx	conservative therapy		59	21	6	17	10	-4					
	Systolic BP	mm Hg	**Tx**	CPAP + conservative therapy	6 mo	66	126	17	122	22	-4			-2		NS
			Cx	conservative therapy		59	132	17	130	16	-2					
	Diastolic BP	mm Hg	**Tx**	CPAP + conservative therapy	6 mo	66	81	12	80	10	-1			-1		NS
			Cx	conservative therapy		59	84	11	84	11	0					

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
	Attention - Digit symbol (WAIS) SS	Units on a scale	**Tx**	CPAP + conservative therapy	6 mo	66	9	3	9	3	0			0		NS
			Cx	conservative therapy		59	9	3	9	2	0					
	Attention - Digits forward and backward (WAIS) SS	Units on a scale	**Tx**	CPAP + conservative therapy	6 mo	66	10	2	11	3	1			0		NS
			Cx	conservative therapy		59	10	3	11	2	1					
	Attention - Mental control (WMS) p	Units on a scale	**Tx**	CPAP + conservative therapy	6 mo	66	48	27	51	27	3			-5		NS
			Cx	conservative therapy		59	45	28	53	27	8					
	Memory - Verbal paired associated (WMS) p	Units on a scale	**Tx**	CPAP + conservative therapy	6 mo	66	30	26	41	30	11			-1		NS
			Cx	conservative therapy		59	31	27	43	32	12					
	Memory - Visual memory (WMS), SS	Units on a scale	**Tx**	CPAP + conservative therapy	6 mo	66	50	27	61	24	11			6		NS
			Cx	conservative therapy		59	58	23	63	25	5					
	Executive function - Verbal fluency, p	Units on a scale	**Tx**	CPAP + conservative therapy	6 mo	66	69	29	69	27	0			-4		NS
			Cx	conservative therapy		59	66	28	70	29	4					
	Executive function - Block design (WAIS), SS	Units on a scale	**Tx**	CPAP + conservative therapy	6 mo	66	10	3	11	3	1			0		NS

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
			Cx	conservative therapy		59	10	3	11	3	1					
	Executive function - TMT A, s	Units on a scale	**Tx**	CPAP + conservative therapy	6 mo	66	56	26	49	19	-7			-2		NS
			Cx	conservative therapy		59	54	18	49	20	-5					
	Executive function - TMT B, s	Units on a scale	**Tx**	CPAP + conservative therapy	6 mo	66	121	44	106	42	-15			10		NS
			Cx	conservative therapy		59	125	47	100	39	-25					
	Executive function - PASAT 4-s, correct	Units on a scale	**Tx**	CPAP + conservative therapy	6 mo	66	13	5	14	4	1			-2		NS
			Cx	conservative therapy		59	13	4	16	4	3					
	Executive function - PASAT 3-s , correct	Units on a scale	**Tx**	CPAP + conservative therapy	6 mo	66	14	5	15	4	1			-1		NS
			Cx	conservative therapy		59	13	5	15	4	2					
	Executive function - PASAT 2-s, correct	Units on a scale	**Tx**	CPAP + conservative therapy	6 mo	66	10	4	12	4	2			0		NS
			Cx	conservative therapy		59	10	5	12	4	2					
	Executive function - PASAT 1-s, correct	Units on a scale	**Tx**	CPAP + conservative therapy	6 mo	66	4	3	5	4	1			0		NS
			Cx	conservative therapy		59	4	3	5	3	1					

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
	Vigilance - Steer-clear, % hits	Units on a scale	**Tx**	CPAP + conservative therapy	6 mo	66	10	8	8	9	-2			0		NS
			Cx	conservative therapy		59	10	3	8	10	-2					
	Compliance	Units on a scale	**Tx**	CPAP + conservative therapy	6 mo	60 (on treatment) [66 ITT]	--		4.8 [3.7]	nd						
			Cx	conservative therapy			--		--							

This study also reported results at 3 months which were not extracted here.

p = percentile; PASAT = paced auditory serial addition test (reduced version with 20 items for each condition); ss = scaled scores (mean 10, SD 3); TMT = trail-making test; WAIS = Wechsler Adults Intelligence Scale; WMS = Wechsler Memory Scale.

* Delete or correct the incorrect value/item. If change, highlight yellow.

** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP + conservative therapy	14	Withdrew early and dropped from analysis
conservative therapy	9	same

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Subset of 40	Monasterio, 2001 Spain 11587974	MSLT		Tx	CPAP + conservative therapy	6 mo	40	10	5	10	5	0			0		
				Cx	conservative therapy			11	5	11	5	0					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	No data on how this subgroup was formed.

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
Monasterio, 2001 Spain 11587974	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
yes	yes	nd	yes	nd	yes (except maybe AHI)	Claim yes, but excluded 17 (12%) who withdrew early	yes	no	NA	yes

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	yes	Possibly, since did not analyze uneven number of dropouts	No. nd CPAP type or machine	No (but references given)	Yes	yes		

Reasons for drop-outs:	nd (abandoned study)
Other Issues:	Did not enroll enough to meet power calculations
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments
Power calculation required 150 (75 & 75) patients. Successfully enrolled only 142 (65 & 77). 17 more withdrew early and excluded so analyzed 125 (59 & 66)

A.

Author, Year	Montserrat, 2001			**Intervention 1**	CPAP
PMID*	11520724	**RefID**	4590	**Intervention 2**	
Key Question(s)	KQ 5 (CPAP vs. CX)			**Intervention 3**	
Design †	RCT			**Control**	Sham CPAP
Extractor	RB			**Comments**	First half of one-way cross over trial

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Excessive daytime somnolence; AHI >10	Severe/unstable cardiovascular dis	>10	nd	No	Spain	Gov	Yes 48 (ESS)	Yes	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**24 (23)**		55.65±9.4		30.31±4.49			
Cx	**24 (22)**		52.59±10.9		33.73±6.62			
Total	**48 (45)**	91	54.2±10.2	nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx		47.8 (39.1)						
Cx		54.5 (9.1)						
Total	nd	(former smoker)	nd	nd			nd	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	None							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	23	50.52±19.83	16.13±1.03					
Control:	22	57.14±21.14	16.86±1.20					
Total:	45	53.8±19.3		nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>10		Airflow cessation ≥10s	Airflow reduction with cyclical Sao2 dip ≥3%		Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Breas PV100 (Breas, Sweeden)	
2				
3				
Control	Placebo	Sham CPAP	Breas PV100 (Breas, Sweeden)	
For CPAP:		**How was the Pressure selected?**	Manual	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
Diet & sleep hygiene	Sufficient sleep, sleep on side, avoid sedatives & alcohol; wt loss prog- home diet	
For CPAP:	**Describe the frequency of the initial education follow-up**	Written info & weekly calls

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	ESS	6 weeks	
2	QoL	FOSQ	6 weeks	
3	QoL	SF-36	6 weeks	
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SD/SE*	P
Montserrat, 2001 Spain 11520724	ESS	Score	Tx	CPAP	6 weeks	23	16.13	1.03	6.65	0.68	-9.48		0	-7.21		<0.001
			Cx	Sham CPAP		22	16.86	1.20	14.59	1.08	-2.27		0.013			
	FOSQ	Score	Tx	CPAP	6 weeks	23	84.45	4.63	109.43	2.63	24.98		0	+10.48		0.124
			Cx	Sham CPAP		22	86.16	5.96	100.66	4.39	14.50		0.008			
	SF-36 physical component summary	Score	Tx	CPAP	6 weeks	23	46.53	1.92	50.71	1.58	4.18		0.002	+2.56		0.230
			Cx	Sham CPAP		22	45.54	2.17	47.16	1.87	1.62		0.364			
	SF-36 mental component summary	Score	Tx	CPAP	6 weeks	23	48.21	2.06	49.53	2.44	1.32		0.606	-3.60		0.518
			Cx	Sham CPAP		22	48.73	2.49	53.65	1.57	4.92		0.006			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	1 (4%)	
Sham CPAP	2 (8%)	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	NA	NA	Yes

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	Yes	No	Yes	Yes	No	Yes	NA	NA

Reasons for drop-outs:	Not defined
Other Issues:	Needed sample size 48 but had only 45
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Norman, 2006			**Intervention 1**	CPAP
PMID*	16585412	**RefID**	3657	**Intervention 2**	Sham CPAP with supplemental oxygen
Key Question(s)	KQ 5 (CPAP vs Cx)			**Intervention 3**	
Design †	RCT			**Control**	Sham CPAP
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
25-65 yrs; 100-170% of ideal body weight; AHI >15	Any major illness; previous CPAP or surgery for OSA; BP >170/105	>15	nd	No	USA	Gov	nd	Yes	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y, SE**	**Race**	**BMI* SE**	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx 1	**18**	15 (83%)	49.7±2.5	W:61%; B:11%; H:11%: A:11%; O:6%	31.5±1.4			
Tx 2	**13**	9 (69%)	44.2±2.4	W:62%; B:23%; H:8%: A:8%; O:0%	29.5±1.3			
Cx	**15**	13 (87%)	49.3±2.7	W:67%; B:7%; H:13%: A:0%; O:13%	29.9±1.3			
Total	**46**						Implies 0%	Implies 0%
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx 1								
Tx 2								
Cx								
Total	Implies 0%	nd	0%	nd			nd	
	Treatments used (prior to trial, including surgery)							
Tx 1	None							
Tx 2	None							
Cx	None							
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth* SE	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment 1:	18	66.1±29.1	12.0±1.3					
Treatment 2:	13	60.7±29.6	12.2±1.5					
Control:	15	53.9±29.8	12.0±1.7					
Total:	46			nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>15		Decrements in airflow ≥90% for ≥10s	Decrements in airflow ≥50% but <50% for ≥10s		Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Aria LX, Respironics	+ room air
2		Supplemental oxygen	Aria LX, Respironics	3L/min
3				
Control	Placebo	Sham CPAP	Aria LX, Respironics	0-0.5cm H2O +room air
For CPAP:		**How was the Pressure selected?**	Manual titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	instructions and then telephone calls & home visits

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance		2 weeks	
2	BP		2 weeks	
3	Sleep quality	AHI	2 weeks	
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SE*	P	Value	SD/SE*	P
Norman, 2006 USA 16585412	Daytime mean BP	mm Hg	**Tx1**	CPAP	2 weeks	18					-3.1	1.3	<0.05	-6.4		
			Tx2	Supplemental oxygen		13					0.9	1.3		-2.4		
			Cx	Sham CPAP		15					3.3	2.0				
	Daytime Systolic BP	mm Hg	**Tx1**	CPAP	2 weeks	18					-2.2	1.3		-5.7		
			Tx2	Supplemental oxygen		13					0.6	1.3		-2.9		
			Cx	Sham CPAP		15					3.5	2.5				
	Daytime Diastolic BP	mm Hg	**Tx1**	CPAP	2 weeks	18					-2.6	1.1	<0.05	-5.2		
			Tx2	Supplemental oxygen		13					0.4	1.3		-2.2		
			Cx	Sham CPAP		15					2.6	1.8				
	AHI	Events/hr	**Tx1**	CPAP	2 weeks	18	66.1	29.1	3.4	3.0	-62.7		<0.05	-58.9		<0.05
			Tx2	Supplemental oxygen		13	60.7	29.6	43.6	32.8	-17.1		<0.05	-13.3		
			Cx	Sham CPAP		15	53.9	29.8	50.1	32.1	-3.8					
	compliance	h/night	**Tx1**	CPAP	2 weeks	18			6.7	1.2						
			Tx2	Supplemental oxygen		13			6.5	1.2						
			Cx	Sham CPAP		15			6.0	2.4						

*BP values are approximated from the graph using digitizer.
Net diff is diff bet Tx and Cx.
Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
nd		

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	nd	No	Yes	nd	Yes	Yes	NA	NA	Yes

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	Yes	No	Yes	Yes	Yes	Yes	NA	NA

Reasons for drop-outs:	nd
Other Issues:	No power calculation
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Redline, 1998			**Intervention 1**	nCPAP
PMID*	9517603	**RefID**	5754	**Intervention 2**	
Key Question(s)	KQ 5 (CPAP vs. Cx)			**Intervention 3**	
Design †	RCT			**Control**	Conservative Therapy (CT)
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
25-65 yrs; RDI 5-30;	Pathologic sleepiness; narcolepsy, insomnia, hypnotic use, sleep insufficiency, h/o periodic leg movements; severe/ unstable MI, CHF, uncontrolled DM, thyroid dis, cirrhosis, recently diagnosed cancer, H/o stroke, seizure, head trauma with >6hr loss of consciousness or memory impairment, alcohol/ drug abuse, regular use of meds that impair sensorium, <8 yrs of schooling	RDI < 30		No	USA	Gov	Yes Total sample size- 112 (treatment response)	No	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**59 (51)**	41%	48.1±9.2	European Americans- 59%	33.4±6.9			
Cx	**52 (46)**	56%	49.2±10.5	European Americans- 65%	32.0±8.5			
Total	**114 (97) 3 refused randomization**	52%	48±9.8	European Americans- 62%			0	0
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	0	nd	0	0				
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	51	14.6±9.8	10.4±4.3	9.9±4.8				
Control:	46	11.8±9.6	10.6±5.6	10.3±5.0				
Total:	97				nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

RDI: Respiratory Disturbance Index, events/h * Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	5-30		Respiratory Disturbance (apnea/ hypopnea): discernable change in air flow or chest movement, lasting > 10s and occurring in association with at least 2.5% decrease in SaO2 or an arousal.			Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	nCPAP	Puritan Bennett, Lenexa, KS or Tranquility Quest, Health Dyne, Marietta, GA	
2				
3				
Control	Placebo	Conservative Therapy (CT)	Breathe-Right mechanical nasal dilators	
For CPAP:		**How was the Pressure selected?**	Manual Titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
Counseling	Sleep posture; sleep hygiene	
Dietitian referral	BMI >29, weight reduction counseling	
Nasal steroid spray	Subjects with symptoms of nasal congestion (Becanase nasal spray)	
For CPAP:	**Describe the frequency of the initial education follow-up**	Phone calls every 2 weeks

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep quality	AHI	10 weeks	
2	Sleepiness measures	ESS	10 weeks	
3	Sleepiness measures	MSLT	10 weeks	
4	Compliance		10 weeks	CPAP usage for % of estimated sleep time

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	SD	P btw	Result	95% CI	P btw	Adjusted for:
Redline, 1998 USA 9517603	Compliance	**Tx**	nCPAP	10 weeks			%	44	34					
		Cx	CT					82	26					

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value	SD/SE*	P
Redline, 1998 USA 9517603	RDI	Events/h	**Tx**	nCPAP	10 weeks	51	14.6	9.8	4.7	7.2	-8.4	9.2	<0.05	-4.7		<0.05
			Cx	CT		46	11.8	9.6	9.8	9.3	-3.7	7.1				
	ESS	Score	**Tx**	nCPAP	10 weeks	51	10.4	4.3			-1.48	4.13	<0.05	-1.09		
			Cx	CT		46	10.6	5.6			-0.39	2.95				
	MSLT		**Tx**	nCPAP	10 weeks	51	9.9	4.8			0.46	5.4		0.39		
			Cx	CT		46	10.3	5.0			0.07	5.3				
	Sleep -% of stage 3/4		**Tx**	nCPAP	10 weeks	51			15.75							
			Cx	CT		46			20.16							
	Sleep -% of stage REM		**Tx**	nCPAP	10 weeks	51			15.79							
			Cx	CT		46			13.95							

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
nCPAP	8/59 (14%)	Problems using CPAP-3; Inability to schedule all day testing battery- 5
CT	6/46 (13%)	Inability to schedule all day testing battery- 6
		Refused randomization- 3

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
Redline, 1998 USA 9517603	Skin irritation on CPAP mask use		nCPAP -2			
	Minor nose bleed related to use of nasal steroid spray		nCPAP -1	CT -2		
	Antibiotic usage		nCPAP -7	CT -2		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	No	Yes	No	Yes	No	Yes	NA	NA	Yes

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	Yes	No	Yes	Yes	Yes	Yes	NA	NA

Reasons for drop-outs:	
Other Issues:	Power calculation: needed sample size -112; analyzed- 97
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Robinson, 2006			**Intervention 1**	AutoCPAP
PMID*	16455835	**RefID**	3744	**Intervention 2**	
Key Question(s)	KQ 5 (CPAP v Cx)			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	Sham CPAP
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
> 18yrs, proven OSA with >10 dips in SaO2 of >4%/h and no daytime hypersomnolence, with ESS <10. On anti HTN drugs/ BP>140/90	Respi failure, decline to participate, inability to consent.	>10 dips in SaO2 of >4%/h	nd	No	UK	British Heart Foundation	Yes (24-h BP) 30 to cross over with at least 26 after dropouts	Yes	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**35(32)**	31/35 (89%)	54±8	nd	33.2±5.3	100% >140/90	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								HTN pts with significant
Cx								OSA, but without sufficient
Total	nd	nd	nd	nd	nd	nd	nd	Daytime hypersomnolence
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:			IQR					
Total:	32	nd	5.3(3.0-7.0)		nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG				No. of dips in SaO2 of >4% every hr		split	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	Auto-titrating CPAP	Autoset Spirit, UK	
2				
3				
Control	Placebo	Sham CPAP	Autoset Spirit, UK	CPAP pressure <1 cm H2O
For CPAP:		**How was the Pressure selected?**	Automatic titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	Advice and support given through out the study

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	BP	BP (sys, dia, mean arterial)	1 month	
2	Sleepiness	ESS	1 month	
3	Compliance		1 month	
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD *	Value	SD/SE*	P	Value	SD/SE*	P
Robinson, 2006 UK 16455835	awake BP	mm Hg	Tx	CPAP	1 month	32	106.1	13.6	105.6	13.2	-0.5			Median +1.1	95% CI -2.9, +5.1	0.61
			Cx	Sham CPAP		32	108.8	13.0	107.6	13.6	-1.2					
	compliance	h/night	Tx	CPAP	1 month	32			5.2	2.1						
			Cx	Sham CPAP		32			4.3	2.4						
	ESS	score	Tx	CPAP	1 month	32					-1.4			-1.1	-2.03, -0.17	<0.02
			Cx	Sham CPAP		32					-0.3					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	3/35 (9%)	Intolerant of BP cuff-2; Inadequate BP data-1

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	95% CI*	P
>4% SaO2 dip rate of ≤28.1	Robinson, 2006 UK 16455835	24-h BP	mm Hg	**Tx**	CPAP	1 month						-3.3			-3.8	-9.6, +2.0	
				Cx	Sham CPAP							+0.5					
>4% SaO2 dip rate of >28.1	Robinson, 2006 UK 16455835	24-h BP	mm Hg	**Tx**	CPAP	1 month						-0.8			+1.5	+8.4, -5.4	
				Cx	Sham CPAP							+2.9					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	Yes	Yes	Yes	Yes	nd	Yes	NA	NA	Yes
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Yes	No	Yes	Yes	Yes	Yes	NA			Yes
Reasons for drop-outs:	Intolerant of BP cuff-2; Inadequate BP data-1									
Other Issues:										
Overall Quality (A, B, C)	**A**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Siccolli, 2008			**Intervention 1**	Auto PAP
PMID*	19014075	**RefID**	3808	**Intervention 2**	
Key Question(s)	5(CPAP)			**Intervention 3**	
Design †	RCT			**Control**	ShamCPAP
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Males 20-75yrs ESS≥ 10 OSA ODI >10/hr	Respiratory failure Driving or job related issues	nd	nd	n	UK		nd	y	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**51(50)**		48.1(9.5)		35.8(7.3)			
Cx	**51(49)**		48.7(10.6)		34.5(5.0)			
Total	**102(99)**	100		nd		**nd**	**nd**	**nd**
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	**nd**	**nd**	**nd**	**nd**	**nd**	**nd**	**nd**	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	50		15.8(4.0)					
Control:	49		15.2(4.0)					
Total:	99	nd		nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd		≥4%			separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	nCPAP	Resmed	
2				
3				
Control	Placebo	Sham CPAP		Patients used the same machine as the intervention group, but pressure were delivered at <1cm H2O
For CPAP:		**How was the Pressure selected?**	auto	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	QOL	SF 36 PCS	4 weeks	
2	QOL	SF 36 MCS	4 weeks	
3	QOL	SQALI total	4 weeks	
4	ESS			

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference*		
							Value	SD	Value	SD	Value	SD	P	Value	SD/SE*	P (based on diff in std effect sizes)
Siccoli, 2008 19014075 UK	SF 36 PCS		Tx	CPAP	4 weeks	50	62.0	20.0	70.8	18.5			<0.0001			0.01
			Cx	Sham CPAP	4 weeks	49	69.4	21.5	70.08	18.8			0.68			
	SF 36 MCS		Tx	CPAP	4 weeks	50	62.2	20.2	76.8	16.2			<0.0001			0.002
			Cx	Sham CPAP	4 weeks	49	64.8	21.2	68.6	22.7			0.17			
	SAQLI total		Tx	CPAP	4 weeks	50	3.5	1.0	4.4	1.1			<0.0001			0.001
			Cx	Sham CPAP	4 weeks	49	3.8	1.1	3.8	1.6			0.65			
	ESS		Tx	CPAP	4 weeks	50	15.8	4.0	6.8	5.1			0.001			<0.0001
			Cx	Sham CPAP	4 weeks	49	15	4.0	11.9	5.9			<0.0001			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	y	y	n	y	na	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	n	y	na	na
Reasons for drop-outs:								
Other Issues:								
Overall Quality (A, B, C)		**B**						

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Smith 2007			**Intervention 1**	autoCPAP
PMID*	17470670	**RefID**	3828	**Intervention 2**	
Key Question(s)	5 (CPAP)			**Intervention 3**	
Design †	Cross over			**Control**	Sham CPAP
Extractor	NO			**Comments**	**Some patients with central sleep apnea included in analysis**

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Symptomatic CHF patients NYHA class 11-IV 18-80yrs LVEF echocardiograph <45% Clinical stability for at least one month Optimal medical therapy AHI>15/hr	Acute coronary syndrome in preceding 3 months Primary valvular heart disease Sustained ventricular arrhythmias (not atrial fibrillation) Stroke with residual neurological deficit	>=15/hr	nd	y	UK	nd	Y(6 min walk distance)	y	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**26(23)**	88	61(8)	nd	31(4)	42 % (nd on definition of HTN)	31%	100
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	27%	69% (smoking history)	nd	nd	nd	nd	nd	Y(CHF patients)
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	23	36(23)	10(5)	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>=15/hr		>=10secs	Reduction in airflow or thoracoabdominal movement >=50%		split	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Autoset Spirit:ResMed	
2				
3				
Control	Placebo	Sham CPAP		Delivered airway pressure was set to a minimum by use of flow restricting connectors at machine outlet and creating an extra hole in the mask
For CPAP:		**How was the Pressure selected?**	Auto titrated	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
	All patients underwent initial daytime education sessions on use of device	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	QOL	SF-36 physical	6 weeks	Probably physical component summary
2	QOL	SR- 36 mental	6 weeks	Probably mental component summary
3	Sleepiness measure	ESS	6 weeks	
4	Sleepiness measure	OSLER	6 weeks	Oxford SLEep Resistance test

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ		
							Value	SD*	Value	SD*	Value	SD*	P	Value	95% CI	P
Smith 2007 UK 17470670	SF-36 physical component summary		Tx	CPAP	6 weeks	23	34	16	34	14	0			-1	-3.6 to1.6	0.43
			Cx	Sham CPAP	6 weeks	23	34	16	35	14	1					
	SF- 36 mental component summary		Tx	CPAP	6 weeks	23	51	10	49	12	-2			-0.5	-4.2 to 3.2	0.79
			Cx	Sham CPAP	6 weeks	23	51	10	50	11	-1					
	ESS		Tx	CPAP	6 weeks	23	10	5	7	4	-3			-1	-1.9 to 0.0	0.04
			Cx	Sham CPAP	6 weeks	23	10	5	8	5	-2					
	OSLER	min	Tx	CPAP	6 weeks	23	27	15	30	14	+3			0.7	-2.2 to 3.6	0.63
			Cx	Sham CPAP	6 weeks	23	27	15	29	13	+2					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Both arms	2/26	Personal reasons
	1/26	Mask claustrophobia

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	y	y	y	y	n	y	n	y	y
	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?			If a Crossover study, was the Washout period adequate?
	y	n	y	y	y	y	y			y
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)	A									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments: Some patients with central sleep apnea included in analysis

A.

Author, Year	Spicuzza, 2006			**Intervention 1**	nCPAP
PMID*	16963674	**RefID**	3832	**Intervention 2**	
Key Question(s)	KQ5 (nCPAP vs Cx)			**Intervention 3**	
Design †	RCT			**Control**	Sham nCPAP
Extractor	RB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Mod-severe OSA	HTN, DM, CVD, COPD, respi failure, thyroid disorders, smoking	>5	nd	No	Italy	nd	No	Yes	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**15**	80	55.9±9.4		31.1±4.2	0	0	0
Cx	**10**	80	55.1±9.3		33.5±5.5	0	0	0
Total	**25**	80		nd		0	0	0
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	0	0					0	
Cx	0	0					0	
Total	0	0	nd	nd	nd	nd	0	
	Treatments used (prior to trial, including surgery)							
Tx	None							
Cx	None							
Total	None							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	15	55.3±11.9						
Control:	10	59.2±17.3						
Total:	25		nd	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>5		Airflow cessation >10s	Reduction of ≥ 50% in airflow for >10s associated with decrease in SaO2 ≥4%		Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	nCPAP	nd	nasal
2				
3				
Control	Placebo	Sham nCPAP		CPAP pressure 1-2 cm H2O
For CPAP:		**How was the Pressure selected?**	1 night PSG titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
none		
For CPAP:	**Describe the frequency of the initial education follow-up**	nd

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	h/night	1 month	
2	AHI		1 month	
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Spicuzza, 2006 Italy 16963674	Compliance	h/night	Tx	nCPAP	1month	15			6.0	1.1						
			Cx	Sham nCPAP		10			6.5	2.4						
	AHI		Tx	nCPAP	1month	15	55.3	11.9	2.1	0.3	-53.2			-51.0		
			Cx	Sham nCPAP		10	59.2	17.3	57.0	8.6	-2.2					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
	nd	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	nd	Yes	Yes	Yes	nd	Yes	NA	NA	Yes
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	No	No	No	Yes	Yes	Yes	NA			NA
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	West,2007			**Intervention 1**	autoCPAP
PMID*	17557769	**RefID**	3958	**Intervention 2**	
Key Question(s)	5 (CPAP)			**Intervention 3**	
Design †	RCT			**Control**	Sham CPAP
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Men aged 18-75yrs Established type 2 DM ESS>9 OSA: >10 oxygen saturation dips of >4% per hour on an overnight sleep study	Urgent CPAP Unstable Dm		2004-2005	n	UK		Y (HbA1c)	y	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**20(19)**	100	57.8(10.4)		36.6(4.9)	nd	nd	nd
Cx	**22(21)**	100	54.5(9.4)		39.1(24.8)	nd	nd	nd
Total	**42(40)**	100				nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify) HbA1c**	**Is this a Special Population? (which?)**
Tx	100	nd	nd	nd	nd	nd	8.5(1.8)	Y (Diabetes mellitus)
Cx	100	nd	nd	nd	nd	nd	8.4(1.9)	
Total	100	nd	nd	nd	nd	nd		
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	Patients were counseled not to change diet, exercise habits or medication during study							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	19		14.7(3.5)	nd	nd	nd	nd	nd
Control:	21		13.6(3.5)	nd	nd	nd	nd	nd
Total:	40	nd		nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG			4% decline in O_2 saturation			same	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Autoset Spirit, Resmed	
2				
3				
Control	Placebo	Sham CPAP		Had the same machine set to lowest pressure, delivering a flow <1 and >0 cmH_20
For CPAP:		**How was the Pressure selected?**	Autotitrating machines	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measure	ESS	3months	
2	Sleepiness measure	MWT	3months	Modification of maintenance of wakefulness test- OSLER
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ		
							Value	SD	Value	SD/SE*	Value	SD	P	95% CI		P
West, 2007 UK 17557769	ESS		**Tx**	CPAP	3months	19	14.7	3.5			-6.6	4.5		-7.0	-0.9	0.01
			Cx	Sham CPAP	3months	21	13.6	3.5			-2.6	4.9				
	MWT		**Tx**	CPAP	3months	19	21.9	12.8			+10.6	13.9		+6.5	+23.9	0.001
			Cx	Sham CPAP	3months	21	32.0	10.8			-4.7	11.8				

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	There was no significant difference in any of the baseline data between the groups (p = 0.3–0.9) except for MWT (p<0.01)

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Sham CPAP	1/22	Unwilling to use CPAP
Sham CPAP	1/22	Machine fault
CPAP	1/21	Machine fault

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis y(y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	y	y	Y	y	na	y	Y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	y	y	na			na
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)	**A**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Question 5
PAP v PAP

A.

Author, Year	Anderson, 2003			**Intervention 1**	Oral CPAP
PMID*	14572126	**RefID**	4024	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Crossover			**Control**	nasal CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; ; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
≥2 symptoms of OSA and AHI >20 and ESS >12	previous CPAP for OSA; concurrent COPD or sleep disorders; claustrophobia, gum or mouth disease, could not communicate in English, no home phone	>20	nd	no	New Zealand	industry	? post hoc 25 per arm	yes	yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**25 (21)**	nd	46	nd	43±8			
Cx	**25 (21)**	nd	46	nd	43±8			
Total	**25 (21)**	nd	46	nd	43±8	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no, but note the BMI
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	no previous CPAP							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	21	85 (95%CI 69-100)	17 (95%CI 16-18)	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	total number of resp events per h		no flow ≥10 s	↓ ≥50% amplitude of a valid measure of breathing ≥10 s or ≥3% O2 desat or arousal		both	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	oral CPAP	Oracle (Fisher & Paykel)	minimum pressure to eliminate all upper airway obstrcution
2				
3				
Control	PAP	nasal CPAP	Aclaim (Fisher & Paykel) or Sullivan Modular, Mirage or Ultra Mirage (ResMed)	minimum pressure to eliminate all upper airway obstruction
For CPAP:		**How was the Pressure selected?**	manual titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	AHI, min O2, REM	baseline, 4 wk	
2	Sleepiness measures	Epworth, arousal index	baseline, 4 wk	
3	Compliance	h per night		
4				

* QoL; ; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; ; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	95%CI*	Value	95%CI*	Value	SD/SE*	P	Value	95%CI*	P
Anderson, 2003 New Zealand 14572126	AHI		**Tx**	oral CPAP	4 wk	21	85	69-100	16	10-22				+4.6	-1 to 10.1	0.06
			Cx	nasal CPAP	4 wk	21	85	69-100	11	5-18						
Anderson, 2003 New Zealand 14572126	Epworth		**Tx**	oral CPAP	4 wk	21	17	16-18	7	5-9				0.7	-1.7 to 3.1	0.20
			Cx	nasal CPAP	4 wk	21	17	16-18	6	4-8						
Anderson, 2003 New Zealand 14572126	arousal index	events per h	**Tx**	oral CPAP	4 wk	21	69	55-83	15	11-19				3	-1.8 to 7.8	0.23
			Cx	nasal CPAP	4 wk	21	69	55-83	12	8-16						
Anderson, 2003 New Zealand 14572126	minimum O2	%	**Tx**	oral CPAP	4 wk	21	70	65-75	86	82-89				-1.3	-5.6 to 3	0.64
			Cx	nasal CPAP	4 wk	21	70	65-75	87	84-90						
Anderson, 2003 New Zealand 14572126	REM	%	**Tx**	oral CPAP	4 wk	21	10	6-14	26	21-31				4.1	-1.5 to 9.8	0.16
			Cx	nasal CPAP	4 wk	21	10	6-14	22	17-27						
Anderson, 2003 New Zealand 14572126	Compliance	h per night	**Tx**	oral CPAP	4 wk	21	NA		3.5					-0.3	-1.1 to 0.5	0.5
			Cx	nasal CPAP	4 wk	21	NA		3.8							

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	95%CI*	Value	95%CI*	Value	SD/SE*	P	Value	95%CI*	P
Anderson, 2003 New Zealand 14572126	sleep efficiency	%	**Tx**	oral CPAP	4 wk	21	82	78-86	93	91-96	11			1# (reported 11.7 [-5.9 to 2.6]?error)		0.85
			Cx	nasal CPAP	4 wk	21	82	78-86	92	87-96	10					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
nasal CPAP	8%	1 refused CPAP; 1 did not tolerate nasal mask
oral CPAP	8%	1 did not tolerate oral mask, 1 had no compliance data

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			oral CPAP	nasal CPAP		
Anderson, 2003 New Zealand 14572126	claustrophobia	4 wk	4/21	1/21		
	skin irritation	4 wk	6/21	6/21		
	sore gum/lips	4 wk	11/21	2/21		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	y	y	nd	y	NA	NA	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	n	y	post hoc (?); no	no washout; no carryover effect

Reasons for drop-outs:	
Other Issues:	small sample size
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Ballard, 2007			**Intervention 1**	flexible bilevel PAP
PMID*	18198804	**RefID**	3062	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA with AHI ≥10; <4 h per night of CPAP use; willingness to continue with CPAP from Phase 1 study (implied)	previous bi level PAP Tx; nocturnal O2 suppl; central sleep apnea; upper airway surgery; facial skin disorders, psychiatric disorders, complicated med conditions	≥10	nd	yes	US	industry	yes; 93 in each group	yes	yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**51**	65	51.9		33.4±7.9			
Cx	**53**	72	52.5		32.6±6.3			
Total	**104**	69	52	nd	33	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	self-estimated nightly use of CPAP of <4 h
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	51	40.4±23.4						
Control:	53	44±26.1						
Total:	104	42.2	nd	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	nd	≥10	nd	nd	separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	flexible bilevel PAP	BiPAP Pro (Respironics)	BiFlex mode; exp pressure reduced in 1-2 cm until obstructive apneas recurred, then increased back to minimal pressure eliminating apnea; insp pressure then increased to abort hypopneas, snoring, airflow limitation and O2 desat
2				
3				
Control	PAP	CPAP	BiPAP Pro (Respironics)	CPAP mode
For CPAP:		**How was the Pressure selected?**	manual	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance		1 mo, 3 mo	>4 h of daily use of PAP; mean h daily use
2	QoL	FOSQ		
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Ballard, 2007 US 18198804	Compliance (>4 h daily use)	Tx	flexible bilevel PAP	3 mo	25	51		49%		0.03				
		Cx	CPAP	3 mo	15	53		28%						

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value	SD/SE*	P
Ballard, 2007 US 18198804	compliance	mean h per d	Tx	flexible bilevel PAP	3 mo	51	NA		3.7	2						<0.05
			Cx	CPAP	3 mo	53	NA		2.9	2.3						
Ballard, 2007 US 18198804	FOSQ		Tx	flexible bilevel PAP	3 mo	46	14.22	3.27	15.67	4.12	1.45	4.52	0.0038	1	0.802	0.213 not reported
			Cx	CPAP	3 mo	43	15.31	3.55	15.76	4	0.45	4.42	0.34			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
flexible bilevel PAP	10%	reason not stated; these pts did not have follow up FOSQ
CPAP	19%	reason not stated; these pts did not have follow up FOSQ

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y (?)	y	y	y	y	n	NA	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y		y	n	NA	y				
Reasons for drop-outs:										
Other Issues:	under-powered									
Overall Quality (A, B, C)	**B/C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Dolan, 2009			**Intervention 1**	C-Flex
PMID*	18551327	**RefID**	3235	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
25-66 y/o; stable med/psyc condition with no sig upper respiratory symptoms or anatomical problems; Epworth ≥10; AHI ≥10 by PSG within past 6 mo; successful titration to AHI <5; Tx pressure 7-17 cm H_20; ≥4 h of compliance during a 1 wk trial	previous surgery for OSA or any mouth, nose, sinus, or airway surgery; hypoventilation req'd O_2; acute med/psyc conditions, COPD, asthma and other sleep disorders; known contraindications or intolerance to CPAP; disease that impacts life expectancy; facial skin disorders; hx of positive airway pressure tx; hx of pneumothorax or pneumomediastinum; pregnancy; med or herbs that would potentially interfere with study results	≥5	nd	y	US; Germany	industry	n	y	n
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**? randomized (92)**	76	48.2	nd	35.1±6.9 (SD)	nd	nd	nd
Cx	**? randomized (92)**	74	47.7	nd	34.8±7.1 (SD)	nd	nd	nd
Total	**184**	75	48	nd	34.9	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	nd	nd	nd	
Cx	nd	nd	nd	nd	nd	nd	nd	
Total	nd	nd	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx	nd							
Cx	nd							
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	92	nd	15±3.5	nd	nd	nd	nd	
Control:	92	nd	14.8±3.7	nd	nd	nd	nd	
Total:	184	51.9±27.7	14.9	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥5		Chicago**	Chicago**		both	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

** "An event characterized by a transient reduction in, or complete cessation of, breathing. In routine clinical practice it is not considered necessary to distinguish obstructive hypopneas from apneas because both types of events have similar pathophysiology. These events must fulfill criterion 1 or 2, plus criterion 3 of the following:

1. A clear decrease (>50%) from baseline in the amplitude of a valid measure of breathing during sleep. Baseline is defined as the mean amplitude of stable breathing and oxygenation in the two minutes preceding onset of the event (in individuals who have a stable breathing pattern during sleep) or the mean amplitude of the three largest breaths in the two minutes preceding onset of the event (in individuals without a stable breathing pattern).
2. A clear amplitude reduction of a validated measure of breathing during sleep that does not reach the above criterion but is associated with either an oxygen desaturation of >3% or an arousal.
3. The event lasts 10 seconds or longer."

from SLEEP , VOL 22, NO. 5, 1999 , P. 670: Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	C-Flex	C-Flex (Respironics, PA)	Comfort level 3 with differential levels of flexible pressurer
2				
3				
Control	PAP	CPAP	REMStar PRO (Respironics, PA)	standard
For CPAP:		**How was the Pressure selected?**	titrated either split night or separate night	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth	30 d; 90 d; 180 d	
2	Compliance	mean h used per night	180 d (?)	
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Dolan, 2009 US Germany 18551327	Epworth		**Tx**	C-Flex	?	92					-6.6					NS
			Cx	CPAP	?	92					-6.4					
Dolan, 2009 US Germany 18551327	h used per night	h	**Tx**	C-Flex	180 d	92			6.23	0.98				0.18	0.105	0.088 NS

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
			Cx	CPAP	180 d	92			6.05	1.04						
Dolan, 2009 US Germany 18551327	total number of h of tx	h	**Tx**	C-Flex	180 d	92			557	(95%CI 521, 593)						NS
			Cx	CPAP	180 d	92			518	(95%CI 480, 556)						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	y	n	n	y	n	NA	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	y				
Reasons for drop-outs:										
Other Issues:	unclear if the participants were randomized before or after the assessment for adherence (participants with <4 h of compliance per night during a trial period of 1 wk were dropped from the study); incomplete reporting									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Fietze, 2007			**Intervention 1**	auto titrated CPAP
PMID*	17337881	**RefID**	3275	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	standard CPAP
Extractor	si			**Comments**	pt had 2 consecutive nights of titration in a cross over design; first night is either APAP or CPAP, then second night is the alternate; the treatment selected for the second night is the treatment for the next 6 wks

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
AHI≥10 by PSG; AHI >10 at home but <10 by PSG, and excessive sleepiness; BMI <40; 35-70 y/o	presence of other sleep disorders; periodic leg movement or restless leg syndrome; acute cardiac, pulmonary or other internal-medicine related disorders; acute psychiatric or neurologic disorders; abuse of sleep-inducing agents or other drugs; central sleep apnea; previous tx (e.g., CPAP, oral devices or UPPP)	≥10	nd	no	Germany	industry	no	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**10**	100	57		32.6±6.6			
Cx	**11**	91	52		29.4±4.4			
Total	**21**	95	54		30.9	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx	none							
Cx	none							
Total	none							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	10	43.3±30.2		17.7±13.6 min				
Control:	11	40.4±26.1		11.2±6.4 min				
Total:	21	41.8		14.3 min	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥10	nd	nd	nd	nd	separate nights	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto-titrating CPAP	REMstar Auto	min 4 cm, max 16 cm H_2O; 90% tile of all individual pressure results to represent effective pressure for the night
2				
3				
Control	PAP	standard CPAP	REMstar Auto	set pressure to abolish apnea, hypopneas, desat ≥3%; resp arousals
For CPAP:		**How was the Pressure selected?**	see above	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth		
2	Sleep study measures	AHI		
3	Compliance			
4	QoL	SF-36		

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference* (Final test – Final control)*		
							Value	SD*	Value	SD*	Value	SE*	P	Value	SD/SE*	P
Fietze, 2007 Germany 17337881	AHI		Tx	APAP	6 wk	20	43.3	30.2	4.4	3.4				0.5	0.863	0.562 (Final value btw group diff)
			Cx	CPAP	6 wk	21	40.4	26.1	3.9	4.3						
Fietze, 2007 Germany 17337881	Epworth		Tx	APAP	6 wk	20	nd		nd							NS (Final value btw group diff)
			Cx	CPAP	6 wk	21	nd		nd							
Fietze, 2007 Germany 17337881	SF-36 scores		Tx	APAP	6 wk	20	nd		nd							NS (Final value btw group diff)
			Cx	CPAP	6 wk	21	nd		nd							
Fietze, 2007 Germany 17337881	Nocturnal usage duration	h	Tx	APAP	6 wk	20	NA	NA	5	1.6				0.8	0.432	0.064 NS (Final value btw group diff)
			Cx	CPAP	6 wk	21	NA	NA	4.2	2.2						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	n	nd	nd	nd	y	NA	NA	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	y	y	y	n	y				
Reasons for drop-outs:										
Other Issues:	Unclear how the patients were initially selected; details of randomized sequence not reported; incomplete reporting									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Galetke, 2008			**Intervention 1**	auto titrated CPAP
PMID*	17148931	**RefID**	3303	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	standard CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
newly dx'd OSA with AHI >10 and clinical symptoms	COPD, CHF, acute neurological or psychiatric disorders, major sleep disorders, malignant disease	>10	nd	no	Germany	nd	nd	yes	no
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**20**	80	55.5	nd	29.3±4.1			
Cx	**20**	80	55.5	nd	29.3±4.1			
Total	**20**	80	55.5	nd	29.3±4.1	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	nd
	Treatments used (prior to trial, including surgery)							
Tx	nd							
Cx	nd							
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	20	32.9±19.1	10.3±5.7					
Control:	20	32.9±19.1	10.3±5.7					
Total:	20	32.9±19.1	10.3±5.7	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>10		no flow ≥10 s	↓flow 50% ≥10 s or ↓flow ≥10 s with a ↓O_2 sat ≥4% or arousal		separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto CPAP	ResMed/MAP, Germany	4 to 15 cm H_2O
2				
3				
Control	PAP	fixed CPAP	ResMed/MAP, Germany	pressure increased until resp. disturbance or arousals became ≤5/h
For CPAP:		**How was the Pressure selected?**	manual or auto titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth	baseline, 8 wk	
2	Sleep study measures	AHI; min SaO2; arousals	baseline, 8 wk	
3	Compliance	min/night		
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference* (Final test – Final control)*		
							Value	SD*	Value	SD*	Value	SE*	P	Value	SD/SE*	P
Galetke, 2008 Germany 17148931	AHI		**Tx**	auto CPAP	8 wk	20 (presumed)	32.9	19.1	5.6	3.6	-27.3		<0.001	1	0.739	0.176 (Final value no diff btw groups)
			Cx	fixed CPAP	8 wk	20 (presumed)	32.9	19.1	4.6	2.9	-28.3		<0.001			
Galetke, 2008 Germany 17148931	Epworth		**Tx**	auto CPAP	8 wk	20 (presumed)	10.3	5.7	4.9	4.6	-5.4		<0.001	-1.7	1.052	0.106 (Final value no diff btw groups)
			Cx	fixed CPAP	8 wk	20 (presumed)	10.3	5.7	6.6	4.8	-3.7		<0.001			
Galetke, 2008 Germany 17148931	Compliance	h/night	**Tx**	auto CPAP	8 wk	20 (presumed)	NA		6.37	1.78				-0.01	0.412	0.981 NS (Final value no diff btw groups)
			Cx	fixed CPAP	8 wk	20 (presumed)	NA		6.38	1.9						
Galetke, 2008 Germany 17148931	Arousals/h		**Tx**	auto CPAP	8 wk	20 (presumed)	17.6	9.2	13.6	8.6	-4		NS	1	1.795	0.578 NS (Final value no diff btw groups)
			Cx	fixed CPAP	8 wk	20 (presumed)	17.6	9.2	12.6	7.3	-5		NS			
Galetke, 2008 Germany 17148931	min SaO2	%	**Tx**	auto CPAP	8 wk	20 (presumed)	77.8	8.4	86.5	5.2	8.7		<0.001	-1.8	1.032	0.081 NS (Final value no diff btw groups)
			Cx	fixed CPAP	8 wk	20 (presumed)	77.8	8.4	88.3	3.6	10.5		<0.001			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
APAP	nd	
CPAP	nd	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	nd	y	n	nd	y	NA	NA	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	y	n			n
Reasons for drop-outs:	no information on dropouts									
Other Issues:	no washout period; small sample size; incomplete reporting									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Gay, 2003			**Intervention 1**	novel bilevel PAP
PMID*	14655921	**RefID**	4302	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
suspected OSA; >18 y/o; AHI >10 and <100 (obstructive events); ability to follow instructions; willing to follow up at 30 d; resides within 200 mi	inability to wear a nasal mask; prior UPPP or other surgeries for OSA or snoring; prior or current use of PAP; complicating medical conditions (see paper); neuromuscular disease; psychiatric disorders that may interfere with cooperation (in the opinion of the investigators)	>5 (?)	nd	no	US	industry	yes; 12 per arm	yes	yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**12 (12)**	nd	43.6		36.6±6			
Cx	**15 (15)**	nd	45.1		34.1±4.7			
Total	**27 (27)**	81	44	nd	35.2	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx	no prior CPAP							
Cx	no prior CPAP							
Total	no prior CPAP							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	12	41.8±25.8	14.2±3.4					
Control:	15	46.1±23.1	13.5±3.4					
Total:	27	44±24.4	12±3.4	nd	nd	nd	0	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG			no flow despite effort ≥10 s	↓ ≥50% flow ≥10 s with ≥2% desat		split night	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	novel bilevel PAP	Prototype from Respironics	IPAP ≥2 cm above P_{base} and initial EPAP fall of 2 to 4 cm for the majority of breaths
2				
3				
Control	CPAP	CPAP		start at 5 cm, and increase in 1 cm increment until snoring and resp arousals were abolished and AHI <5
For CPAP:		**How was the Pressure selected?**	manual titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth	baseline, 1 mo	
2	QoL	FOSQ	baseline, 1 mo	
3	Compliance	h per night	1 mo	
4				

* ; ; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD	Value	SE*	P	Value	SE*	P
Gay, 2003 US 14655921	Epworth		Tx	novel BIPAP	1 mo	12	14.2	3.4	7.8	3.8	-6.4	1.044	<0.05	-0.9	1.519	NS
			Cx	CPAP	1 mo	15	13.5	3.4	8	4.8	-5.5	1.104	<0.05			
Gay, 2003 US 14655921	FOSQ		Tx	novel BIPAP	1 mo	12	89.7	11.1	107.2	7.7			<0.05			NS
			Cx	CPAP	1 mo	15	88.4	21.2	103.7	18.4			<0.05			
Gay, 2003 US 14655921	compliance	h per night	Tx	novel BIPAP	1 mo	12	NA		5.6							NS
			Cx	CPAP	1 mo	15	NA		5.6							

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
novel BIPAP	0	
CPAP	0	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Y	nd	nd	y	y	y	y	y	NA	NA	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	y				
Reasons for drop-outs:										
Other Issues:	conduct of randomization unclear: 27 pts randomized before PSG (paper also stated that 13/40 pts became ineligible after PSG) and "slightly more pts became ineligible for the NBL than the CPAP treatment limb" resulted in "an uneven number of patients in each group" (?); power calculation assumption overestimated compliance difference									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Hudgel, 2000			**Intervention 1**	auto titrated CPAP
PMID*	10947032	**RefID**	4381	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	fixed CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA or upper airway resistance syndrome (heavy snoring and excessive daytime sleepiness)	previous CPAP; facial oropharyngeal abnormalities req'd surgery; chronic airways disease; obesity-hypoventilation syndrome; night or rotating shift work; severe CHF needed >1 diuretic; seizure; mental retardation; sedative/hypnotic/antidepressant tx	nd	nd	no	US	nd	no	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	60(39)	54	46	79% white; 21% black	42±2			
Cx	60(39)	54	46	79% white; 21% black	42±2			
Total	60(39)	54	46	79% white; 21% black	42±2	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx	no prior CPAP							
Cx	no prior CPAP							
Total	no prior CPAP							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	39	30±4	16±8					
Control:	39	30±4	16±8					
Total:	39	30±4 (SE)	16±0.8 (SE)					
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	nd	nd	nd	nd	both	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto titrated CPAP	Respironics Virtuoso smart CPAP system	auto mode; 3 to 20 cm H_2O
2				
3				
Control	PAP	fixed CPAP	Respironics Virtuoso smart CPAP system	fixed mode; set pressure to abolish snoring, apneas, hypopneas, and respiratory-related arousals
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth	12 wk	
2	Compliance	≥4 h used per night	12 wk	
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	SE(?)	P btw	Result	95% CI	P btw	Adjusted for:
Hudgel, 2000 US 10947032	% time machine used ≥4 h per night	**Tx**	auto CPAP	12 wk	10	14	%	73	±5	0.07				
		Cx	fixed CPAP	12 wk	13	19		66	±5					

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SD/SE*	P	Value	SE*	P
Hudgel, 2000 US 10947032	Epworth		**Tx**	auto CPAP	12 wk	39	16	0.8	9	1				1	1	0.317
			Cx	fixed CPAP	12 wk	39	16	0.8	8	1						
Hudgel, 2000 US 10947032	no. of h machine used during the nights machine was used	h	**Tx**	auto CPAP	12 wk	14	NA		6	0.3				0.5	0.243	<0.04 (final value btw groups)
			Cx	fixed CPAP	12 wk	19	NA		5.5	0.3						
Hudgel, 2000 US 10947032	total h machine used	h	**Tx**	auto CPAP	12 wk	14			492	40						NS (final value btw groups)
			Cx	fixed CPAP	12 wk	19			428	37						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
APAP or CPAP	35% (21/60)	discontinued because of medical complications unrelated to OSA (2)
initial APAP	32% (8/25)	
initial CPAP	44% (11/25)	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	n	nd	n	nd	nd	n	y	n	NA	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	n	n	y	y	n	y				n
Reasons for drop-outs:										
Other Issues:	incomplete reporting; apparently no washout period; discrepancy in text regarding the number started (60 or 50?)									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Hukins, 2004			**Intervention 1**	auto PAP
PMID*	15683142	**RefID**	4385	**Intervention 2**	
Key Question(s)	5; 6 (?)			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	fixed CPAP
Extractor	si			**Comments**	2 mo treatment, only last 30 day data from Autoset T were analyzed to allow a "washout period" between treatment modes

* or Cochrane number
† RCT; ; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
unselected consecutive pts in a tertiary referral sleep disorder unit; hypersomnolence with AHI ≥5; optimal (not defined) CPAP pressure determined by overnight PSG	previous home CPAP; significant comorbidity (see paper); significant complication (PaCO2 >45 or right heart failure); central apnea >10 per h	≥5	nd	no	Australia	industry	yes; 52 per arm	yes	no
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**55 (46)**							
Cx	**55 (46)**							
Total	**55 (46)**	87% (in 55 pts)	50 (in 55 pts)	nd	35.2 (in 55 pts)	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	no previous home CPAP							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	55	55.7 (in 55 pts)	12.5 (in 55 pts)	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG			ndnd	nd		nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto PAP	Autoset T	4 to 20 cm H2O; pressure varies per snoring, hypopneas, or apneas and the flattening index
2				
3				
Control	PAP	fixed CPAP	Autoset T	nd
For CPAP:		**How was the Pressure selected?**	manual titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	mean h used per night	1 to 2 mo	
2	Sleepiness measures	Epworth	2 mo	
3	QoL	SF-36	2 mo	
4				

* ; ; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Hukins, 2004 Australia 15683142	Compliance	h per night	**Tx**	auto PAP	1 to 2 mo	46	NA		5.05	2.38				0.19	0.129	0.14
			Cx	fixed CPAP	1 to 2 mo	46	NA		4.86	2.65						
Hukins, 2004 Australia 15683142	Epworth		**Tx**	auto PAP	1 to 2 mo	46	12.5 (est. from Fig 2))		8 (est.)					-0.2		NS
			Cx	fixed CPAP	1 to 2 mo	46	12.5 (est. from Fig 2)		8.2 (est.)							
Hukins, 2004 Australia 15683142	SF-36 (role physical)		**Tx**	auto PAP	1 to 2 mo	46	35 (est. from Fig 3))		64 (est.)				<0.001			NS
			Cx	fixed CPAP	1 to 2 mo	46	35 (est. from Fig 3)		58 (est.)				<0.05			
Hukins, 2004 Australia 15683142	SF-36 (vitality)		**Tx**	auto PAP	1 to 2 mo	46	35 (est. from Fig 3))		55 (est.)				<0.001			NS
			Cx	fixed CPAP	1 to 2 mo	46	35 (est. from Fig 3)		50 (est.)				<0.005			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Hukins, 2004 Australia 15683142	SF-36	Physical function	2 mo	APAP	46	CPAP	46	0					
	SF-36	bodily pain	2 mo	APAP	46	CPAP	46	0					
	SF-36	general health	2 mo	APAP	46	CPAP	46	0					
	SF-36	social function	2 mo	APAP	46	CPAP	46	0					
	SF-36	role emotional	2 mo	APAP	46	CPAP	46	0					
	SF-36	mental health	2 mo	APAP	46	CPAP	46	0					

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Other Results	Difference between compliance in each treatment mode did not correlate with baseline AHI, AHI supine and nonsupine, AHI during REM and non-REM, and optimal CPAP.

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
APAP	5/55 (9%)	nd
CPAP	4/55 (7%)	nd

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			APAP	CPAP		
Hukins, 2004 Australia 15683142	nasal irritation or obstruction	2 mo	5/55	10/55		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	y	n	y	y	n	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	y	yes, but under-powered			see comment at the beginning
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Hussain, 2004			**Intervention 1**	auto PAP
PMID*	15072173	**RefID**	4389	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	fixed CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
symptomatic OSA with AHI >15	previous CPAP	>15	nd	no	Pakistan or Canada	industry	no	yes	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**10 (10 presumed)**	90	45	nd	35.9±12.9	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	no previous CPAP							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	10	47.2±35.6	11.1±6.4	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG			nd	nd		separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto PAP	Virtuoso (Respironics, PA)	3 to 20 cm H2O
2				
3				
Control	PAP	CPAP	Virtuoso (Respironics, PA)	
For CPAP:		**How was the Pressure selected?**	manual titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth	baseline, 4 wk	
2	Sleep study measures	AHI, ODA< AI, min O2, S3, S4, REM	baseline, 4 wk	
3	Compliance	h per night	4 wk	
4				

* QoL; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; ; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference* (Final test – Final control)*		
							Value	SD*	Value	SD*	Value	SE*	P	Value	SD/SE*	P
Hussain, 2004 Pakistan/Canada 15072173	AHI		**Tx**	auto PAP	4 wk	10 (presumed)	47.2	35.6	13.1	8.3			<0.05	3.5	2.307	0.129
			Cx	CPAP	4 wk	10 (presumed)	47.2	35.6	9.6	5.4			<0.05			
Hussain, 2004 Pakistan/Canada 15072173	Arousal index		**Tx**	auto PAP	4 wk	10 (presumed)	17.3	17.7	5.9	6.5			<0.05	1	1.786	0.575
			Cx	CPAP	4 wk	10 (presumed)	17.3	17.7	4.9	3.7			<0.05			
Hussain, 2004 Pakistan/Canada 15072173	desat index		**Tx**	auto PAP	4 wk	10 (presumed)	53	36	15	14			<0.05			NS
			Cx	CPAP	4 wk	10 (presumed)	53	36	10	13			<0.05			
Hussain, 2004 Pakistan/Canada 15072173	min O2	%	**Tx**	auto PAP	4 wk	10 (presumed)	67.8	12.5	81.8	6.2	14		<0.05	-3.9	1.712	0.023
			Cx	CPAP	4 wk	10 (presumed)	67.8	12.5	85.7	3.8	17.9		<0.05			
Hussain, 2004 Pakistan/Canada 15072173	stage 3-4 sleep	%	**Tx**	auto PAP	4 wk	10 (presumed)	14	25	10	7			NS	-8	5.263	0.129
			Cx	CPAP	4 wk	10 (presumed)	14	25	18	19			NS			
Hussain, 2004 Pakistan/Canada 15072173	REM sleep	%	**Tx**	auto PAP	4 wk	10 (presumed)	15	7	19	6			NS	-1	1.897	0.598
			Cx	CPAP	4 wk	10 (presumed)	15	7	20	6			NS			
Hussain, 2004 Pakistan/Canada 15072173	Epworth		**Tx**	auto PAP	4 wk	10 (presumed)	11.1	6.4	8	5.7			<0.05	1.4	1.835	0.445
			Cx	CPAP	4 wk	10 (presumed)	11.1	6.4	6.6	5.9			<0.05			

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference* (Final test – Final control)*		
							Value	SD*	Value	SD*	Value	SE*	P	Value	SD/SE*	P
Hussain, 2004 Pakistan/Canada 15072173	Compliance	h per night	**Tx**	auto PAP	4 wk	10 (presumed)	NA		4.3	1.9				0.6	0.737	0.416 NS
			Cx	CPAP	4 wk	10 (presumed)	NA		3.7	2.6						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y(?)	y	nd	nd	y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	n	n	y	y	n	y	n			?
Reasons for drop-outs:										
Other Issues:	small sample size, unclear where the patients are from or how they were recruited									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Khanna, 2003			**Intervention 1**	oral CPAP
PMID*	14592306	**RefID**	4434	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	nasal CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
RDI >15	severe cardiac disease, chronic pulmonary disease, significant psychiatric illness	RDI >5	2000-2001	no	US	nd	no	no	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**nd (21)**	62	52.5		34.9±5.4			
Cx	**nd (17)**	65	50.9		34.2±6			
Total	**42 (38)**	63	51.8	nd	34.6	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx	nd							
Cx	nd							
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	RDI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	21	58.5±34.8	13.8±5.1					
Control:	17	63±39.3	12.6±3.6					
Total:	38	60.5	13.3	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	RDI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>5	nd	nd	nd	nd	separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	oral CPAP	Oracle™, Fisher-Paykel HC201 CPAP	humidified
2				
3				
Control	PAP	nasal CPAP	Fisher-Paykel HC201 CPAP	humidified
For CPAP:		**How was the Pressure selected?**	manual titration to abolish apneas and arousals	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	compliance	h/night use	1 mo; 2 mo	
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Khanna, 2003 US 14592306	stroke	**Tx**	oral CPAP	2 mo	1	21	%	4.8						
		Cx	nasal CPAP	2 mo	0	17	%	0						

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Khanna, 2003 US 14592306	compliance	h/night	**Tx**	oral CPAP	1 mo	21	NA		5.8	1.4	NA			0	0.37	NS (final diff btw groups)
			Cx	nasal CPAP	1 mo	17			5.8	1.7						
Khanna, 2003 US 14592306	compliance	h/night	**Tx**	oral CPAP	2 mo	15 (?)	NA		5.8	1.7	NA			0.1	0.65	NS (final diff btw groups)
			Cx	nasal CPAP	2 mo	12 (?)			5.7	2.6						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Khanna, 2003 US 14592306	11/38 (29%) dropped out	In the oral group, 1/21 stopped because of a cerebral vascular accident; 1 stopped CPAP; 1 declined to participate further; 3 switched to nasal because of oral dryness and gum pain. In the nasal group, 5/17 abandoned therapy; reasons included congestion, pharyngitis, severe claustrophobia, and excessive pressure from the tight fitting mask (numbers not reported).

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			oral CPAP	nasal CPAP		
Khanna, 2003 US 14592306	severe claustrophobia	1 mo	1/18	2/15		
		2 mo	0	3/13		
	epistaxis	1 mo		2		
	gum pain	1 mo	3			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	n	n	nd	nd	y	NA	NA	n

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	n	y		

Reasons for drop-outs:	"Pts who abandoned therapy or used their CPAP <20 min per night were considered droputs and removed from analysis in the month that therapy was not used."
Other Issues:	small sample size; incomplete reporting
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Khayat, 2008			**Intervention 1**	Bilevel PAP
PMID*	18641111	**RefID**	7467	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
LVEF ≤45%; stable AHA II or III; no hosp or med change 3 mo prior; AHI >10; >50% obstructive; reduction of AHI >50% on titration night	medical instability (recent ischemic or unstable angina, heart failure within past 6 mo, stroke, renal failure req'd dialysis); long-term CPAP or biPAP; central sleep apnea or Cheyne-Stokes; COPD or need for supplemental O_2; pts who req'd bilevel PAP on titration night, at the technician's discretion, were automatically disqualified from enrollment	>10	2005-2007	no	US	industry	no	yes	yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**13**		51.3		35±1.6 (SE)			100
Cx	**11**		54.8		32±1.8 (SE)			100
Total	**24**	nd	53	nd	33.6	nd	nd	100 (AHA II or III)
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								AHA II or III
Cx								AHA II or III
Total	nd	nd	nd	nd	nd	nd		AHA II or III
	Treatments used (prior to trial, including surgery)							
Tx	nd							
Cx	nd							
Total	nd (newly dx'd with OSA though)							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	13	34±4.8 (SE)	11.8±1.8 (SE)	18±4.4 (SE)	nd	nd	newly dx'd with OSA	
Control:	11	30±4.4 (SE)	13.5±1.8 (SE)	17±3.6 (SE)	nd	nd	newly dx'd with OSA	
Total:	24	32.2±16.24 (SD)	12.6±6.31(SD)	17.5	nd	nd	newly dx'd with OSA	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>10	AASM	AASM	AASM	nd	separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	Bilevel PAP	BiPAP-Pro (Respironics, PA)	insp pressure: pressure required to abolish hypopneas and snoring exp pressure: lowest pressure req'd to eliminate apneas
2				
3				
Control	PAP	CPAP	BiPAP-Pro (Respironics, PA)	pressure req'd to abolish hypopneas and snoring
For CPAP:		**How was the Pressure selected?**	manual?	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	AHI	baseline, 3 mo	
2	Sleepiness measures	Epworth	baseline, 3 mo	
3	Compliance	average h used per night	3 mo	
4	QoL	Minnesota Living with Heart Failure Questionnaire	baseline, 3 mo	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ* (Δ test – Δ control)		
							Value	SE*	Value	SE*	Value	SE*	P	Value	95%CI	P
Khayat, 2008 US 18641111	AHI		**Tx**	BIPAP	3 mo	13	34	4.8	1.43	nd	-33.6			-8.0	-21.3, 5.3	0.24
			Cx	CPAP	3 mo	10 or 11	30	4.4	3.95	nd	-25.6					
Khayat, 2008 US 18641111	Epworth		**Tx**	BIPAP	3 mo	13	11.8	1.8			-2.6			2.1	-2.7, 6.9	0.38
			Cx	CPAP	3 mo	10 or 11	13.5	1.8			-4.7					
Khayat, 2008 US 18641111	average h use per night in 90 d		**Tx**	BIPAP	3 mo	13	NA		4.5					0.9	-1.6, 3.4	0.46 (Final diff btw groups)
			Cx	CPAP	3 mo	10 or 11	NA		3.6							
Khayat, 2008 US 18641111	Minnesota Questionnaire for heart failure		**Tx**	BIPAP	3 mo	13	NA				-11.1			-8.2	-32.6, 16.3	0.49
			Cx	CPAP	3 mo	10 or 11	NA				-2.9					
Khayat, 2008 US 18641111	systolic BP	mm Hg	**Tx**	BIPAP	3 mo	13	115	4.8		nd	-6.3			-4.9	-10.9, 20.6	0.53
			Cx	CPAP	3 mo	10 or 11	110	5.2		nd	-1.4					
Khayat, 2008 US 18641111	diastolic BP	mm Hg	**Tx**	BIPAP	3 mo	13	68	3.3		nd	-7.5			-5.3	-10.9, 20.6	0.31
			Cx	CPAP	3 mo	10 or 11	68	3.6		nd	-2.2					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	1/11 in CPAP (9%)	nd

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	y	nd	nd	y	n	NA	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	y	y	y	n	y		

Reasons for drop-outs:	
Other Issues:	pilot study, small sample size, technician's discretion to automatically disqualify those who needed BIPAP on titration nights (possible selection bias)
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Leidag, 2008			**Intervention 1**	C-Flex
PMID*	19218664	**RefID**	3509	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Crossover			**Control**	CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; ; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
suspect OSA	severe comorbidity (eg, NYHA 3 or 4); severe COPD; dementia, alcoholism, drug abuse, <18 y/o	≥5	nd	no	Germany	industry	no	yes	yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**30 (25)**							
Cx	**30 (23)**							
Total	**30 (25?)**	73	55	nd	32±7.4	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	30	35.4±24.8	nd	nd	nd	nd	0 (?)	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	A+H per h of total sleep time		↓ flow for ≥50% for ≥10 s	↓ flow for ≥20% for ≥10 s		separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	C-Flex	REMstar Pro (Respironics)	
2				
3				
Control	PAP	CPAP	REMstar Pro (Respironics)	
For CPAP:		**How was the Pressure selected?**	manual titration from 5 cm in steps of 1 cm increment	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	min per night	6 wk	
2	Sleep study measures	AHI; min O2; REM	6 wk	
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; ; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Leidag, 2008 Germany 19218664	AHI		**Tx**	C-Flex	6 wk	25	35.4 (30 pts)	24.8	6.2	5						NS (Final value btw groups)
			Cx	CPAP	6 wk	23	35.4 (30 pts)	24.8	5.4	4.4						
Leidag, 2008 Germany 19218664	min SO2	%	**Tx**	C-Flex	6 wk	25	79.1 (30 pts)	7.7	87.7	4.1						NS (Final value btw groups)
			Cx	CPAP	6 wk	23	79.1 (30 pts)	7.7	88	4.2						
Leidag, 2008 Germany 19218664	REM	%	**Tx**	C-Flex	6 wk	25	13.7 (30 pts)	8	19.5	6.7						NS (Final value btw groups)
			Cx	CPAP	6 wk	23	13.7 (30 pts)	87.7	21.7	8.9						
Leidag, 2008 Germany 19218664	Stage 3	%	**Tx**	C-Flex	6 wk	25	18.6 (30 pts)	7.9	25.3	10.4						NS (Final value btw groups)
			Cx	CPAP	6 wk	23	18.6 (30 pts)	7.9	21	13.5						
Leidag, 2008 Germany 19218664	Stage 4	%	**Tx**	C-Flex	6 wk	25	4.9 (30 pts)	6.2	9	10.3						NS (Final value btw groups)
			Cx	CPAP	6 wk	23	4.9 (30 pts)	6.2	10.2	7.8						
Leidag, 2008 Germany 19218664	Compliance	min per night	**Tx**	C-Flex	6 wk	25	NA		347	70.8				-0.05	0.24	NS (Final value btw groups)
			Cx	CPAP	6 wk	23	NA		350	70.2						

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Leidag, 2008 Germany 19218664	Arousal index	events per h	**Tx**	C-Flex	6 wk	25	18.7	10.7 (30 pts)	9.3	4.6						NS (Final value btw groups)
			Cx	CPAP	6 wk	23	18.7	10.7 (30 pts0	8.9	3.5						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	16% (5/30)	nd
C Flex	23% (7/30)	nd

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	n	y	y	nd	nd	n	NA	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	n	y	y	y	n	y				
Reasons for drop-outs:										
Other Issues:	small sample size; high absolute drop out rate									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments
unconventional definition of apnea: “reduction in airflow of at least 50% compared with baseline for 10 s or more”

A.

Author, Year	Mador, 2005			**Intervention 1**	heated humidified nasal CPAP
PMID*	16236868	**RefID**	3560	**Intervention 2**	
Key Question(s)	5, 7			**Intervention 3**	
Design †	RCT			**Control**	standard nasal CPAP with heated humidified nasal CPAP to tx upper airway symptoms not responsive to simple measures
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
AHI ≥10; majority OSA and subjective sleepiness; no previous CPAP; willingness and successful titration for nasal CPAP	comorbid conditions that can potentially interfere with nasal CPAP	≥10	2002-2003	no	US	nd	yes; 94 pts required	no	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**49**	96	59.9		35.3±7			
Cx	**49**	98	57.1		36.6±7.4			
Total	**98**	97	58.5	nd	36	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx	no prior CPAP							
Cx	no prior CPAP							
Total	no prior CPAP							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	49	46.9±30	12.9±5.2					
Control:	49	45.8±30	14.1±5.3					
Total:	98	46.4	13.5	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥10		no flow >10 s	visible ↓flow ≥10 s with O2 desat of 4% or EEG arousal		both	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	nasal CPAP with heated humidified	HC221, Fisher & Paykel, New Zealand	initial pressure at 4 cm H_2O, then 2 cm increment; final pressure to minimize resp events and snoring; pts were instructed on how to use the heated humidifier
2				
3				
Control	PAP	standard nasal CPAP, heat humidified as needed only	HC221, Fisher & Paykel, New Zealand	initial pressure at 4 cm H_2O, then 2 cm increment; final pressure to minimize resp events and snoring; pts told not to use humidification
For CPAP:		**How was the Pressure selected?**	manual	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	QoL	Calgary sleep apnea QoL Index	baseline, 1 mo, 3 mo, 12 mo	4 domains (daily functioning; social interactions; emotional functioning, symptoms)
2	Sleepiness measures	Epworth	baseline, 1 mo, 3 mo, 12 mo	
3	Compliance	mean h used at prescribed pressure	1 mo, 3 mo, 12 mo	
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Mador, 2005 US 16236868	Compliance	h/night	**Tx**	heated humidified n-CPAP	1 mo	49	NA	NA	4.3	2.0						NS
			Cx	n-CPAP	1 mo	49	NA	NA	4.3	2.4						
Mador, 2005 US 16236868	Compliance	h/night	**Tx**	heated humidified n-CPAP	3 mo	nd	NA	NA	4.3	2						NS
			Cx	n-CPAP	3 mo	nd	NA	NA	4.8	2.3						
Mador, 2005 US 16236868	Compliance	h/night	**Tx**	heated humidified n-CPAP	12 mo	nd	NA	NA	4.2	2.3						NS
			Cx	n-CPAP	12 mo	nd	NA	NA	4.8	2.4						
Mador, 2005 US 16236868	Epworth		**Tx**	heated humidified n-CPAP	1 mo	49	12.9	5.2	10.5	4.8	-2.4		<0.05			NS
			Cx	n-CPAP	1 mo	49	14.1	5.3	11.1	5.7	-3		<0.05			
Mador, 2005 US 16236868	Epworth		**Tx**	heated humidified n-CPAP	3 mo	nd	12.9	5.2	4.5	1.5	-8.4		<0.05			NS
			Cx	n-CPAP	3 mo	nd	14.1	5.3	4.6	1.6	-9.5		<0.05			
Mador, 2005 US 16236868	Epworth		**Tx**	heated humidified n-CPAP	12 mo	nd	12.9	5.2	9	4.9	-3.9		<0.05			NS
			Cx	n-CPAP	12 mo	nd	14.1	5.3	8.8	5.8	-5.3		<0.05			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Mador, 2005 US 16236868	Calgary sleep apnea QoL Index	Total	1, 3, 12 mo	heated humidified n-CPAP	49	standard CPAP	49	0					
		Daily functioning	1, 3, 12 mo	heated humidified n-CPAP	49	standard CPAP	49	0					
		Social interactions	1, 3, 12 mo	heated humidified n-CPAP	49	standard CPAP	49	0					
		Emotional	1, 3, 12 mo	heated humidified n-CPAP	49	standard CPAP	49	0					
		Symptoms	1, 3, 12 mo	heated humidified n-CPAP	49	standard CPAP	49	0					

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
heated humidified n-CPAP	10/49 (20.4%)	no wish to continue n-CPAP (5)
standard n-CPAP	11/49 (22.4%)	no wish to continue n-CPAP (4)
either intervention		moved (2); death (1); transportation problems (3); unavailable for f/u (1); no wish to continue participating in the study (5)

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			heated humidified n-CPAP	standard n-CPAP		
Mador, 2005 US 16236868	dry mouth or throat	1 mo		more		
	dry nose	1 mo		more		
	death (1)	?	?	?		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	n	n	nd	n	y	n	NA	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	y				
Reasons for drop-outs:	see Table L									
Other Issues:	1 death, cause not reported; 6/49 in standard n-CPAP crossed over and received heated humidified n-CPAP; unclear if the analysis accounted for the cross over									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Marrone, 2004			**Intervention 1**	auto CPAP
PMID*	15165530	**RefID**	4544	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	fixed CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSAS with AHI ≥30	overt cardiopulmonary disease	>5	nd	yes	Italy	nd	no	yes (?)	no
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**22**	95	53.4	nd	32.9			
Cx	**22**	95	53.4	nd	32.9			
Total	**22**	95	53.4	nd	32.9	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	22	68.4±12.1	16.3±5					
Control:	22	68.4±12.1	16.3±5					
Total:	22	68.4±12.1	16.3±5	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG			ASDA	↓flow with ↓O_2 sat >3% or arousal		separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto CPAP	AutoSet T, Australia	auto 4 to 18 cm H_2O
2				
3				
Control	PAP	fixed CPAP	Sullivan Elite, Australia	pressure determined by PSG
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth		
2	Compliance			mean h per day used
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Marrone, 2004 Italy 15165530	Epworth		Tx	auto CPAP	1 mo	22	16.3	5	3.9	2.8	-12.4		<0.001	-1	0.713	0.16 NS (Final value btw groups)
			Cx	fixed CPAP	1 mo	22	16.3	5	4.9	3.7	-11.4		<0.001			
Marrone, 2004 Italy 15165530	Compliance	mean h/night	Tx	auto CPAP	1 mo	22	NA		4.9	1.7				0.5	0.386	0.195 NS (Final value btw groups)
			Cx	fixed CPAP	1 mo	22	NA		4.4	1.9						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	preference data not extracted

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	y	n	nd	y	n	NA	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	y	no			no washout
Reasons for drop-outs:										
Other Issues:	unclear how pts were blinded given that the two groups received different machines; small sample size									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Massie, 1999			**Intervention 1**	Heated humidity for the CPAP titration
PMID*	10453869	**RefID**	5583	**Intervention 2**	Cold passover humidity for the CPAP titration
Key Question(s)	KQ 7; KQ5			**Intervention 3**	
Design †	Randomized cross-over			**Control**	No humidity (washout period)
Extractor	MC			**Comments**	Patients were not informed that the study was designed to assess compliance, but they were debriefed at the conclusion of the study regarding compliance monitoring.

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
18-75 y, had an OSA diagnosis (RDI ≥10) No previous CPAP	Comorbid medical or psychological conditions that interfered with the patient's ability to successfully utilize CPAP. Wake resting pulse oximetric saturation <90%, evidence of upper airway tract infection or flue-like symptoms at the time of titration, hospitalization 3 months prior to the study initiation, elective surgery scheduled the conclusion of the study, or prior surgical intervention for OSA. Required bilevel positive airway pressure ventilation, a full face mask, or supplemental oxygen.	RDI ≥10	nd	no	New Zealand	Fisher & Paykel Healthcare (Device manufacturer)	no	yes	no
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Heated humidity	**(22)**	77	44.9		37.5 ± 7.2			
Cold Passover humidity	**(16)**	81	43.1		37.7 ± 9.8			
Total (no humidity, washout period)	**47 (38)**	79	44.1	nd	37.6 ± 8.3	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Heated humidity								
Cold Passover humidity								
Total (no humidity, washout period)	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Heated humidity								
Cold Passover humidity								
Total (no humidity, washout period)	No prior surgical intervention for OSA							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Heated humidity	22	44.8±29.5						
Cold Passover humidity	16	67.0±44.8						
Total:	38	54.2±37.9	nd	nd	nd	nd	nd	

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify)	Other characteristics
Dry nose (39%), runny nose (26%), postnasal dip (34%), epistaxis (3%), reduced sense of smell (29%), sinus infections (24%), dry throat (58%), sore throat (21%), hoarse voice (29%), cough (34%), allergies (34%)	nd	

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
RDI	≥10	nd	Airflow tracing between 0% and 20% of baseline for ≥10 s, accompanied by an arousal or desaturation. Evidence of continued thoracic and/or abdominal effort was required.	Same as apnea except for airflow tracing between 20% and 75% of baseline	nd	Heated humidity: 45% full night titration; 55% split night titration Cold passover humidity: 44% full night titration; 56% split night titration	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	Heated humidity	Titrated with an appropriate humidifier, and titration protocols were identical. Each patient underwent either an all night CPAP titration following a full night of diagnostic study or a split-night study protocol. CPAP was initiated during a split-night study if the RDI was >30 and oxyhemoglobin desaturation ≥4% occurred consistently in association with the sleep breathing events.	Humidifier: HC100; Fisher & Paykel Healthcare; Auckland, New Zealand	3 weeks	a 2-week washout period in which no humidity was used
2	Cold Passover humidity		Humidifier: Oasis; Respironics; Murrysville, PA	3 weeks	
3					
Control	No humidity	Washout period			

Sleep apnea Intervention†‡: CPAP (Sullivan V Elite Real Time Clock; ResMed) and a Sullivan Mirage nasal mask.	**For CPAP, how was the pressure selected?**	Pressure increases were performed manually: 2 cm for obstructive apneas, and 1 cm for obstructive hypopneas, snores, desaturations, and arousals. All patients were titrated using a nasal mask. Effective pressure was attained when evidence of apneas, hypopneas, snoring, hypoxemia, and arousals were ameliorated.

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	Compliance h/night	Compliance data were downloaded at each of the 3 follow-up visits: at the end of each active treatment period, and 1 at the end of the washout period.	Compliance data were downloaded from the CPAP machine using compliance software (SCAN 2.01; ResMed) The actual use per 24-h period was recorded; a pressure transducer recorded use only when the patient was breathing with mask in place
2	Harms	"global side effect score"	nd	nd
3	General symptom scales	Epworth sleepiness scale	At each of the 3 follow-up visits	nd
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference		
							Value	SD/SE*	Value	SD	Value	SD/SE*	P	Value	SE*	P
Massie, 1999 New Zealand 10453869	Compliance – CPAP use	hr/night	**Tx**	Heated humidity	3 weeks	38 (crossover study)			5.52	2.1				0.59	0.222	0.008 (compared to no humidity) NS (compared to cold passover humidity)
			Tx	Cold Passover humidity	3 weeks	38			5.15	1.9						NS
			Cx	No humidity	2 weeks	38			4.93	2.2						

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference		
							Value	SD/SE*	Value	SD	Value	SD/SE*	P	Value	SE*	P
Massie, 1999 New Zealand 10453869	Epworth sleepiness scale		**Tx**	Heated humidity	3 weeks	38 (crossover study)			6.2	3.8						P<0.0001 from baseline in all 3 groups; NS btw groups
			Tx	Cold Passover humidity	3 weeks	38			7.2	4.8						
			Cx	No humidity	2 weeks	38			6.7	3.9						
Massie, 1999 New Zealand 10453869	Adverse side effects (global score)		**Tx**	Heated humidity	3 weeks	38 (crossover study)			4.9	3.3						P=0.09 between 3 groups
			Tx	Cold Passover humidity	3 weeks	38			6.2	3.8						
			Cx	No humidity	2 weeks	38			6.5	4.9						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	In addition to the "adverse side effect global score", AE item analysis comparisons were conducted but just like the score, exactly what AE items were assessed were not reported. The author reported that "To control for multiple pairwise comparisons, the p value was set at 0.01. Patients reported that dry mouth or throat and dry nose interfered to a greater degree when CPAP was used without humidity compared to CPAP use with heated humidity (p <0.001).

	These side effects were not different between cold passover humidity and no humidity (p values >0.35)."

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Heated humidity		• 1 patient titrated with heated humidity exhibited poor sleep efficiency and a significant degree of sleep discontinuity.
Cold Passover humidity		• 1 patient titrated with cold passover humidity exhibited persistent central apneas. • 1 patient receiving cold passover humidity developed a severe headache during the second day of the study. This patient was subsequently prescribed heated humidity. • 1 patient removed the gasket in his cold Passover humidifier after 3 days of use. He was unable to replace it after washing, and he did not contact anyone for a replacement.
Washout period – no humidity		• 1 patient developed a severe dry nose and epistaxis on the second day of the washout period. He was immediately reinitiated on heated humidity, with complete resolution of the epistaxis.
All periods	19	Total 9 patients were unable to complete the protocol. Specific dropouts that happened during heated humidity, cold Passover humidity and washout period are described above. The remaining is described below. • 2 patients were dropped from the study at the time of CPAP titration. • 1 patient was lost to follow-up. • 2 patients were excluded from analyses because average daily use was , 1 h/night during both treatment periods

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
Massie, 1999 New Zealand 10453869	See Comments on Results					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	y	nd	n	unclear	NA	nd	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	n	NA	y				n

Reasons for drop-outs:	See Table L.
Other Issues:	Washout period (no humidity) was used to compare to the cross-over treatment periods as control. If so, it is unclear why the washout period was 2 weeks while the treatment period was 3 week? More patients dropped out during cold passover humidity period due to adverse events or intolerance. This could result in biased comparison (away from null) regarding compliance outcome. Statistical and methodological problems to use washout period as “control”. “Global side effect score” was not defined.
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Massie, 2003			**Intervention 1**	auto PAP
PMID*	12406840	**RefID**	4553	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	fixed CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
CPAP titration showed the need to have ≥10 cm H_2O; OSA with AHI ≥15; 18-65 y/o	lung disease, awake resting O2sat <90%; ≥10 central apnea-hypopnea events per h; meds that interfered with sleep or respiration	nd	nd	yes	multi (Australia, UK, US) (?)	industry	no	yes	no
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**46 (44)**	82	49	nd	32±4			
Cx	**46 (44)**	82	49	nd	32±4			
Total	**46 (44)**	82	49	nd	32±4	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx	none							
Cx	none							
Total	none							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	44	nd	nd	nd	nd	nd	0	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	nd	nd	nd	nd	both	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto PAP	AutoSet	4 to 20 cm H_2O
2				
3				
Control	PAP	CPAP	AutoSet	titrated, minimum 10 cm (3 pts had <10 cm because of intolerance)
For CPAP:		**How was the Pressure selected?**	titrated	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth	baseline, 6 wk	
2	QoL	SF-36	baseline, 6 wk	
3	Compliance	min/d	6 wk	
4	Sleep study measures	AHI	baseline, 6 wk	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference* (Final test – control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SE*	P
Massie, 2003 (Australia, UK, US) 12406840	Epworth		Tx	auto PAP	6 wk	44	nd		8	4				-1	0.542	0.065
			Cx	CPAP	6 wk	44	nd		9	4						
Massie, 2003 (Australia, UK, US) 12406840	Compliance	h	Tx	auto PAP	6 wk	44	NA		5.1	nd				0.58	0.207	0.005
			Cx	CPAP	6 wk	44	NA		4.52	nd						
Massie, 2003 (Australia, UK, US) 12406840	SF-36 Mental Health		Tx	auto PAP	6 wk	44	nd		80	14						<0.05 (Final value btw groups)
			Cx	CPAP	6 wk	44	nd		75	18						
Massie, 2003 (Australia, UK, US) 12406840	AHI		Tx	auto PAP	6 wk	44	nd		9.6	5.3				-1.1	0.913	0.228 (Final value btw groups)
			Cx	CPAP	6 wk	44	nd		10.7	6.6						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Massie, 2003 (Australia, UK, US) 12406840	SF-36	Mental Health	6 wk	auto PAP	44	CPAP	44	auto PAP	80±14 vs 75±18 (Final score)	5	0	100	<0.05
		Vitality	6 wk	auto PAP	44	CPAP	44	auto PAP	65±20 vs 58±23 (Final score)	7	0	100	<0.05
		Physical function	6 wk	auto PAP	44	CPAP	44	0					NS
		Role physical	6 wk	auto PAP	44	CPAP	44	0					NS
		Bodily pain	6 wk	auto PAP	44	CPAP	44	0					NS
		General health	6 wk	auto PAP	44	CPAP	44	0					NS
		Social function	6 wk	auto PAP	44	CPAP	44	0					NS
		Role emotional	6 wk	auto PAP	44	CPAP	44	0					NS

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	2.3	did not wish to continue
CPAP	2.3	no compliance data

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	y	n	nd	y	n	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	y				
Reasons for drop-outs:										
Other Issues:	incomplete data reporting									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Meurice, 2007			**Intervention 1**	auto CPAP (AutoSet)
PMID*	17638595	**RefID**	3596	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	fixed CPAP
Extractor	si			**Comments**	only comparative data on AutoSet were extracted because it had the largest number

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA with AHI >30 or micro-arousals >10/h	>20% central apnea; on sedatives or hypnotics	nd	nd	yes	France	nd	yes; 12 per arm	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**17 (15)**	nd	58.1 (17 pts)	nd	nd			
Cx	**17 (14)**	nd	52.2 (17 pts)	nd	nd			
Total	**34 (29)**	nd	55	nd	30.8±5.3 (83 pts)	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx	none							
Cx	none							
Total	none							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	17	58.1±10.2	12.9±4.3 (15 pts)					
Control:	17	52.2±9.5	10.6±5.2 (14 pts)					
Total:	34	55.1±10.29	11.8±4.89	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG			no flow >10 s	↓flow for ≥50% for ≥10 s with desat ≥4% or arousal		separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto CPAP	AutoSet	
2				
3				
Control	PAP	fixed CPAP		effective pressure to abolish snoring, apnea and hypopnea in all stages and all body positions
For CPAP:		**How was the Pressure selected?**	manual and auto	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth; stage 3-4; REM; min O2 sat	baseline, 3 mo, 6 mo	
2	Sleep study measures	AHI	baseline, 6 mo	
3	QoL	SF-36	baseline, 3 mo, 6 mo	
4	Compliance	mean h per night	3 mo, 6 mo	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SE*	P	Value	SE*	P
Meurice, 2007 France 17638595	Epworth		**Tx**	AutoSet	3 mo	15	12.9	4.3	3.8	2.5	-9.1			-3.3	1.727	0.056 NS btw groups (actual values not specified)
			Cx	fixed	3 mo	14	10.6	5.2	4.8	5.5	-5.8					NS btw groups (actual values not specified)
Meurice, 2007 France 17638595	Epworth		**Tx**	AutoSet	6 mo	15	12.9	4.3	5.2	4.1	-7.7			-3	1.753	0.087 NS btw groups (actual values not specified)
			Cx	fixed	6 mo	14	10.6	5.2	5.9	5.1	-4.7					NS btw groups (actual values not specified)
Meurice, 2007 France 17638595	Stage 3-4 sleep	%	**Tx**	AutoSet	6 mo	15	25.5	14.7	21.1	13	-4.4			-5.2	4.238	0.22 NS btw groups (actual values not specified)
			Cx	fixed	6 mo	14	17.1	7	17.9	9.3	0.8					NS btw groups (actual values not specified)
Meurice, 2007 France 17638595	REM	%	**Tx**	AutoSet	6 mo	15	18.9	6.6	16.5	7.7	-2.4			-2.9	2.342	0.216 NS btw groups (actual values not specified)
			Cx	fixed	6 mo	14	19.1	5.9	19.6	4.4	0.5					NS btw groups (actual values not specified)
Meurice, 2007 France 17638595	minimum O2 sat	%	**Tx**	AutoSet	6 mo	15	82.1	12.8	88.6	4.9	6.5			0.2	3.71	0.957 NS btw groups (actual values not specified)
			Cx	fixed	6 mo	14	82.3	9.9	88.6	3.4	6.3					NS btw groups (actual values not specified)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SE*	P	Value	SE*	P
Meurice, 2007 France 17638595	AHI		**Tx**	AutoSet	6 mo	15	53.4 (17 pts)	15.1	2.3 (15 pts)	2.9	-51.1	3.35		2.6	5.85	0.657
			Cx	fixed	6 mo	14	56.1 (17 pts)	21.4	2.4 (14 pts)	3.4	-53.7	4.8				NS btw groups (actual values not specified)
Meurice, 2007 France 17638595	SF-36 (emotional items)		**Tx**	AutoSet	3 mo	15	45.7	7.9	49.7	10	4			-2.2		NS btw groups (actual values not specified)
			Cx	fixed	3 mo	14	43.1	9.4	49.3	7.7	6.2					NS btw groups (actual values not specified)
Meurice, 2007 France 17638595	SF-36 (emotional items)		**Tx**	AutoSet	6 mo	15	45.7	7.9	46.2	13.3	0.5			-3.7		NS btw groups (actual values not specified)
			Cx	fixed	6 mo	14	43.1	9.4	47.3	8.7	4.2					NS btw groups (actual values not specified)
Meurice, 2007 France 17638595	SF-36 (physical items)		**Tx**	AutoSet	3 mo	15	48.6	5.3	48.6	6.4	0			-2.8		NS btw groups (actual values not specified)
			Cx	fixed	3 mo	14	45.6	8.6	48.4	9.2	2.8					NS btw groups (actual values not specified)
Meurice, 2007 France 17638595	SF-36 (physical items)		**Tx**	AutoSet	6 mo	15	48.6	5.3	47.8	8.7	-0.8			-2.7		NS btw groups (actual values not specified)
			Cx	fixed	6 mo	14	45.6	8.6	47.5	9.0	1.9					NS btw groups (actual values not specified)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SE*	P	Value	SE*	P
Meurice, 2007 France 17638595	Compliance	mean h/night	**Tx**	AutoSet	3 mo	15	NA		6	1.5				-0.1	0.35	NS btw groups (actual values not specified)
			Cx	fixed	3 mo	14	NA		6.1	1.1						NS btw groups (actual values not specified)
Meurice, 2007 France 17638595	Compliance	mean n/night	**Tx**	AutoSet	6 mo	15	NA		6.1	1.6				-0.4	0.45	0.375 NS btw groups (actual values not specified)
			Cx	fixed	6 mo	14	NA		6.5	1.8						NS btw groups (actual values not specified)

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
fixed CPAP	18	technical problem (1/17); stopped CPAP or no follow up PSG (2/17)
AutoSet	12	technical problem (1/17); stopped CPAP or no follow up PSG (1/17)

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	y	y	nd	nd	nd	y	n	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	y (?)	y	y	n	y				
Reasons for drop-outs:										
Other Issues:	unclear how the pts were prospectively recruited;									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments: only the comparative data from AutoSet were extracted (data from the other 3 active auto-titrated devices were not extracted).

A.

Author, Year	Mortimore, 1998			**Intervention 1**	mask CPAP
PMID*	9741373	**RefID**	8614	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	nasal CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
no explicit criteria stated; consecutive newly dx'd pts with sleep apnea hypopnea	nd	nd	nd	no	UK	Wellcome Trust	no	no	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**20**	nd	52	nd	32±1 (SE)			
Cx	**20**	nd	52	nd	32±1 (SE)			
Total	**20**	nd	52	nd	32±1 (SE)	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	nd
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	20	35±5.2 (SE)						
Control:	20	35±5.2 (SE)						
Total:	20	35±5.2 (SE)	nd	nd	nd	nd	0	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG (?)	nd	nd	nd	nd	nd	separate (?)	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	mask CPAP	Respironics (PA, US)	titration using a nose mask
2				
3				
Control	PAP	nasal CPAP	Resmed (Sydney, Australia) or Respironics	titration using a nose mask
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	sleepiness measures	Epworth	4 wk	
2	Compliance	h/night	4 wk	
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SE*	Value	SD/SE*	P	Value	SD/SE*	P
Mortimore, 1998 UK 9741373	Epworth		Tx	mask CPAP	4 wk	nd	nd		9.8	0.9				1.6	0.62	<0.01 (Final value btw groups)
			Cx	nasal CPAP	4 wk	nd	nd		8.2	0.9						
Mortimore, 1998 UK 9741373	Compliance	h/night	Tx	mask CPAP	4 wk	nd	nd		4.3	0.5				-1	95%CI (-1.8 to -0.3)	0.01 (Final value btw groups)
			Cx	nasal CPAP	4 wk	nd	nd		5.3	0.4						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	n	nd	nd	y	NA	NA	n
	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?			If a Crossover study, was the Washout period adequate?
	n	n	n	y	n	y	n			
Reasons for drop-outs:										
Other Issues:	both arms titrated using nasal CPAP; no washout period reported; small study; incomplete reporting									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Neill, 2003			**Intervention 1**	Heated humidity CPAP
PMID*	12952257	**RefID**	4610	**Intervention 2**	
Key Question(s)	5- CPAP vs Cx			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	Sham humidity CPAP
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
-newly diagnosed OSAS of sufficient severity to warrant treatment with nCPAP	Significant nasal obstruction unable to breathe via a nasal route) or were unable to tolerate nCPAP during the titration study, required treatment for respiratory tract infection in the previous month, were mentally or legally incapacitated or suffered significant comorbidity, including psychiatric or cerebrovascular disease and respiratory or cardiac failure. Also, patients requiring supplemental oxygen were excluded.	nd	nd	n	New Zealand	Otago University research grant	A power calculation based on a parallel design assumed a SD for the primary outcome variable (compliance) of 1.97 h A sample size per treatment arm of 42 has an 80% power to detect a difference of 1.22 h at a type-one error rate of 5%.	y	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**42 (37)**							
Cx	**42 (37)**							
Total	**42 (37)**	89%	48.7	nd	34.8	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	RDI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	**37(42)**							
Control:	**37(42)**							
Total:	**37(42)**	50.1±25.7	12.1	nd	nd	Nd	Nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
RDI = 50.1								

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	Nd	nd	obstructive apnoea was defined as cessation of breathing for 10 seconds or more with ongoing respiratory effort. 10 second apnoea or longer plus cessation of airflow was defined as a central apnoea; combinations of central and obstructive apnea lasting ≥10 s.	>50% reduction in the amplitude of at least two of the three respiratory channels (nasal pressure, chest or abdominal effort) for ≥10 s	nd	Either (split if severe OSAS)	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	Heated humidity CPAP	Sullivan Elite; ResMed Ltd, Sydney, Australia	Humidity was achieved by passing air from the CPAP machine through a heated water chamber (HC100; Fisher and Paykel HealthCare Ltd, Auckland, New Zealand).
2				
3				
Control	PAP	Placebo humidity CPAP	Sullivan Elite; ResMed Ltd, Sydney, Australia	HC100 unit was used without the heating unit turned on and the chamber was used without added water connected via tubing to the CPAP machine
For CPAP:		**How was the Pressure selected?**	manually titrated without added humidity by an experienced polysomnography technician.	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	ESS	3 weeks	
2	General symptom scales	Upper airway symptoms	3 weeks	Dry nose, sinus infection, cough, etc.
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD	Value	SD/SE*	P	Value	SE*	P
Neill 2003 New Zealand 12952257	ESS	scale	**Tx**	Heated humidity CPAP	3 weeks	37	12.1	5.1	4.1	2.1	-8	Nd	<0.01	-0.4	0.446 nd	0.37
			Cx	Placebo humidity CPAP	3 weeks	37	12.1	5.1	4.5	3.1	-7.6	nd	<0.01			
	Compliance	h/d	**Tx**	Heated humidity CPAP	3 weeks	37	-		5.7	1.5				0.4	0.05, 0.76 (CI)	0.03
			Cx	Placebo humidity CPAP	3 weeks	37	-		5.3	1.7						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Marshall, 2005 New Zealand 15860720	Upper airway symptoms	All except "median symptom frequency"	3 weeks	Heated humidity CPAP	37	Placebo humidity CPAP	37	0					
	Upper airway symptoms	median symptom frequency	3 weeks	Heated humidity CPAP	37	Placebo humidity CPAP	37	Heated humidity CPAP	Net difference	-1	nd	0	<0.02

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Both	12%	Three developed acute respiratory tract infections (two while receiving placebo humidity and one while receiving heated humidity). One patient breached the protocol by continuing to use water in the humidification chamber during the nCPAP placebo humidity arm of the trial and another patient was lost to follow-up.

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	y	y	n	y	NA	NA	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	y	y	N	y

Reasons for drop-outs:	Three developed acute respiratory tract infections (two while receiving placebo humidity and one while receiving heated humidity). One patient breached the protocol by continuing to use water in the humidification chamber during the nCPAP placebo humidity arm of the trial and another patient was lost to follow-up.
Other Issues:	
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Nilius, 2006			**Intervention 1**	C-flex
PMID*	17035433	**RefID**	3650	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	CPAP
Extractor	si			**Comments**	randomized cross over treatments for 2 nights in the laboratory, the treatment received at the 2nd night continued on for the next 7 wks

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA with AHI >20	acute infection, cardiac disease, NYHA 3 or 4, acute pulmonary thromboembolism, inability to follow directions	>20	nd	no	Germany	industry (?)	no	yes	yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**25**							
Cx	**26**							
Total	**51**	88	57	nd	32.7±5.5	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx	none							
Cx	none							
Total	none							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	25	nd	10.9					
Control:	26	nd	10.2					
Total:	51	53.3±21.2	10.5	nd	nd	nd	0	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	nd	↓ flow ≥20% for ≥10 s	↓ flow ≥50% for ≥10 s		separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	pressure relief CPAP	C-flex (Respironics, PA)	setting 3 (max reduction at expiration)
2				
3				
Control	PAP	CPAP		to abolish snoring, resp related arousals, and to reach AHI <5
For CPAP:		**How was the Pressure selected?**	manual	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth	baseline, 7 wk	
2	Compliance	mean h per night	7 wk	
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
Nilius, 2006 Germany 17035433	Epworth		Tx	C flex	7 wk	25	10.9		5.8		-5.1			-1		0.83 (Final value btw groups)
			Cx	CPAP	7 wk	26	10.2		6.1		-4.1					
Nilius, 2006 Germany 17035433	Compliance	h/night	Tx	C flex	7 wk	25	NA		5.3							0.99 (Final value btw groups)
			Cx	CPAP	7 wk	26	NA		5.2							

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
C flex or CPAP	2%	refused further participation (1/52)

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			C flex	CPAP		
Nilius, 2006 Germany 17035433	mouth dryness	7 wk		more		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	y	y	nd	y	n	NA	n

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	y	y	y	n	y		
Reasons for drop-outs:	refused further participation							
Other Issues:	unclear how the pts were recruited							
Overall Quality (A, B, C)	**B**							

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Nolan, 2007			**Intervention 1**	auto PAP
PMID*	17326544	**RefID**	3654	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	fixed CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; ; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA with AHI ≥5 and <30; waiting for CPAP trial; Epworth ≥7	known CVD other than HTN; previous CPAP; chronic airway disease; upper airway surgery	≥5	nd	no	Ireland	not industry	Yes. 28 per arm	no	yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**34 (29)**	90% (26/29)	53	nd	29.9±4.7	47% (>140/90)		
Cx	**34 (29)**	90% (26/29)	53	nd	29.9±4.7	47% (>140/90)		
Total	**34 (29)**	90% (26/29)	53	nd	29.9±4.7	47% (>140/90)	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx	no prior CPAP							
Cx	no prior CPAP							
Total	no prior CPAP							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	29							
Control:	29							
Total:	29	14.7±8	12.3±4	nd	nd	nd	0	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	nd	nd	nd		separate (?)	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto PAP	Auto T (ResMed Ltd, UK)	4 to 20 cm H2O
2				
3				
Control	PAP	CPAP	Sullivan Elite 6 (ResMed Ltd, UK)	
For CPAP:		**How was the Pressure selected?**	95th %tile pressure of an overnight autotitration study	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth	baseline, 8 wk	
2	Compliance	mean h per night	8 wk	
3	Sleep study measures	AHI; min O2; arousals; sleep efficiency; REM	baseline, 8 wk	
4				

* QoL; ; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; ; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference (Final test – Final control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Nolan, 2007 Ireland 17326544	AHI		**Tx**	auto PAP	8 wk	29	14.7	8	2.7	2.1	-12		<0.001	-0.8	0.556	0.15
			Cx	CPAP	8 wk	29	14.7	8	3.5	3.5	-11.2		<0.001			
Nolan, 2007 Ireland 17326544	Epworth		**Tx**	auto PAP	8 wk	29	12.3	4	8.6	4	-3.7		<0.001	0.9	0.963	0.35
			Cx	CPAP	8 wk	29	12.3	4	7.7	4.6	-4.6		<0.001			
Nolan, 2007 Ireland 17326544	min SaO2	%	**Tx**	auto PAP	8 wk	29	79	11.5	87.5	3.5			<0.001	4.8	6.216	0.44
			Cx	CPAP	8 wk	29	79	11.5	82.7	11			<0.001			
Nolan, 2007 Ireland 17326544	arousals	number per h	**Tx**	auto PAP	8 wk	29	16	14	2	3			<0.001	-3	1.382	0.03
			Cx	CPAP	8 wk	29	16	14	5	4			<0.001			
Nolan, 2007 Ireland 17326544	sleep efficiency	%	**Tx**	auto PAP	8 wk	29	79	9	83	8			0.15			0.39
			Cx	CPAP	8 wk	29	79	9	84	10			0.02			
Nolan, 2007 Ireland 17326544	REM	%	**Tx**	auto PAP	8 wk	29	17.6	5.1	17.1	7.3			0.21	-2.5	1.329	0.06
			Cx	CPAP	8 wk	29	17.6	5.1	19.6	6.5			0.40			
Nolan, 2007 Ireland 17326544	Compliance	h per night	**Tx**	auto PAP	8 wk	29	NA		4.9	2.1				0	0	0.94
			Cx	CPAP	8 wk	29	NA		4.9	1.9						

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference (Final test – Final control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Nolan, 2007 Ireland 17326544	BP	mm Hg	**Tx**	auto PAP	8 wk	29	132/84	23/13	nd				NS			
			Cx	CPAP	8 wk	29	132/84	23/13	nd				NS			
Nolan, 2007 Ireland 17326544	SWS	%	**Tx**	auto PAP	8 wk	29	13.7	7.8	15	7.4			0.45	0.3	1.833	0.87
			Cx	CPAP	8 wk	29	13.7	7.8	14.7	8.4			0.47			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
APAP or CPAP	15% (5/34)	1 had unacceptable side effects; 4 failed to follow up

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	n	y	nd	y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	n	y; no (power was based on 20% difference in compliance, actual reported difference = 0)			no washout
Reasons for drop-outs:										
Other Issues:	relatively small sample size									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Noseda, 2004			**Intervention 1**	auto PAP
PMID*	15249439	**RefID**	4623	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
high variability in pressure requirement during 2 wk run-in period in APAP; AHI >20 and a microarousal index >30	previous tx with CPAP, central sleep apnea, Cheyne-Stokes, facial or pharyngeal problems needing surgery, night or rotating shift work, severe CHF, COPD, seizure, mental retardation, sedative, hypnotic, or antidepressant tx; UPPP, prolonged hypoventilation during REM	nd	nd	no	Belgium	nd	no	yes	no
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**27 (24)**							
Cx	**27 (24)**							
Total	**27 (24)**	96	49	nd	32.3±4.9	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	pts had high variability in pressure requirement during 2 wk run-in period in APAP
	Treatments used (prior to trial, including surgery)							
Tx	none							
Cx	none							
Total	none							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	24	50.9±25.2	10.7±2.4	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG			no flow ≥10 s	↓flow ≥50% with O2 desat ≥3%		separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto PAP	GK418A (Malinckrodt, France)	
2				
3				
Control	PAP	CPAP	GK418A (Malinckrodt, France)	
For CPAP:		**How was the Pressure selected?**	manual; until most apneas and hypopneas were abolished and all snoring was eliminated	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth, subjective sleep latency	baseline, 8 wk	
2	Sleep study measures	Apnea Index	baseline, 8 wk	
3	Compliance	h per effective night	8 wk	
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; ; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Noseda, 2004 Belgium 15249439	Epworth		**Tx**	APAP	8 wk	24	10.7 (27 pts)	2.4	5.1	2.8	nd			-1	0.388	<0.01 (Final value btw groups)
			Cx	CPAP	8 wk	24	10.7 (27 pts)	2.4	6.1	2.8	nd					
Noseda, 2004 Belgium 15249439	self-estimated sleep latency	min	**Tx**	APAP	8 wk	24	NA		12	12						NS (Final value btw groups)
			Cx	CPAP	8 wk	24	NA		14	12						
Noseda, 2004 Belgium 15249439	Compliance	h use per effective night	**Tx**	APAP	8 wk	24	NA		5.3	1.9						NS (Final value btw groups)
			Cx	CPAP	8 wk	24	NA		5.5	1.5						
Noseda, 2004 Belgium 15249439	Apnea index		**Tx**	APAP	8 wk	24	24.6 (27 pts)	22.6	0.45 (median)	0-5.8 (range)						NS (Final value btw groups)
			Cx	CPAP	8 wk	24	24.6 (27 pts)	22.6	0.40 (median)	0-2.40 (range)						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	8%	1/13 (data could not be downloaded)
APAP	14%	1/14 (did not tolerate machine); 1/14 (felt well, refused to switch to alternate mode)

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	y	n	nd	y	n	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	y				
Reasons for drop-outs:										
Other Issues:	no power calculation									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Nussbaumer, 2006			**Intervention 1**	auto PAP
PMID*	16537862	**RefID**	3659	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	fixed CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
consecutive pts with excessive sleepiness and AHI >10 obstructive events per h	CHF, chronic rhinitis, other sleep disorders	>10	nd	no	Switzerland	industry	30 per arm (?post hoc)	yes	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**34 (30)**	90	49	nd	31.1±0.6 (SE)			
Cx	**34 (30)**	90	49	nd	31.1±0.6 (SE)			
Total	**34 (30)**	90	49	nd	31.1±0.6 (SE)	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	sleep resistance* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	30	41.1±3.6 (SE)	12.7±0.6 (SE)	26.3±2.1 (SE)				
Control:	30	41.1±3.6 (SE)	12.7±0.6 (SE)	26.3±2.1 (SE)				
Total:	30	41.1±3.6 (SE)	12.7±0.6 (SE)	26.3±2.1 (SE)	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
unattended home PSG	nd	nd	no flow ≥10 s	↓ flow ≥50% with O2 desat ≥3%	nd	separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto PAP	REMStar Auto	5 to 15 cm H2O
2				
3				
Control	PAP	fixed CPAP	REMStar Auto	90th %tile pressure
For CPAP:		**How was the Pressure selected?**	manual	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth; sleep resistance	baseline, 1 mo	
2	Sleep study measures	AHI, ODI	baseline, 1 mo	
3	QoL	SF-36	baseline, 1 mo	
4	Compliance	h per night	1 mo	

* QoL; ; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference (Final test – control)		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SD/SE*	P
Nussbaumer, 2006 Switzerland 16537862	Epworth		Tx	auto PAP	1 mo	30	12.7	0.6	6.6	0.6			<0.05	0	0.688 95%CI - 1.6 to 1.1	1.00 NS
			Cx	CPAP		30	12.7	0.6	6.6	0.6			<0.05			
Nussbaumer, 2006 Switzerland 16537862	sleep resistance	min	Tx	auto PAP	1 mo	30	26.3	2.1	37.2	1.1	10.9	2	<0.001			NS

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference (Final test – control)		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SD/SE*	P
			Cx	CPAP		30	26.3	2.1	34.4	1.7	8.1	1.7	<0.05			
Nussbaumer, 2006 Switzerland 16537862	AHI		**Tx**	auto PAP	1 mo	30	41.1	3.6	4.6	0.7			<0.05	-0.8	95% CI: -1.7, +3.3 1.276	0.531 (NS)
			Cx	CPAP		30	41.1	3.6	5.4	1.2			<0.05			
Nussbaumer, 2006 Switzerland 16537862	ODI		**Tx**	auto PAP	1 mo	30	29	4	4.2	0.7	-24.8	3.8	<0.05			NS
			Cx	CPAP		30	29	4	4.1	0.7	-25	3.5	<0.05			
Nussbaumer, 2006 Switzerland 16537862	Compliance	mean h used per night	**Tx**	auto PAP	1 mo	30	NA		5.1	0.3			NS	0.3	0.3	NS
			Cx	CPAP		30	NA		4.8	0.3						
Nussbaumer, 2006 Switzerland 16537862	SF-36 vitality		**Tx**	auto PAP	1 mo	30	43	4	67	3			<0.05			NS
			Cx	CPAP		30	43	4	66	3			<0.05			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Nussbaumer, 2006 Switzerland 16537862	SF-36	Physical functioning	1 mo	auto PAP	30	CPAP	30	0					
		role physical	1 mo	auto PAP	30	CPAP	30	0					
		bodily pain	1 mo	auto PAP	30	CPAP	30	0					
		general health	1 mo	auto PAP	30	CPAP	30	0					
		vitality	1 mo	auto PAP	30	CPAP	30	0					
		social funcitoning	1 mo	auto PAP	30	CPAP	30	0					
		role emotional	1 mo	auto PAP	30	CPAP	30	0					
		mental health	1 mo	auto PAP	30	CPAP	30	0					

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
auto PAP or CPAP	12%	given humidifiers (2/34); claustrophobia (1/34); not available for follow up (1/34)

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			APAP or CPAP			
Nussbaumer, 2006 Switzerland 16537862	claustrophobia	1 mo	1/34			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	y	nd	nd	y	n	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	n	n	y	y	n	y	? post hoc analysis			no apparent crossover
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Patruno, 2007			**Intervention 1**	auto PAP
PMID*	17494789	**RefID**	3687	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	fixed CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
newly dx'd OSA (AHI >20; Epworth >12)	previous tx for OSA; BP meds other than ACE inhibitors; Ca channel blockers; and diuretics	nd	nd	no	Italy	University	no	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**?(15)**	80	46.7		36.4±7.1	60%		
Cx	**?(16)**	81	47		35.2±4	50%		
Total	**40(31)**	81	48		36.5±3.9	55%	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	some with HTN; mean BMI = 36.5
	Treatments used (prior to trial, including surgery)							
Tx	none							
Cx	none							
Total	none							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	15	47.3±14.7	15.8±3.5					
Control:	16	46±14.6	14.1±1.7					
Total:	31	46.5±13.5	15±2.7	nd	nd	nd	0	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
lab PSG	A+H per h	# of SaO2 desat >3% from baseline	no flow >10 s	↓ ≥30% thoracoabdominal movement or airflow ≥10 s and >3% desat		separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto PAP	Autoset T (ResMed, Australia)	4 to 15 cm H2O
2				
3				
Control	PAP	CPAP	Somnoconfort (Weinmann, Germany)	pressure set in 1 cm increment until obstructive apnea, hypopnea, snoring and arousal associated with flow-limited breathing disappeared
For CPAP:		**How was the Pressure selected?**	manual	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	mean h per night	3 mo	
2	Sleep study measures	AHI; ODI; O2 nadir	baseline, 3 mo	
3	Sleepiness measures	Epworth		
4	CVD	BP	baseline, 3 mo	

* QoL; ; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; ; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Patruno, 2007 Italy 17494789	Epworth		**Tx**	auto PAP	3 mo	15	15.8	3.5	nd		nd		<0.05	nd		NS
			Cx	CPAP	3 mo	16	14.1	1.7	nd		nd		<0.05			
Patruno, 2007 Italy 17494789	AHI		**Tx**	auto PAP	3 mo	15	47.3	14.7	6	2.3	-41.3	3.536	<0.05	2.7	4.952	0.586 <0.001 (Final value diff btw groups)
			Cx	CPAP	3 mo	16	46	14.6	2	1.6	-44	3.467	<0.05			
Patruno, 2007 Italy 17494789	ODI		**Tx**	auto PAP	3 mo	15	41.6	14.8	4.8	2.1			<0.05			<0.001 (Final value diff btw groups)
			Cx	CPAP	3 mo	16	38.4	13	1.1	1.3			<0.05			
Patruno, 2007 Italy 17494789	SaO_2 nadir	%	**Tx**	auto PAP	3 mo	15	71.7	10.6	88.1	1.6	16.4	2.56	<0.05	-4.4	3.774	0.244 NS (Final value diff btw groups)
			Cx	CPAP	3 mo	16	70	11.7	90.8	1.3	20.8	2.78	<0.05			
Patruno, 2007 Italy 17494789	systolic BP		**Tx**	auto PAP	3 mo	15	142	12	136	6	-6	2.68	NS	6	3.528	0.089 nd
			Cx	CPAP	3 mo	16	144	10	132	8	-12	2.29	<0.001			
Patruno, 2007 Italy 17494789	diastolic BP		**Tx**	auto PAP	3 mo	15	87.5	4	86	4	-1.5	1.03	NS	7.5	1.678	0.00 nd
			Cx	CPAP	3 mo	16	88	4	79	6	-9	1.32	<0.001			
Patruno, 2007 Italy 17494789	Compliance	mean h /day	**Tx**	auto PAP	3 mo	15	NA		6.2	0.8				0.2	0.231	0.387 NS (Final value diff btw groups)
			Cx	CPAP	3 mo	16	NA		6	1						

* Delete or correct the incorrect value/item. If change, highlight yellow.

** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
auto PAP or CPAP	22.5%	voluntarily withdrew (6/40); low compliance (<4 h/d) (3/40)

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	n	nd	nd	nd	y	n	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	y				
Reasons for drop-outs:										
Other Issues:	small sample size; incomplete reporting									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Pepin 2009			**Intervention 1**	CPAP
PMID	19567496	**RefID**	* 3695	**Intervention 2**	C-Flex
Key Question(s)	5			**Intervention 3**	
Design*	RCT			**Control**	
Extractor	DM			**Comments**	

* RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Newly diagnosed sleep apnea patients ➢ 18 years of age ➢ Referred for CPAP treatment by the consulting physician	➢ Pregnant ➢ medically unstable ➢ had predominantly central sleep apnea.	≥ 15	Nd	Y	France	Commercial and non-commercial	N	Y	Y

* or Cochrane number

C. BASELINE CHARACTERISTICS: If data provided per group only, record Control group and color red or highlight turquoise *unless* ***sig difference (record both and bold/italicize)***

N enrolled, total	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
218	71	56 ± 9	nd	31 ± 6.3	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	12.2	nd	nd	nd	nd	nd	no

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	AHI ≥ 30 events/h (%)
Treatment:	83	42.7 ± 20.8	11.7 ± 5.1	nd	nd	nd	nd (Newly diagnosed)	68.7
Control:	82	44.9 ± 21.8	11.4 ± 5.2	nd	nd	nd	nd (Newly diagnosed)	80.2
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
						Mean nocturnal SaO_2: (%): Tx: 93 ± 2.9 Control: 92.6 ± 3.6 Minimal nocturnal SaO_2,(%): Tx: 78.3 ± 10.7Control: 77.5 ± 11.1		

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥15	nd	≥ 30% reduction of airflow followed by a 3% desaturation and/or a microarousal	nd	Separate night	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	C-Flex	REMstar Auto (Respironics)	nd
Control	**Conventional CPAP**			
For CPAP:		**How was the Pressure selected?**	Effective pressure was determined using 2 nights with an autotitration device without C-Flex activated. The pressure range used during the titration was left to the judgment of the physicians. Following the autotitration period, fixed CPAP was used at the pressure that was effective for > 90% of the night after visual editing of the device curves.	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; Control; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES **(all outcomes listed should match one-for-one with outcomes in results sections)**

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	Objective compliance	3 month	Hours of use per night
2	Sleepiness measures	ESS scores	3 month	Average score on the Epworth sleepiness scale (ESS) questionnaire

3	QoL	Quality of life measured by SF-36, and Grenoble SAQOL questionnaires	3 month	Average score on the Medical Outcomes Study 36-item short form [SF-36]) Grenoble Sleep Apnea Quality of Life [GrenobleSAQOL]) - a questionnaire specific to OSA (The GrenobleSAQOL includes 40 questions rated according to a 5-point scale, with higher scores indicating worse conditions (13 related to sleep quality, 5 related to sleepiness, 6 related to every-day life, 7 related to emotions, and 9 related to "other functioning")).

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Intervention (control in bold)	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
						Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit	Intervention (treatment in bold)	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Change (Δ test – Δ control)		
						Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
Pepin 2009 France 19567496	Objective compliance	Hrs of use /night	**C-Flex** / CPAP	3 months	165	0	0	**4.98** / 4.91	**1.96** / 2.41	**4.98** / 4.91					
Pepin 2009 France 19567496	ESS scores		**C-Flex** / CPAP	3 months		**11.7**/11.4	**5.1**/5.2	**7.8**/8.0	**4.6**/5.5	**- 3.9** / -3.4			- 0.5		
Pepin 2009 France 19567496	Quality of life measured by SF-36, and Grenoble SAQOL questionnaires		**C-Flex** / CPAP	3 months											

* Delete the incorrect value

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Intervention (control in bold)	Follow-up	Results

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION / LACK OF COMPLIANCE

Intervention	Reasons
C-Flex	initial refusal of PAP treatment
CPAP	initial refusal of PAP treatment

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome	Intervention (control in bold)	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit	Intervention (control in bold)	Follow-up	No. Analyzed	Baseline		Final		Change			Net Change (Δ test – Δ control)		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P

* Delete the incorrect value

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome	Intervention (control in bold)	Follow-up	Results

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	y	n	y	y	y	y	nd	Y
	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)			
	y	n	n	y	N	y			

Reasons for drop-outs:	The main reason was due to an initial refusal of PAP treatment
Other Issues:	
Overall Quality (A, B, C)	**A**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention for quality to be A
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments
QOL scores were not reported in text; and Symptom scores not reported.

A.

Author, Year	Pépin, 2009			**Intervention 1**	C-Flex
PMID	19567496	**RefID**	3695	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design*	RCT			**Control**	CPAP (sham C-Flex)
Extractor	EB			**Comments**	Also 6 month cohort data (open label, cross-over allowed). Not included here.

* RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	Exclusion	AHI Criteria	Enrollment Years	Multicenter?	Country	Funding source	Power calculation? (specify outcome)	Blinding, patient	Blinding, outcome assessor
Newly diagnosed SA Age >18 y Referred for CPAP	Pregnant Medically unstable Predominantly central SA	≥15	nd	Yes	France	Gov't Industry (Respironics)	nd	Yes	Yes

* or Cochrane number

C. BASELINE CHARACTERISTICS: If data provided per group only, record Control group and color red or highlight turquoise *unless* ***sig difference (record both and bold/italicize)***

N enrolled, total	Male, %	Age, y	Race	BMI*	HTN, % (how defined?)	AFib/AFlutter, %	CVD †, % (specifiy
218	72%	56	nd	31 ≥30 kg/m^2: 57%	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population (which?)**
nd	12% ("consumption")	nd	nd	nd	nd	nd	No
	Treatments used (prior to trial, including surgery)						
Tx							
Cx							
Total	None						

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	83	42.7±20.8	11.7±5.1 >12: 52%	nd	nd	nd	~0	None
Control:	82	44.9±21.8	11.4±5.2 >12:54%					

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify)	Other characteristics
None	nd	None

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
In-lab PSG or Cardio-respiratory polygraphy	≥15		Apnea: >10 s Hypo: ≥30% reduction of airflow, 3% desaturation and/or microarousal	NA	Separate (all referred for CPAP)	None

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	C-Flex	C-Flex	no specific
2				
3				
Control	PAP	CPAP (C-Flex not activated)	C-Flex	no specific
For CPAP:		**How was the Pressure selected?**	2 nights with an autotitration device without C-Flex activated (REMstar Auto; Respironics). Fixed CPAP at pressure effective >90% of night	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; Control; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; CFlex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	nd

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	Compliance	During 3 months	Downloaded from device; hours/night
2	Sleep study	AHI	During 3 months	Downloaded from device
3	Harms	Side effects	During 3 months	Questionnaire asking re: presence, absence, & severity
4	Sleepiness	ESS	3 mo	

5	QoL	SF-36	3 mo	
6	QoL	GrenobleSAQOL	3 mo	specific to OSA, 40 questions rated on 5 point scale, higher scores indicating worse conditions

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Intervention (control in bold)	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
						Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data).

Author, Year Country PMID	Outcome	Unit	Intervention (treatment in bold)	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference (test – control)		
						Value	SD	Value	SD	Value			Value	SD/SE*	P
Pépin, 2009 France 19567496	Compliance	hr/noc	**C-Flex**	3 mo	83	--		4.98	1.96	NA			+0.07		NS
			CPAP		82	--		4.91	2.41						
													Net Change (Δ test – Δ control)		
Pépin, 2009 France 19567496	ESS	score	**C-Flex**	3 mo	83	11.7	5.1	7.8	4.6	-3.9			-0.5	0.797	0.531 NS
			CPAP		82	11.4	5.2	8.0	5.5	-3.4					
Pépin, 2009 France 19567496	SF-36, 8 domains	score	C-Flex v CPAP	3 mo	110 v 108	Graphical data		Graphical data		Improved all except PF & BP (C-Flex & CPAP)					NS, all
Pépin, 2009 France 19567496	Grenoble SAQOL, 6 domains	score	C-Flex v CPAP	3 mo	110 v 108	Graphical data		Graphical data		Improved all domains					NS, all

* Delete the incorrect value

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Intervention (control in bold)	Follow-up	Results

Comments on Results	If we meta-analyze QoL, graphs can be digitized.

L. REASONS FOR TREATMENT DISCONTINUATION / LACK OF COMPLIANCE

Intervention	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. NO SUBGROUPS

P. MAJOR ADVERSE EVENTS

Author Year Country UI	Adverse Event	Follow-up	Intervention	Intervention		
Pépin, 2009 France 19567496	"Side Effects"	3 mo	nd	nd	NS	

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes (computer, stratified by centers in blocks)	Yes (central)	No	Yes	Yes	No. Claim ITT, but only completers analyzed)	Yes	NA	Yes
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**			
	Yes	No	Yes	Not compliance		Yes			

Reasons for drop-outs:	53/218: 27 refusal/discontinuation; 16 technical problems; 4 titration failure; 6 lost to follow-up
Other Issues:	Difficult to assess details of QoL, reported in small graphs only
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention for quality to be A
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Pepin 2009			**Intervention 1**	C-Flex
PMID	19567496	**RefID**		**Intervention 2**	
Key Question(s)	5,6			**Intervention 3**	
Design*	RCT			**Control**	CPAP
Extractor	KP			**Comments**	

* RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	Exclusion	AHI Criteria	Enrollment Years	Multicenter?	Country	Funding source	Power calculation? (specify outcome)	Blinding, patient	Blinding, outcome assessor
-Newly diagnosed sleep apnea patients ->18 years of age and -Referred for CPAP treatment by the consulting physician.	-Pregnant -medically unstable -predominantly central sleep apnea.		nd	Y	France	grants from "Comite´ National des Maladies Respiratoires" and Respironics.	nd	y	y

* or Cochrane number

C. BASELINE CHARACTERISTICS: If data provided per group only, record Control group and color red or highlight turquoise *unless* ***sig difference (record both and bold/italicize)***

N enrolled, total	Male, %	Age, y	Race	BMI*	HTN, % (how defined?)	AFib/AFlutter, %	CVD †, % (specifiy)
218	72%	56	nd	31	Nd	Nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	12.2	Nd	Nd	Nd	Nd	Nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	83	42.7	11.7	Nd	nd	Nd	Nd	Nd
Control:	82	44.9	11.4	nd	Nd	Nd	Nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>15 episodes of apnea and hypopnea per hour of sleep.		>30% reduction of airflow followed by a 3% desaturation and/or a microarousal		split	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP		
2	PAP	C-Flex	?	designed to give pressure relief during early exhalation while maintaining optimal pneumatic splinting
3				
Control				
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; Control; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; CFlex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	Compliance		
2	Harms	Side effects		
3		Comfort		
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes)

Author, Year Country PMID	Outcome	Intervention (control in bold)	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
						Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:

* RR, OR, HR, RD

J. RESULTS (continuous measures)

Author, Year Country PMID	Outcome	Unit	Intervention (treatment in bold)	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Change (Δ test – Δ control)		
						Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P

* Delete the incorrect value

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Intervention (control in bold)	Follow-up	Results

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION / LACK OF COMPLIANCE

Intervention	Reasons
Both	Refusal/discontinued

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome	Intervention (control in bold)	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit	Intervention (control in bold)	Follow-up	No. Analyzed	Baseline		Final		Change			Net Change (Δ test – Δ control)		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P

* Delete the incorrect value

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome	Intervention (control in bold)	Follow-up	Results

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
	y	Y (?)	n	y	y	y	y	n	y
	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)			
	y	n	y	y	y	y			
Reasons for drop-outs:	refusal								
Other Issues:									
Overall Quality (A, B, C)	B								

*non-randomized cannot be A, retrospective study is always C
N must be ≥X per intervention for quality to be A
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Pepin 2009	**Intervention 1**	CPAP plus C-FLEX
PMID	19567496	**Intervention 2**	CPAP
Key Question(s)	5,7	**Intervention 3**	
Design*	RCT	**Intervention 4**	
Extractor	NO	**Comments**	

* RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
>18 years Referred for CPAP by physician	Pregnant Medically unstable Central sleep apnea	?	nd	Y	France	Comite´ National des Maladies Respiratoires" and Respironics	Compliance	Y	Y

* or Cochrane number

C. BASELINE CHARACTERISTICS: If data provided per group only, record Control group and color red or highlight turquoise *unless* ***sig difference (record both and bold/italicize)***

N enrolled, total	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specifiy)**
218	Nd (data provided for male analyzed= 72% of 165)	56(9)	nd	31(6.3) 57.3 (% with BMI>=30)	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	11.4(5.2) 53.7 (% with ESS >=12)	nd	nd	nd	nd	nd	N

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:83	42.7(20.8)	11.7(5.1)					
Control:82	44.9(21.8)	11.4(5.2)					
Other Clinical symptoms, % (specify)					**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG or Cardio respiratory polygraphy	>=15		3% decline in O_2 saturation		Split night	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1		CPAP		
2		CFLEX	Respironics, Murrysville, PA	Gives pressure relief during exhalation to maintain optimal pneumatic splinting
3				
4				
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; Control; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; CFlex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	compliance	Objective compliance	3 months	Objective compliance over 3 months
2	QOL	QOL		
3	Sleepiness day time	Sleepiness day time		
4	tolerance	tolerance		
5	comfort	comfort		
6	Side effects	Side effects		

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes)

Author, Year Country PMID	Outcome	Intervention (control in bold)	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
						Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Pepin 2009 19567496													

* RR, OR, HR, RD

J. RESULTS (continuous measures)

Author, Year Country PMID	Outcome	Unit	Intervention (treatment in bold)	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Change (Δ test – Δ control)		
						Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
Pepin 2009 19567496	compliance		CFLEX		83			4.98	1.96						
			CPAP		82			4.91	2.41						

* Delete the incorrect value

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Intervention (control in bold)	Follow-up	Results

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION / LACK OF COMPLIANCE

Intervention	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome	Intervention (control in bold)	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit	Intervention (control in bold)	Follow-up	No. Analyzed	Baseline		Final		Change			Net Change (Δ test – Δ control)		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P

* Delete the incorrect value

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome	Intervention (control in bold)	Follow-up	Results

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)			

Reasons for drop-outs:	
Other Issues:	
Overall Quality (A, B, C)	

*non-randomized cannot be A, retrospective study is always C
N must be ≥X per intervention for quality to be A
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Piper, 2008			**Intervention 1**	bilevel PAP
PMID*	18203817	**RefID**	3709	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
BMI ≥30; compensated resp failure; no significant resp, neuromuscular or other disorder to explain↑$PaCO_2$; FEV1/FVC ≥70%	major psychiatric illness, current tx with PAP; significant and prolonged desat or CO_2 retention during an initial CPAP trial before enrollment into this study	nd	nd	no	Australia	government	yes; 13 per group to detect change in arterial CO_2 of 7 mm Hg	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**18**	50	47		54±9			
Cx	**18**	78	52		52±7			
Total	**36**	64	50		53	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd		yes, morbidly obese
	Treatments used (prior to trial, including surgery)							
Tx	none							
Cx	none							
Total	none							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	18		14 median (IQR 12-19)					
Control:	18		15 median (IQR 8-17)					
Total:	36	nd	14.5	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
nd	nd	nd	nd	nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	bilevel PAP		see online supplement
2				
3				
Control	PAP	CPAP		see online supplement
For CPAP:		**How was the Pressure selected?**	manual titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth	baseline, 3 mo	
2	QoL	SF-36	baseline, 3 mo	
3	Compliance	h/night use		
4	Psych scale	Psychomotor vigilance test	baseline, 3 mo	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD*	Value	SD*	P	Value	SD/SE*	P
Piper, 2008 Australia 18203817	Epworth		**Tx**	BIPAP	3 mo	18	14 (median)	IQR (12-19)			-9	5	<0.001	-2.89	95% CI (-7.56 to 1.78)	0.21
			Cx	CPAP	3 mo	18	15 (median)	IQR (8-17)			-6	8	<0.05			
Piper, 2008 Australia 18203817	Compliance	mean h per night	**Tx**	BIPAP	3 mo	18			6.1	2.1				0.33	95% CI (-1.8 to 1.2)	0.66
			Cx	CPAP	3 mo	18			5.8	2.4						
Piper, 2008 Australia 18203817	SF-36 Physical		**Tx**	BIPAP	3 mo	18					20 median	!QR (9-34)				0.22
			Cx	CPAP	3 mo	18					7 median	!QR (-6-28)				
Piper, 2008 Australia 18203817	SF-36 Mental		**Tx**	BIPAP	3 mo	18					21 median	!QR (6-33)				0.28
			Cx	CPAP	3 mo	18					12 median	!QR (8-19)				
Piper, 2008 Australia 18203817	Psychomotor vigilance test Lapses		**Tx**	BIPAP	3 mo	18					-2 median	!QR (-4-0)				0.07
			Cx	CPAP	3 mo	18					0.6 median	!QR (0-0.5)				
Piper, 2008 Australia 18203817	Psychomotor vigilance test Median	ms	**Tx**	BIPAP	3 mo	18					-21 median	!QR (-29-0)				0.07
			Cx	CPAP	3 mo	18					9 median	!QR (-16-27)				

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD*	Value	SD*	P	Value	SD/SE*	P
Piper, 2008 Australia 18203817	Psychomotor vigilance test Mean of slowest 10% reaction	ms	**Tx**	BIPAP	3 mo	18					0.32 median	!QR 0.05-0.5)				0.03
			Cx	CPAP	3 mo	18					0.07 median	!QR (-0.2-0.2)				

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	y	y	n	nd	nd	y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	n	n	n	y	n	y				
Reasons for drop-outs:										
Other Issues:	unclear the proportion of pts with central apnea vs. OSA									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Planes, 2003			**Intervention 1**	home initiated auto PAP
PMID*	12683473	**RefID**	8705	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	lab initiated fixed CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
AHI ≥30; obstructive events >80%; clinical indication for nCPAP	nd	≥10	1998-1999	4 centers	France	industry (?)	no	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**18 (16)**	82%	54		33.6±6.7			
Cx	**17 (14)**	71%	54		30.9±6.1			
Total	**35 (30)**	77%	54	nd	32.4±6.5	20% (not defined)	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	"no comorbidities noted"	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	no prior CPAP							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	16	57.5±16.5	15.5±4.7					
Control:	14	61±17.4	14.7±3.9					
Total:	30	59.1	15.1	nd	nd	nd	0	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG			no flow >10 s	↓ ≥50% flow ≥10 s followed by eeg arousal		separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	home initiated auto PAP	REM+auto (Nellcore Puritan-Bennett, France)	home initiation; pressure set at 2 cm above to 4 cm below the maximum pressure to abort all obstructive events, including snoring and airflow limitation in all stages and positions
2				
3				
Control	PAP	lab initiated fixed CPAP	REM+auto (Nellcore Puritan-Bennett, France)	pressure set to abolish all obstructive events, including snoring and airflow limitation in all stages and positions.
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	AHI; REM; arousals	baseline, 2 mo	
2	Sleepiness	Epworth	baseline, 2 mo	
3	Compliance	mean h per night	2 mo	
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SE	P	Value	SD/SE*	P
Planes, 2003 France 12683473	AHI		Tx	auto PAP	2 mo	16	57.5	16.5	7.6	6.9	-49.9	3.588	<0.0001	0.7	5.489	0.899
			Cx	CPAP	2 mo	14	61	17.4	10.4	12.5	-50.6	4.153	<0.0001			
Planes, 2003 France 12683473	Arousal index		Tx	auto PAP	2 mo	16	44.4	19.1	13.7	7.8			<0.0001	3.3	5.327	0.536
			Cx	CPAP	2 mo	14	48.5	14.2	14.5	9.1			<0.0001			
Planes, 2003 France 12683473	REM	%	Tx	auto PAP	2 mo	16	12.4	7	16.6	6.5			<0.0001	0.5	3.029	0.869
			Cx	CPAP	2 mo	14	13.7	9.3	17.4	9.5			<0.0001			
Planes, 2003 France 12683473	Epworth		Tx	auto PAP	2 mo	16	15.5	4.7	7.5	3.4			<0.0001	-0.9	1.439	0.532
			Cx	CPAP	2 mo	14	14.7	3.9	7.6	3.4			<0.0001			
Planes, 2003 France 12683473	Compliance	h per night	Tx	auto PAP	2 mo	16	NA		4.5	1.7				-0.8		NS
			Cx	CPAP	2 mo	14	NA		5.3	1.4						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
auto PAP	11% (2/18)	did not tolerate PAP
fixed CPAP	18% (3/17)	did not tolerate CPAP

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	nd	nd	nd	y	n	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	n	see below	y	y	n	y				
Reasons for drop-outs:										
Other Issues:	small sample size; unclear how the pts were recruited									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Randerath, 2001			**Intervention 1**	auto PAP
PMID*	11254519	**RefID**	5747	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	fixed CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; ; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
newly dx'd OSA, AHI ≥10	nd	≥10	1999	no	Germany	industry	no	yes	yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**52 (46?)**	87	55	nd	32.4±5.8			
Cx	**52 (46?)**	87	55	nd	32.4±5.8			
Total	**52 (46?)**	87	55	nd	32.4±5.8	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	none (presumed)							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	52(?46)	35.1±26	11.1±5.1	nd	nd	nd	0	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
lab PSG	nd	nd	no flow ≥10 s	↓ flow ≥50% with desat ≥4%		separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto PAP	Somnosmart (Weinmann, Germany)	4 to 18 cm H2O
2				
3				
Control		fixed CPAP	Somnosmart (Weinmann, Germany)	pressure increased in 1 cm increment until minimal resp disturances (not specified) and resp-related arousals reduced to ≤5
For CPAP:		**How was the Pressure selected?**	manual	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth; REM, Stage 3 & 4	baseline, 6 wk	
2	Sleep study measures	AHI; min O2 sat	baseline, 6 wk	
3	Compliance	mean h / d	6 wk	
4				

* QoL; ; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; ; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference* (test – control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SE*	P
Randerath, 2001 Germany 11254519	Epworth		**Tx**	auto PAP	6 wk	52(?46)	11.1	5.1	7.8	4.7			<0.05	-1	0.645	0.121 NS (?)
			Cx	CPAP	6 wk	52(?46)	11.1	5.1	8.8	4.6			NS			
Randerath, 2001 Germany 11254519	AHI		**Tx**	auto PAP	6 wk	52(?46)	35.1	26	5	5.2			<0.001	0.7	0.808	0.386
			Cx	CPAP	6 wk	52(?46)	35.1	26	4.3	6.3			<0.001			
Randerath, 2001 Germany 11254519	stage 3 and 4 sleep	%	**Tx**	auto PAP	6 wk	52(?46)	14	11	14	9			NS	-1	1.248	0.423 NS
			Cx	CPAP	6 wk	52(?46)	14	11	15	9			NS			
Randerath, 2001 Germany 11254519	REM sleep	%	**Tx**	auto PAP	6 wk	52(?46)	11	8	17	6			<0.001	1	0.832	0.229 NS (?)
			Cx	CPAP	6 wk	52(?46)	11	8	16	6			<0.001			
Randerath, 2001 Germany 11254519	min SaO2	%	**Tx**	auto PAP	6 wk	52(?46)	81	8	88	4			<0.001	-1	0.555	0.071 NS (?)
			Cx	CPAP	6 wk	52(?46)	81	8	89	4			<0.001			
Randerath, 2001 Germany 11254519	Compliance	h/d	**Tx**	auto PAP	6 wk	52(?46)	NA		5.26	1.58						NS
			Cx	CPAP	6 wk	52(?46)	NA		5.26	1.62						
Randerath, 2001 Germany 11254519	arousals	events per h	**Tx**	auto PAP	6 wk	52(?46)	34	21.7	10.9	5.7			<0.001	-1.7	1.02	0.095 NS
			Cx	CPAP	6 wk	52(?46)	34	21.7	12.6	8.3			<0.001			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
autoPAP or CPAP	11.5%	no follow up (1/52); left the study (2 in auto CPAP; 2 in CPAP); excluded 1 pt with bronchial carcinoma (1/52)

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	y	y	nd	y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	n	n	y	y	n	y				
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Randerath, 2003			**Intervention 1**	bilevel PAP
PMID*	12942031	**RefID**	4697	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	auto PAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; ; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
AHI ≥10; intolerance to CPAP during titration or needed pressure ≥12 cm H2O or central disturbance ≥10% of AHI, which increased with CPAP	COPD; central stimulants or suppressants; neurologic or psychiatric disorders	≥10	nd	no	Germany	industry	yes, ≥17 per group	no	yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**27 (27)**	85	57	nd	33.5±7.8	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	pts who did not tolerate conventional CPAP during titration
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	no prior CPAP							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	27	49±27.3	12.1±5.1	nd	nd	nd	0	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	nd	no flow ≥10 s	↓ effort ≥50% ≥10 s or any ↓ effort and arousal or with ↓O2 sat ≥4%		separate night	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	bilevel PAP	Vector Bi (Hoffrichter, Germany)	Insp pressure starts at 6 cm, increase until no resp disturbances and resp arousals ≤10/h, then decreased by 1 cm increment until disturbances reappeared; Min exp pressure 4 cm; diff between insp and exp pressure set to ≥4 cm (if insp Pressure >7 or ≥8 cm H2O)
2				
3				
Control	PAP	auto PAP	Somnosmart (Weiman, Germany)	4 cm minimum to 5 cm above insp pressure
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth	baseline, 6 wk	
2	Sleep study measures	AHI, min O2, S3/4, REM, AR	baseline, 6 wk	
3				
4				

* QoL; ; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value	SD/SE*	P
Randerath, 2003 Germany 12942031	AHI		**Tx**	bilevel PAP	6 wk	27 (?)	49	27.3	9.8	12.5	-39.2		<0.01			NS
			Cx	APAP	6 wk	27 (?)	49	27.3	13.8	13.2	-35.2		<0.01			
Randerath, 2003 Germany 12942031	min SaO2	%	**Tx**	bilevel PAP	6 wk	27 (?)	75.6	9.8	83	15.6			NS			NS
			Cx	APAP	6 wk	27 (?)	75.6	9.8	85	5.8			<0.05			
Randerath, 2003 Germany 12942031	Stage 3/4	%	**Tx**	bilevel PAP	6 wk	27 (?)	13.5	11.7	21.3	11.1			NS			NS
			Cx	APAP	6 wk	27 (?)	13.5	11.7	18.2	11.1			NS			
Randerath, 2003 Germany 12942031	REM	%	**Tx**	bilevel PAP	6 wk	27 (?)	12.9	8.3	11.9	7.1			NS			NS
			Cx	APAP	6 wk	27 (?)	12.9	8.3	12.9	7.5			NS			
Randerath, 2003 Germany 12942031	Arousals	number per h	**Tx**	bilevel PAP	6 wk	27 (?)	43	28.3	17.7	8.8			<0.01			NS
			Cx	APAP	6 wk	27 (?)	43	28.3	20.5	10.7			<0.01			
Randerath, 2003 Germany 12942031	Epworth		**Tx**	bilevel PAP	6 wk	27 (?)	12.1	5.1	8.4	4.7			NS	1.2	0.935	0.199 NS
			Cx	APAP	6 wk	27 (?)	12.1	5.1	7.2	5			<0.05			
Randerath, 2003 Germany 12942031	Compliance	% days used	**Tx**	bilevel PAP	6 wk	27 (?)	NA		94.4	14.8				4.8	4.051	0.236 NS
			Cx	APAP	6 wk	27 (?)	NA		89.6	24.1						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
bilevel PAP or APAP	26%	7/27 terminated participation prematurely; 3 failed to turn up for either of the f/u exams; one on APAP and 3 on bilevel PAP left the study

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	n	n	y	y	y	NA	NA	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	y	y			no washout
Reasons for drop-outs:										
Other Issues:	pts were randomized by drawing lots; stat calculations done in whole study population (unclear what assumptions were made for the missing participants)									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Reeves-Hoche, 1995			**Intervention 1**	bilevel PAP
PMID*	7842204	**RefID**	5755	**Intervention 2**	
Key Question(s)	5, 7			**Intervention 3**	
Design †	RCT			**Control**	CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA with AHI ≥10; pts who chose CPAP therapy	concomitant illness (cardiac, lung, neuromuscular, or musculoskeletal) required hospitalization 6 mo before dx; psychiatric or mental retardation that could affect cooperation; pregnancy or actively seeking pregnancy; unable to f/u	≥10	nd	yes (2)	US	industry	no	no	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**31 (26)**	62	48		40±1			
Cx	**52 (36)**	81	46		39±1			
Total	**83 (62)**	73	47		39.4	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	9 had restrictive lung pattern on PFTs 2° to obesity	increased BMI
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	no prior tx for CPAP							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	26	51±4.2						
Control:	36	52±3.1						
Total:	62	51.6	nd	nd	nd	nd	0	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥10		no flow during continued efforts to breathe	↓ insp volume of ≥50% with persistent resp efforts and a 4% drop in O2 Sat	presence of heavy snoring bothersome to bed partner or other household members	separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	bilevel PAP	BIPAP S	insp and exp pressure starts at 2 cm, increased together to abort apneas; then insp pressure increased to abort hypopneas and snoring
2				
3				
Control	PAP	CPAP	BIPAP S	starts at 4 cm, increased by 2.5 cm until apneas, hypopneas, snoring were abolished in REM and non REM sleep (maximum 20 cm)
For CPAP:		**How was the Pressure selected?**	manual titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	3 d, 2 wk

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	mean h per night	52 wk	
2	effective use			mask pressure time/machine-on time
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SD/SE*	P	Value	SD/SE*	P
Reeves-Hoche, 1995 US 7842204	Compliance	h/night	Tx	bilevel PAP	52 wk	26	NA		4.9	0.23				-0.1	0.213	0.638 NS
			Cx	CPAP	52 wk	36	NA		5	0.19						
Reeves-Hoche, 1995 US 7842204	effective use	%	Tx	bilevel PAP	52 wk	26	NA		82							NS
			Cx	CPAP	52 wk	36	NA		80							

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	1. drop out rate significantly higher in CPAP group (P=0.003) 2. effective use was higher in those with a higher AHI, lower in those with lower AHI (bilevel PAP, r=0.30, P<0.005; CPAP, r=0.33, P<0.001) 3. BMI associated with hours use in bilevel PAP (r=0.24, P=0.01), not in CPAP (r= -0.11, P=0.24) 4. Age was not associated with hours use in bilevel PAP (r= -0.16, P=0.09); was associated in CPAP (r= -0.23, P=0.005) 5. No correlation between sex and average hours use 6. mean hours use correlated with initial AHI (bilevel PAP, r=0.31, P=0.003; CPAP, r=0.23, P=0.05)

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
bilevel PAP or CPAP	25% (21/83)	not provided

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	n	nd	n	n	nd	n	n	n	NA	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	y	y				
Reasons for drop-outs:										
Other Issues:	randomization led to unbalanced groups; differential sex distribution in the two follow up groups; differential drop out rate between the 2 groups									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments
"randomization by binomial probability chart for 100 participants; a separate computer generated list of numbers for randomization was used by each center";

A.

Author, Year	Resta, 2004			**Intervention 1**	auto PAP
PMID*	15679008	**RefID**	4709	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
untreated OSA; RDI >30 (80% obstructive events); meets indications for CPAP (Am Thora Soc)	cardiac failure or lung disease	nd	nd	no	Italy	nd	no	yes	no
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	10 (?)		45.5		35.1±7.1			
Cx	10 (?)		50		38.3±7.2			
Total	20	90	33	nd	36.7	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	overweight
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	no prior treatment							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	10 (?)	48±14.3	15.7±5.1					
Control:	10 (?)	45.3±10.7	12±3.2					
Total:	20	46.7	13.9	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG			↓ flow of ≥90% ≥10 s	↓ flow of ≥50% and ↓O2Sat ≥4%		nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto PAP	AutoSet T (ResMed, Australia)	4 to 16 cm
2				
3				
Control	PAP	CPAP	Sullivan Elite (ResMed, Australia)	set during titration - lowest level that abolished all obstructive resp events
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	h per day	1 mo	
2	Sleepiness measures	Epworth	baseline, 1 mo	
3	Sleep study measures	RDI, sleep efficiency, S3/4, REM, AI, Min O2	baseline, 1 mo	
4				

* QoL; ; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; ; ; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SE*	P	Value	SE*	P
Resta, 2004 Italy 15679008	Compliance	h per day	**Tx**	auto PAP	1 mo	10 (?)	NA		5.2	1.4				-0.1	0.518	NS
			Cx	CPAP	1 mo	10 (?)	NA		5.3	1.8						
Resta, 2004 Italy 15679008	Epworth		**Tx**	auto PAP	1 mo	10 (?)	15.7	5.1	5.2	2.9				-2.6	1.654	0.116
			Cx	CPAP	1 mo	10 (?)	12	3.2	4.1	1.4						
Resta, 2004 Italy 15679008	RDI		**Tx**	auto PAP	1 mo	10 (?)	48	14.3	8.3	2	-39.7	4.24	<0.001	-2.8	5.18	0.589
			Cx	CPAP	1 mo	10 (?)	45.3	10.7	8.4	3.6	-36.9	2.98	<0.001			
Resta, 2004 Italy 15679008	Arousal Index		**Tx**	auto PAP	1 mo	10 (?)	43.1	11.9	7.4	2.3			<0.001	0.1	4.28	0.981
			Cx	CPAP	1 mo	10 (?)	43.1	9.1	7.3	3.3			<0.001			
Resta, 2004 Italy 15679008	sleep efficiency	%	**Tx**	auto PAP	1 mo	10 (?)	86.9	8	86.4	8.1				-2.5	3.26	0.443
			Cx	CPAP	1 mo	10 (?)	84.2	4.9	86.2	7.3						
Resta, 2004 Italy 15679008	stage 3/4	%	**Tx**	auto PAP	1 mo	10 (?)	19.8	10.9	33.8	11				7.3	4.921	0.138
			Cx	CPAP	1 mo	10 (?)	22.8	12.5	29.5	8.5						
Resta, 2004 Italy 15679008	REM	%	**Tx**	auto PAP	1 mo	10 (?)	15	8.1	21.7	12.4				-2	4.24	0.637
			Cx	CPAP	1 mo	10 (?)	15.9	4.2	24.6	9						
Resta, 2004 Italy 15679008	min O2	%	**Tx**	auto PAP	1 mo	10 (?)	72.4	10.5	88.3	3.3				0.9	4.219	0.831
			Cx	CPAP	1 mo	10 (?)	74.1	10.8	89.1	3.4						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
	0	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	n	y	nd	y	NA	NA	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	y				
Reasons for drop-outs:										
Other Issues:	small sample size; incomplete reporting; sample size in each group not reported									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Salgado, 2008			**Intervention 1**	humidified APAP
PMID*	18982206	**RefID**	3769	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	non-humidified APAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA being treated for sleep disorders	UPPP; medical tx for rhinitis; prior CPAP; long-term O2 tx	nd	nd	no	Portugal	none	no	no	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**17**	76	57.4					
Cx	**22**	73	56.5					
Total	**50 (39)**	74	56	nd	nd	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	no prior CPAP							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	17	28.1±14	11.2±5.8					
Control:	22	28.8±20.5	11.9±6.3					
Total:	39	28.5	11.6					
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
nd	nd	nd	nd	nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto PAP with humidification	AutoSet Spirit (ResMed, CA)	4 to 16 cm
2				
3				
Control	PAP	auto PAP without humidification	AutoSet Spirit (ResMed, CA)	4 to 16 cm
For CPAP:		**How was the Pressure selected?**	uniformly set; not titrated (?)	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
	nasal steroid in pts with nasal obstruction complaints in both arms	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	h per night	4 wk	
2	Sleep study measures	AHI	baseline, 1 wk, 4 wk	
3	Sleepiness measures	Epworth	baseline, 1 wk, 4 wk	
4				

* QoL; ; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; ; ; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Salgado, 2008 Portugal 18982206	AHI		**Tx**	humidified APAP	1 wk	17 (?)	28.1	14	6.3	5.8						NS
			Cx	non-humidified APAP	1 wk	22 (?)	28.8	20.5	5.8	4.3						
Salgado, 2008 Portugal 18982206	AHI		**Tx**	humidified APAP	4 wk	17	28.1	14	4.6	5.2						NS
			Cx	non-humidified APAP	4 wk	22	28.8	20.5	4.7	3.4						
Salgado, 2008 Portugal 18982206	Epworth		**Tx**	humidified APAP	1 wk	17 (?)	11.2	5.8	7.5	5.7				1	1.92	NS
			Cx	non-humidified APAP	1 wk	22 (?)	11.9	6.3	7.2	6						
Salgado, 2008 Portugal 18982206	Epworth		**Tx**	humidified APAP	4 wk	17	11.2	5.8	6.9	5.4						NS
			Cx	non-humidified APAP	4 wk	22	11.9	6.3	6.7	5.3						
Salgado, 2008 Portugal 18982206	Compliance	h per night	**Tx**	humidified APAP	1 wk	17 (?)	NA		4.9	2.6						NS
			Cx	non-humidified APAP	1 wk	22 (?)	NA		5.2	2.3						
Salgado, 2008 Portugal 18982206	Compliance	h per night	**Tx**	humidified APAP	4 wk	17	NA		5.3	2.4						NS
			Cx	non-humidified APAP	4 wk	22	NA		5.2	2.3						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			humidified APAP	non-humidified APAP		
Salgado, 2008 Portugal 18982206	nasal obstruction	1 wk	5/denom unclear	6/denom unclear		
		4 wk	3/17	9/22		
	dry nose	1 wk	2/denom unclear	3/denom unclear		
		4 wk	1/17	4/22		
	dry mouth	1 wk	8/denom unclear	8/denom unclear		
		4 wk	6/17	12/22		
	epistaxis	1 wk	0/denom unclear	0/denom unclear		
		4 wk	0/17	2/22		
	eye irritation	1 wk	2/denom unclear	4/denom unclear		
		4 wk	2/17	3/22		
	abd distension	1 wk	0/denom unclear	1/denom unclear		
		4 wk	0/17	3/22		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	n	n	nd	nd	y	NA	NA	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	n	n	n	y	n	n				
Reasons for drop-outs:										
Other Issues:	randomization over an 8 wk period; small sample size; incomplete study information reported									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Senn, 2003			**Intervention 1**	auto PAP – AutoSet T
PMID*	14525804	**RefID**	4780	**Intervention 2**	auto PAP – AutoAdjust LT
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; ; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA with AHI >10	previous CPAP	>10	nd	no	Switzerland	nd	post hoc	yes	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx1	31 (29)	79	53	nd	33.3±1.3 (SE)			
Tx2	31 (29)	79	53	nd	33.3±1.3 (SE)			
Cx	31 (29)	79	53	nd	33.3±1.3 (SE)			
Total	31 (29)	79	53	nd	33.3±1.3 (SE)	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx1								
Tx2								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx1								
Tx2								
Cx								
Total	no previous CPAP							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	29	45.8±4.2 (SE)	14.2±0.7 (SE)	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
nd	nd	nd	nd	nd	nd	separate (adaptation over 2 wk)	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto PAP	AutoSet T (ResMed, Australia)	responds to apnea-hypopnea, snoring, and changes in inspiratory flow contour; 4 to 15 cm H2O
2	PAP	auto PAP	DeVilbiss AutoAdjust LT (Sunrise Medical, PA)	responds to apnea-hypopnea and snoring, 4 to 15 cm H2O
3				
Control	PAP	CPAP	AutoSet T or AutoAdjust LT in fixed mode	fixed pressure mode at the 90th % tile determined by autoCPAP during initial adaptation over 2 wk
For CPAP:		**How was the Pressure selected?**	auto/manual (?)	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	AHI	baseline, 1 mo	
2	Sleepiness measures	Epworth, Vigilance	baseline, 1 mo	
3	Compliance	h per night	1 mo	
4	QoL	SF-36	baseline, 1 mo	

* QoL; ; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; ; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference (Final test – control)		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P
Senn, 2003 Switzerland 14525804	AHI		**Tx1**	Auto PAP (Autoset T)	1 mo	29	45.8	4.2	6.0	1.0			<0.01	0.7	1.00	0.48
			Tx2	Auto PAP (AutoAdjust LT)	1 mo	29	45.8	4.2	7.7	1.6			<0.01	2.4	1.40	0.086
			Cx	Fixed CPAP	1 mo	29	45.8	4.2	5.3	1.0			<0.01			
																NS (presumed) (Tx1 vs Tx2)
Senn, 2003 Switzerland 14525804	Epworth		**Tx1**	Auto PAP (Autoset T)	1 mo	29	14.2	0.7	9	0.6			<0.01	0.8	0.656	0.222 NS (presumed)
			Tx2	Auto PAP (AutoAdjust LT)	1 mo	29	14.2	0.7	8	0.8			<0.01	-0.2	0.755	0.791 NS (presumed)
			Cx	Fixed CPAP	1 mo	29	14.2	0.7	8.2	0.7			<0.01			
																NS (presumed) (Tx1 vs Tx2)
Senn, 2003 Switzerland 14525804	Vigilance by OSLER	min	**Tx1**	Auto PAP (Autoset T)	1 mo	29	29.7	1.9	35.7	1.2			<0.01			NS (presumed)
			Tx2	Auto PAP (AutoAdjust LT)	1 mo	29	29.7	1.9	34.2	1.9			<0.01			NS (presumed)
			Cx	Fixed CPAP	1 mo	29	29.7	1.9	35.8	1.1			<0.01			
																NS (presumed) (Tx1 vs Tx2)
Senn, 2003 Switzerland 14525804	Compliance	h per night	**Tx1**	Auto PAP (Autoset T)	1 mo	29	NA		5.5							NS (presumed)
			Tx2	Auto PAP (AutoAdjust LT)	1 mo	29	NA		5.5							NS (presumed)
			Cx	Fixed CPAP	1 mo	29	NA		5.6							
																NS (presumed) (Tx1 vs Tx2)
Senn, 2003 Switzerland 14525804	SF-36 –mental component summary score		**Tx1**	Auto PAP (Autoset T)	1 mo	29	47	2	52	2			<0.01			NS (presumed)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference (Final test – control)		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P
			Tx2	Auto PAP (AutoAdjust LT)	1 mo	29	47	2	51	2			<0.01			NS (presumed)
			Cx	Fixed CPAP	1 mo	29	47	2	52	2			<0.01			
																NS (presumed) (Tx1 vs Tx2)

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Cx		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Senn, 2003 Switzerland 14525804	SF-36	vitality	1 mo	Tx1 or Tx2	29	CPAP	29	0					
		social functioning	1 mo	Tx1 or Tx2	29	CPAP	29	0					

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
autoPAP1 or autoPAP2 or CPAP	6.5 (2/31)	unable to follow up (no time, moved away)

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			AutoSet T	AutoAdjust LT	CPAP	
Senn, 2003 Switzerland 14525804	skin irritation	1 mo	9/29	8/29	10/29	
	nasal irritation	1 mo	5/29	8/29	8/29	

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	y	nd	nd	y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	n	n	y	n	n	y	post hoc analysis			?
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Series, 1997			**Intervention 1**	auto PAP estimated effective reference pressure
PMID*	9341056	**RefID**	5825	**Intervention 2**	auto PAP measured effective reference pressure
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	fixed CPAP at a measured effective pressure
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
pts chose to have nasal CPAP; OSA confirmed by PSG	life-threatening OSA; OSA with sleep-related breathing disorders; estimated pressure >15 cm H2O	nd	1995-1996	no	Canada	industry	no	yes	no
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx1 (est)	12				35.8±7.2			
Tx2 (measured)	12				36.8±7.8			
Cx	12				36.8±8.3			
Total	36	nd	range 36 to 65	nd	36.4±7.6	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx1								
Tx2								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx	none							
Tx2	none							
Cx	none							
Total	none							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Tx1:	12	61.5±27.9	17±4.1					
Tx2:	12	46.9±22.3	13.5±4.7					
Control:	12	50.1±14.5	16.1±4.5					
Total:	36	43.6±19.8 (?)	15.5	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	nd	no flow ≥10 s	↓ >50% thoracoabdominal movement ≥10 s with a ≥2% O2 desat or arousal		separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto PAP estimated ref pressure	Morphee Plus (Nellcor Puritan-Bennett, MN)	set estimated reference pressure (3 cm H2O above to 4 cm H2O below the reference pressure)
2	PAP	auto PAP measured ref pressure	Morphee Plus (Nellcor Puritan-Bennett, MN)	set measured reference pressure (3 cm H2O above to 4 cm H2O below the reference pressure)
3				
Control	CPAP	fixed CPAP	Morphee Plus (Nellcor Puritan-Bennett, MN)	
For CPAP:		**How was the Pressure selected?**	manual titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth; latency	baseline, 3 wk	
2	Sleep study measures	AHI; stage 3&4; REM; arousal	baseline, 3 wk	
3	Compliance	h per night	3 wk	
4				

* QoL; ; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; ; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SE*	P	Value	SE*	P
Series, 1997 Canada 9341056	Epworth		**Tx1**	auto PAP (est)	3 wk	12	17	4.1	7.9	4	-9.1	1.169		-0.8	1.782 95%CI (-3 to 6.5)***	0.653 NS
			Tx2	auto PAP (meas)	3 wk	12	13.5	4.7	7	3.7	-6.5	1.238		1.8	1.83 95%CI (-2.2 to 7.4)	0.325 NS
			Cx	CPAP	3 wk	12	16.1	4.5	7.8	4.8	-8.3	1.344				
Series, 1997 Canada 9341056	AHI		**Tx1**	auto PAP (est)	3 wk	12	61.5	27.9						4.1	12.09 95%CI (-19.6 to 27.8)	NS
			Tx2	auto PAP (meas)	3 wk	12	46.8	22.3						9.3	12.09 95%CI (-14.4 to 33)	NS

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SE*	P	Value	SE*	P
			Cx	CPAP	3 wk	12	50.1	14.5								
Series, 1997 Canada 9341056	Compliance	h per night	**Tx1**	auto PAP (est)	3 wk	12	NA							0.1	0.561 95%CI (-1 to 1.2)	NS
			Tx2	auto PAP (meas)	3 wk	12	NA							0.15	0.536 95%CI (-0.9 to 1.2)	NS
			Cx	CPAP	3 wk	12	NA									
Series, 1997 Canada 9341056	stage 3 and 4 sleep	% of total sleep time	**Tx1**	auto PAP (est)	3 wk	12	nd							0.35	4.41 95%CI (-8.3 to 9)	NS
			Tx2	auto PAP (meas)	3 wk	12	nd							-2.35	3.7 95%CI (-9.6 to 4.9)	NS
			Cx	CPAP	3 wk	12	nd									
Series, 1997 Canada 9341056	REM sleep	% of total sleep time	**Tx1**	auto PAP (est)	3 wk	12	nd							-1.6	4.03 95%CI (-9.5 to 6.3)	NS
			Tx2	auto PAP (meas)	3 wk	12	nd							-4.5	4.03 95%CI (-12.4 to 3.4)	NS
			Cx	CPAP	3 wk	12	nd									
Series, 1997 Canada 9341056	sleep latency	min	**Tx1**	auto PAP (est)	3 wk	12	nd							1.75	4.566 95%CI (-7.2 to 10.7)	NS
			Tx2	auto PAP (meas)	3 wk	12	nd							2.1	4.54 95%CI (-6.8 to 11)	NS
			Cx	CPAP	3 wk	12	nd									
Series, 1997 Canada 9341056	arousal index	events per h	**Tx1**	auto PAP (est)	3 wk	12	nd							5.2	12.143 95%CI (-18.6 to 29)	NS
			Tx2	auto PAP (meas)	3 wk	12	nd							-5.3	12.143 95%CI (-8.5 to 39.1)	NS

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SE*	P	Value	SE*	P
			Cx	CPAP	3 wk	12	nd									

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper
***unclear which way is the comparison

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
	0	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	y	n	nd	y	n	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	y				
Reasons for drop-outs:										
Other Issues:	small sample size; randomization by block of 3 patients, estimated pressure could not differ by more than 1 cm H2O from the value of the first patient included in that block to ensure comparison of patients with similar severity of disease (selection bias toward null?)									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Teschler, 2000			**Intervention 1**	auto PAP
PMID*	10885414	**RefID**	5894	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
newly dx'd OSA with AHI >20; resides within 50 km of clinic	primary dx of asthma, emphysema, allergic rhinitis, or cardiac failure	nd	nd	no	Germany	nd	?	yes	yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	10 (10?)	100	52	nd	33.8±1.3			
Cx	10 (10?)	100	52	nd	33.8±1.3			
Total	10 (10?)	100	52	nd	33.8±1.3	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	no prior tx (presumed)							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	10	52.9±8.1 (SE)	nd	nd	nd	nd	0	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG			no thermistor signal >10 s with chest wall and abd movt device defn: 75% reduction in airflow ≥10 s	>10 s of thermistor signal <50% of normal unobstructed breathing and O2 desat ≥4% device defn: 50-75% reduction in airflow ≥10 s	nd	separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	auto PAP	AutoSet portable (ResMed, Australia)	
2				
3				
Control	PAP	CPAP	AutoSet portable (ResMed, Australia)	
For CPAP:		**How was the Pressure selected?**	manual/auto	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	AHI	2 mo	measured by AutoSet machine at home
2	compliance	h/day	2 mo	
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; ; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference* (test – control)*		
							Value	SE*	Value	SE*	Value	SD/SE*	P	Value	SD/SE*	P
Teschler, 2000 Germany 10885414	AHI		Tx	auto PAP	2 mo	10 (presumed)	52.9 (lab)	8.1	4 (home)	0.3				0.3	0.300	0.317
			Cx	CPAP	2 mo	10 (presumed)	52.9 (lab)	8.1	3.7 (home)	0.3						
Teschler, 2000 Germany 10885414	Compliance	h per d	Tx	auto PAP	2 mo	10 (presumed)	NA		6.3	0.4				0.2	0.458	0.663 NS
			Cx	CPAP	2 mo	10 (presumed)	NA		6.1	0.5						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	y	y	nd	y	n	NA	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	y	n			
Reasons for drop-outs:										
Other Issues:	data incompletely reported; had to presume all pts completed the study; small sample size; device measured AHI had a different definition from lab PSG									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	To, 2008			**Intervention 1**	auto CPAP
PMID*	18197915	**RefID**	3884	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	fixed CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
18-65 y/o newly dx'd OSA; AHI >30; no previous tx	facial abnl led to poor mask fit; COPD with resp failure; uncontrolled heart failure; hypothyroid; predominant central apnea; hypoventilation needed bi-level PAP; difficulty with follow up	>30 (severe)	nd	n	China	nd	post hoc; 20 pts per arm	n	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**43 (41)**	nd	45.6	nd	28.7	nd	nd	nd
Cx	**43 (41)**	nd	45.6	nd	28.7	nd	nd	nd
Total	**43 (41)**	nd	45.6	nd	28.7	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	nd	nd	nd	severe OSA
Cx	nd	nd	nd	nd	nd	nd	nd	severe OSA
Total	nd	nd	nd	nd	nd	nd	nd	severe OSA
	Treatments used (prior to trial, including surgery)							
Tx	none							
Cx	none							
Total	none							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	41	54.3	13.4	nd	nd	nd	nd	
Control:	41	54.3	13.4	nd	nd	nd	nd	
Total:	41	54.3	13.4	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>5 (?)		no flow >10 s	↓flow of ≥50% for >10 s and O2 desat >3% or arousal		separate (?)	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	Auto-titrating CPAP	AutoSet Spirit, ResMed, Australia	
2				
3				
Control	PAP	fixed CPAP	S6 Elite, ResMed, Australia	
For CPAP:		**How was the Pressure selected?**	auto: abolish 95% of obstructive events; fixed: manual determination	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	QoL	Sleep Apnea QoL Index (SAQLI)	baseline, 1 mo, 2 mo	
2	Sleepiness measures	Epworth	baseline, 1 mo, 2 mo	
3	Sleep study measures	AHI	baseline, 1 mo, 2 mo	
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SD/SE*	P
To, 2008 China 18197915	SAQLI		**Tx**	Auto CPAP	1 mo	41	4.6	0.2	5	0.2	0.4		<0.05	0.1		NS
			Cx	Fixed CPAP	1 mo	41	4.6	0.2	4.9	0.2	0.3		<0.05			
To, 2008 China 18197915	SAQLI		**Tx**	Auto CPAP	2 mo	41	4.6	0.2	4.8	0.2	0.2			0		NS
			Cx	Fixed CPAP	2 mo	41	4.6	0.2	4.8	0.2	0.2					
To, 2008 China 18197915	Epworth		**Tx**	Auto CPAP	1 mo	41	13.4	0.9	8.5	0.9	-4.9		<0.01	0.3	0.9	NS
			Cx	Fixed CPAP	1 mo	41	13.4	0.9	8.2	0.9	-5.2		<0.01			
To, 2008 China 18197915	Epworth		**Tx**	Auto CPAP	2 mo	41	13.4	0.9	8.5	0.9	-4.9		<0.01	0	0.9	NS
			Cx	Fixed CPAP	2 mo	41	13.4	0.9	8.5	0.9	-4.9		<0.01			
To, 2008 China 18197915	AHI		**Tx**	Auto CPAP	1 mo	41	54.3	30-103 (range)	4.4	0.5	-49.9					
			Cx	Fixed CPAP	1 mo	41	54.3	30-103 (range)	nd							
To, 2008 China 18197915	AHI		**Tx**	Auto CPAP	2 mo	41	54.3	30-103 (range)	3.6	0.4	-50.7					
			Cx	Fixed CPAP	2 mo	41	54.3	30-103 (range)	nd							
To, 2008 China 18197915	Compliance	h/night	**Tx**	Auto CPAP	1 mo	41	NA	NA	4.3					0.5		0.04 (Final value btw groups)
			Cx	Fixed CPAP	1 mo	41	NA	NA	3.8							
To, 2008 China 18197915	Compliance	h/night	**Tx**	Auto CPAP	2 mo	41	NA	NA	4.4					0.7		0.01 (Final value btw groups)
			Cx	Fixed CPAP	2 mo	41	NA	NA	3.7							

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Auto or fixed CPAP	4.7 (2/43)	lost to follow up

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			auto CPAP	fixed CPAP		
To, 2008 China 18197915	pressure discomfort	2 mo	17/41	30/41		
	gum pain	2 mo		more		
	dry mouth /nose	2 mo		more		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	n	nd	n	y	n	NA	Y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Y	N	Y	Y	N	Y				
Reasons for drop-outs:										
Other Issues:	?post hoc power calculation									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Question 5
Oral vs No Treatment

A.

Author, Year	Barnes , 2004			**Intervention 1**	CPAP
PMID*	15201136	**RefID**	4054	**Intervention 2**	MAS
Key Question(s)	5			**Intervention 3**	
Design †	Cross over			**Control**	Placebo
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA At least 2 teeth in upper and lower jaws on both sides >18yrs	Minimum blood oxygen saturation <75% in REM and 80% in non REM Significant coexisting disease(Dm, unstable ischemic heart diseases) Sleepiness unsafe and requiring urgent treatment	5-30	nd	y	Australia	nd	Y(ESS)		y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

Eligibility criteria and other study design extracted from supplemental online material and its references

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) >140/90mmHg**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Tx2								
Cx								
Total	**104 (80)**	79.8	47(0.9)	nd	31.1(0.5)	14	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	0	nd	nd	nd	nd	nd		n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Treatment2:								
Control:								
Total:	80	21.3(1.3)	10.7(0.4)	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	5-30		Standard AASM	Standard AASM	snoring	same	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Sullivan Elite, ResMed Limited, Sydney, Australia	
2	Oral appliance	MAS	Medical Dental Sleep Appliance, RJ & VK Bird, Melbourne, Australia	Made from dual laminate splinting material hooked at the jaws to cause manidublar advancement
3				
Control	placebo	placebo		Placebo Lactose tablet
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	3 months	
2	Sleep study measure	Arousal index	3 months	
3	Sleep study measure	ODI	3 months	
4	Sleep study measure	Mino2sat	3 months	
5	Sleepiness measures	ESS	3 months	
6	Psych scale	Beck Depression Inventory	3 months	
7	Sleep quality	FOSQ mean score, Social Outcome domain	3 months	
8	QOL	Sf36 mean score	3 months	
9	Sleep study measure	Stage 3 and 4	3 months	
10	Sleep study measure	REM	3 months	
11	Sleep study measure	Sleep efficiency	3 months	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (ΔcPAP – Δ control)*			Net Δ /Difference* (ΔMAS – Δ control)*			Net Δ /Difference* (ΔCPAP – Δ MAS*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P	Value	SE*	P	Value	SE*	P
Barnes, 2004 Australia 15201136	AHI	/hr	**Tx**	CPAP	3 months	80	21.3	1.3	4.8	0.5	-16.5		0.001	-15.5		0.001	-6.3		0.001	-9.2		<0.05
			Tx2	MAS		80	21.3	1.3	14.0	1.1	-7.3		0.001									
			Cx	Placebo	3 months	80	21.3	1.3	20.3	1.1	-1		NS									
	Arousal index		**Tx**	CPAP	3 months	80	22.0	1.2	18.3	0.9	-3.7		0.01	-6.9		0.001	-1.4		NS	-5.5		<0.05
			Tx2	MAS		80	22.0	1.2	23.8	1.2	1.8		NS									
			Cx	Placebo	3 months	80	22.0	1.2	25.2	1.1	3.2		NS									
	ODI(4%o2 desaturation)	%	**Tx**	CPAP	3 months	80	12.4	1.5	1.6	0.2	-10.8		0.001	-10.9		0.001	-4.4		0.001	-6.5		<0.05
			Tx2	MAS		80	12.4	1.5	8.1	1.3	-4.3		0.001									
			Cx	Placebo	3 months	80	12.4	1.5	12.5	1.6	0.1		NS									
	Mino2sat	%	**Tx**	CPAP	3 months	80	86.7	0.6	91.9	0.3	5.2		0.001	6.5		0.001	2.4		0.001	4.1		<0.05
			Tx2	MAS		80	86.7	0.6	87.8	0.4	1.1		NS									
			Cx	Placebo	3 months	80	86.7	0.6	85.4	0.6	-1.3		NS									
	ESS		**Tx**	CPAP	3 months	80	10.7	0.4	9.2	0.4	-1.5		0.001	-1		0.001	-1		0.001	0		NS
			Tx2	MAS		80	10.7	0.4	9.2	0.4	-1.5		0.001									
			Cx	Placebo	3 months	80	10.7	0.4	10.2	0.4	-0.5		NS									
	Beck Depression Inventory		**Tx**	CPAP	3 months	80	9.2	0.5	6.7	0.5	-2.5		0.001	-1		NS	-0.8		NS	-0.2		NS
			Tx2	MAS	3 months	80	9.2	0.5	6.9	0.5	-2.3		0.001									
			Cx	Placebo		80	9.2	0.5	7.7	0.6	-1.5		0.01									
	FOSQ social outcome domain		**Tx**	CPAP	3 months	80	3.1	0.1	3.3	0.1	0.2		0.001	0		NS	0		NS	0		NS
			Tx2	MAS		80	3.1	0.1	3.3	0.1	0.2		0.001									
			Cx	Placebo	3 months	80	3.1	0.1	3.3	0.1	0.2		0.01									
	Sf36 mean score		**Tx**	CPAP	3 months	80	69.4	1.3	74.1	1.2	4.7		0.001	2.7		<0.05	2.3		NS	0.4		NS
			Tx2	MAS		80	69.4	1.3	73.7	1.2	4.3		0.001									
			Cx	Placebo	3 months	80	69.4	1.3	71.4	1.4	2		NS									
	Stage 3 and 4	%	**Tx**	CPAP	3 months	80	17.9	1.2	20.7	1.1	2.8		0.001	2.2		<0.05	1.6		NS	0.6		NS
			Tx2	MAS	3 months	80	17.9	1.2	20.1	1.1	2.2		<0.05									
			Cx	Placebo		80	17.9	1.2	18.5	1.2	0.6											
	REM	%	**Tx**	CPAP	3 months	80	18.8	0.7	18.9	0.5	0.1		NS	0		NS	0.9		NS	-0.9		NS
			Tx2	MAS	3 months	80	18.8	0.7	19.8	0.6	1		NS									
			Cx	Placebo	3 months	80	18.8	0.7	18.9	0.6	0.1		NS									
	Sleep efficiency	%	**Tx**	CPAP	3 months	80	79.5	1.1	82.1	0.8	2.6		<0.05	1.4		NS	1.3		NS	0.1		NS

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (ΔcPAP – Δ control)*			Net Δ /Difference* (ΔMAS – Δ control)*			Net Δ /Difference* (ΔCPAP – Δ MAS*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P	Value	SE*	P	Value	SE*	P
			Tx2	MAS	3 months	80	79.5	1.1	82.0	1.0	2.5		<0.01									
			Cx	Placebo	3 months	80	79.5	1.1	80.7	0.9	1.2		NS									

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	8.2	Time commitments, relocated, unable to tolerate , illness
MAS	14.1	Teeth unsuitable, time commitments, unable to tolerate, relocated, unrelated illness, lost weight and felt better, lost to follow up
Placebo	8.2	Time commitments , wanted CPAP, subject illness

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	y	n		y	y	y	y	y	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	y	nd	y			y
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Bloch, 2000			**Intervention 1**	OSA-Monobloc (single piece mandibular advancement device)
PMID*	10903249	**RefID**	5077	**Intervention 2**	OSA-Herbst (two piece mandibular advancement device)
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	no tx
Extractor	SI			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
unable to use CPAP; typical OSA hx; AHI ≥5 or sleep-disruptive snoring with arousal >20/h	other sleep disorders	nd	nd	no	Switzerland	nd	no	no	no
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx1	**24 (24)**	nd	51	nd	27.4 ± 0.6	nd	nd	nd
Tx2	**24 (24)**	nd	51	nd	27.4 ± 0.6	nd	nd	nd
Cx	**24 (24)**	nd	51	nd	27.4 ± 0.6	nd	nd	nd
Total	**24**	nd	51	nd	27.4 ± 0.6	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	nd	nd	nd	no
Cx	nd	nd	nd	nd	nd	nd	nd	no
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx1	trial of CPAP in some; then 1 mo of adjustment to the two mandibular advancement devices before the trial commences							
Tx2	trial of CPAP in some; then 1 mo of adjustment to the two mandibular advancement devices before the trial commences							
Cx	trial of CPAP in some; then 1 mo of adjustment to the two mandibular advancement devices before the trial commences							
Total	trial of CPAP in some; then 1 mo of adjustment to the two mandibular advancement devices before the trial commences							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Arousal index
Tx1:	24	26.7 ± 3.3	11.9 ± 0.8	nd	nd	nd	nd	36 ± 4.3
Tx2:	24	26.7 ± 3.3	11.9 ± 0.8	nd	nd	nd	nd	36 ± 4.3
Control:	24	26.7 ± 3.3	11.9 ± 0.8	nd	nd	nd	nd	36 ± 4.3
Total:	24	26.7 ± 3.3	11.9 ± 0.8	nd	nd	nd	nd	36 ± 4.3
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SE † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	nd	Σ signal resp plethys ≤baseline >10 s	Σ signal resp plethys ≤baseline >10 s	nd	nd	nd

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	MAD-1 piece	Monobloc	protrusion 10 ± 0.4 mm; vertical 5 to 10 mm
2	Oral appliance	MAD-2 piece	Herbst	protrusion 10 ± 0.4 mm; vertical 6 to 6 mm
3				
Control	no tx			
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth	1 wk	
2	Sleep study measures	AHI	1 wk	
3	Sleep study measures	REM	1 wk	
4	Sleep study measures	Stage 3 and 4	1 wk	
5	treatment success		1 wk	AHI <10 & satisfaction

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
5077}	tx success	**Tx1**	MAD-1 piece	1 wk	18	24	%	75		NS				
		Tx2	MAD-2 piece	1 wk	16	24	%	67						
		Cx	no tx	1 wk										
				1 wk										

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE	P	Value	SD/SE*	P
Bloch, 2000 Switzerland 10903249	Epworth		Tx1	MAD-1 piece	1 wk	24	11.9 ±	0.8	9 (med)	6.5-10 (IQR)						<0.001
			Tx2	MAD-2 piece	1 wk	24			9 (med)	6.5-11 (IQR)						<0.001
			Cx	no tx	1 wk	24			13.5 (med)	9.5-16 (IQR)						
Bloch, 2000 Switzerland 10903249	AHI		Tx1	MAD-1 piece	1 wk	24	26.7	3.3	7.9	1.6 (SE)	-18.8			-14.7		<0.05
			Tx2	MAD-2 piece	1 wk	24	26.7	3.3	8.7	1.5	-18			-13.9		<0.05
			Cx	no tx	1 wk	24	26.7	3.3	22.6	3.1	-4.1					
Bloch, 2000 Switzerland 10903249	REM sleep	%	Tx1	MAD-1 piece	1 wk	24	13	1	15	1	2			1		NS
		%	Tx2	MAD-2 piece	1 wk	24	13	1	16	1	3			2		NS
		%	Cx	no tx	1 wk	24	13	1	14	1	1					
Bloch, 2000 Switzerland 10903249	stages 3 &4 sleep	%	Tx1	MAD-1 piece	1 wk	24	nd		18	2						<0.05
		%	Tx2	MAD-2 piece	1 wk	24	nd		16	2						NS
		%	Cx	no tx	1 wk	24	nd		12	2						
Bloch, 2000 Switzerland 10903249	sleep efficiency	%	Tx1	MAD-1 piece	1 wk	24	85	2	88	2	3			-1		NS
		%	Tx2	MAD-2 piece	1 wk	24	85	2	89	1	4			0		NS
		%	Cx	no tx	1 wk	24	85	2	89	2	4					
Bloch, 2000 Switzerland 10903249	arousal index	events per h	Tx1	MAD-1 piece	1 wk	24	36	4.3	26.5	3.9						<0.05
			Tx2	MAD-2 piece	1 wk	24	36	4.3	30.9	3.6						NS
			Cx	no tx	1 wk	24	36	4.3	41	3.7						

* Delete or correct the incorrect value/item. If change, highlight yellow.

** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
nd		

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			MAD-1 or MAD-2	MAD-1	MAD-2	
Bloch, 2000 Switzerland 10903249	TMJ pain		7			
	muscle discomfort		4			
	dental discomfort		3			
	transient mucosal erosions				3	

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	NA	y	n	nd	n	y	y	y
	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?		If a Crossover study, was the Washout period adequate?
	y	y	y	y	n	NA	n		n
Reasons for drop-outs:									
Other Issues:		pts who refused CPAP or declined continued use of CPAP were enrolled; tx success included pt satisfaction as a component (pts may be predisposed to prefer MADs)							
Overall Quality (A, B, C)		**B**							

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Kato, 2000			**Intervention 1**	OA2
PMID*	10767241	**RefID**	5450	**Intervention 2**	OA4
Key Question(s)	5(mandibular)			**Intervention 3**	OA6
Design †	Randomized cross-over			**Control**	No OA
Extractor	NO			**Comments**	Paper specified total number of subjects required, not number per group. no baseline data per intervention

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Symptoms suggestive of sleep disordered breathing (excessive daytime sleepiness, loud snoring, and witnessed repetitive apneas	Inadequate anchoring of teeth (too few teeth) TMJ dysfunction History of UPPP	nd	nd	n	Japan	nd	nd	**nd**	**nd**
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**37**		49(27.1-66.6)	nd	28.7(23.0-40.0)	**nd**	**nd**	**nd**
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	**nd**	**nd**	**nd**	**nd**	**nd**	**nd**	**nd**	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Median (ragne) If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Baseline ODI
Treatment:								
Control:								
Total:	37	nd	nd	nd	nd	nd	nd	26(11.2-72.0)
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Nocturnal oximetry		4% decline in O_2 saturation	nd	nd			

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	OA 2	Erkodur; Erkodent Inc.; Pfalzgrafenweiler	clear acrylic resin and 1-mm polyethylene plate made in plastic models with 2 mm mandibular advancement
2	Oral appliance	OA 4	Erkodur; Erkodent Inc.; Pfalzgrafenweiler	clear acrylic resin and 1-mm polyethylene plate made in plastic models with 4 mm mandibular advancement
3	Oral appliance	OA 6	Erkodur; Erkodent Inc.; Pfalzgrafenweiler	clear acrylic resin and 1-mm polyethylene plate made in plastic models with 6 mm mandibular advancement
Control	No treatment	No oral appliance		No Oral appliance
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	ODI	8 nights	
2	Sleep study measures	Mean min O2 sat	8 nights	
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							median	95% CI*	median	95% CI*	median	95% CI*	P	median	95% CI*	P
Kato 2000 Japan 10767241	ODI		Tx	OA2	8 nights	37	26.0	11.2, 72.0	17.3	2.6-70.1	-8.7					<0.05 (test vs control)
			Tx2	OA4	8 nights	37	26.0	11.2, 72.0	14.7	2.9-58.9	-11.3					<0.05 (test vs control)
			Tx3	OA6	8 nights	37	26.0	11.2, 72.0	10.8	2.3-48.6	-15.2					<0.05 (test vs control)
			Cx	No OA	8 nights	37	26.0	11.2, 72.0	26	11.2-72.0	0					
	Mean min O2 sat	%	Tx	OA2	8 nights	37	87.2	78.0, 91.8	89.2	80.0-92.6	2					<0.05 (test vs control)
			Tx 2	OA4	8 nights	37	87.2	78.0, 91.8	89.5	78.1-93.4	2.3					<0.05 (test vs control)
			Tx 3	OA6	8 nights	37	87.2	78.0, 91.8	89.6	81.3-92.6	2.4					<0.05 (test vs control)
			Cx	No OA	8 nights	37	87.2	78.0, 91.8	87.2	78.0-91.8	0					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
both	13	2 desired UPP, 1 preferred nCPAP, 1 lost weight and felt better, and 2 failed to construct their OA before completion of the study protocol

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Y	nd	nd	y	nd	nd	n		n		n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y		n	y	n	na	na			na
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Lam, 2007			**Intervention 1**	Conservative management plus Mandibular advancement device (OA)
PMID*	17121868	**RefID**	3499	**Intervention 2**	Conservative management plus CPAP (CPAP)
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	Conservative management (CM)
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSAS AHI≥5-40 ESS >9(for those with AHI 5-20)	Sleepiness which contributes risk to self or others Unstable medical diseases Other sleep disorders Previous surgery of upper airway except for nasal problems Pregnant women	5-40	nd	n	Hong Kong	nd	Y(ESS)	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
MDA	**34(34)**	76	45(2)		27.3(0.6)	Morning systolic127.1 Morning diastolic76.2 Evening systolic131.9 Evening diastolic77.8		
CPAP	**34 (34)**	79	45(1)		27.6(0.6)	Morning systolic127.9 Morning diastolic77.0 Evening systolic130.9 Evening diastolic78.0		
Cx	**33(33)**	79	47(2)		27.3(0.6)	Morning systolic125.5 Morning diastolic74.2 Evening systolic127.2 Evening diastolic73.5		
Total	**101(101)**			nd			nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SEM. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI (SE)*	Epworth (SE)*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
MDA	34	20.9(1.7)	12(1)					
CPAP	34	23.8(1.9)	12(1)					
Control:	33	19.3(1.9)	12(1)					
Total:	101			nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	5-40		AASM	AASM	nd	nd	nd

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	Conservative management plus Mandibular advancement device (OA)		Tailored made non adjustable oral appliance, mde from dental acrylic. Function was to hold the mandible in a forward position with vertical opening.
2	PAP	Conservative management plus CPAP (CPAP)	Repironics, ARIA LX (Atlanta, Georgia)	
3				
Control	Physical therapy	Conservative management (CM)		Advice on sleep hygiene measures plus weight loss program for overweight patients BMI≥23)
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measure	ESS	10 weeks	
2	Sleep study measure	AHI	10 weeks	
3	Sleep study measure	Min o2 sat	10 weeks	
4	Sleep study measure	Arousal index	10 weeks	
5	Sleep quality	SAQLI	10 weeks	Calgary sleep apnea quality of life index
6	QoL	SF 36	10 weeks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*			
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P	comparison
Lam 2007 Hong Kong 17121868	ESS		**Tx**	CM+OA	10 weeks	34	12	1	9	1	-3					<0.05	CPAP vs OA
			Tx2	CM+CPAP	10 weeks	34	12	1	7	1	-5					<0.05	CM vs CPAP
			Cx	CM	10 weeks	33	12	1	10	1	-2						
	AHI		**Tx**	CM+OA	10 weeks	34	20.9	1.7	10.6	1.7	-10.3					<0.001	CM vs OA
			Tx2	CM+CPAP	10 weeks	34	23.8	1.9	2.8	1.1	-21					<0.001	CM vs CPAP
			Cx	CM	10 weeks	33	19.3	1.9	20.5	2.5	1.2					<0.001	CM vs OA
	Min o2 sat	%	**Tx**	CM+OA	10 weeks	34	73.8	1.9	81.0	1.6	7.2					NS	
			Tx2	CM+CPAP	10 weeks	34	75.0	1.4	87.2	2.9	12.2						
			Cx	CM	10 weeks	33	76.1	2.6	77.4	2.0	1.3						
	Arousal index		**Tx**	CM+OA	10 weeks	34	24.5	2.2	21.6	2.5	-2.9					<0.05	CM vs CPAP
			Tx2	CM+CPAP	10 weeks	34	21.6	1.7	16.3	1.8	-5.3						
			Cx	CM	10 weeks	33	23.5	2.2	28.8	2.5	5.3						
	SQALI	summary score (A-D)[a]	**Tx**	CM+OA	10 weeks	34	5.0	0.2	5.6	0.1	0.6					<0.05	CPAP vs OA
			Tx2	CM+CPAP	10 weeks	34	5.0	0.1	5.9	0.1	0.9					<0.001	CM vs OA
			Cx	CM	10 weeks	33	5.1	0.1	5.0	0.1	-0.1					<0.001	CM vs CPAP
	SQALI	summary score (A-E)[a]	**Tx**	CM+OA	10 weeks	34			5.5	0.1						<0.05	CM vs CPAP
			Tx2	CM+CPAP	10 weeks	34			5.5	0.2						<0.05	CM vs OA
			Cx	CM	10 weeks	33			5.0	0.1							

* Delete or correct the incorrect value/item. If change, highlight yellow. [a] A:daily functioning, B: social interactions, C: emotional, D: symptoms E: Treatment related symptom

** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Lam 2007 Hong Kong 17121868	SF 36	Physical function	10 wk	OA	34	CPAP	34						
		Physical function	10 wk	OA	34	CM	33						
		Physical function	10 wk	CM	33	CPAP	34	CPAP	Net difference	6.9	0	100	<0.05
		Bodily pain	10 wk	OA	34	CPAP	34	CPAP	Net difference	15.7	0	100	<0.001
		Bodily pain	10 wk	OA	34	CM	33						
		Bodily pain	10 wk	CM	33	CPAP	34	CPAP	Net difference	11.7	0	100	<0.05

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	3%	Device intolerance
Oral appliance	12%	Gum problems
Conservative measures	15%	Refuse PSG at 10 wks

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	nd	nd	y	y	n	y	

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	y	nd	na	na

Reasons for drop-outs:	
Other Issues:	
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Petri, 2008			**Intervention 1**	mandibular advancement appliance (MAA)
PMID*	18482111	**RefID**	3702	**Intervention 2**	manidibular non-advancement appliance (MNA)
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	no intervention
Extractor	si			**Comments**	all pts offered CPAP but preferred oral appliances

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
AHI >5; >20 y/o; teeth okay to hold splint	severe somatic or psychiatric disease; periodontal disease; temporomandibular dysfunction; pregnancy	>5	nd	no	Denmark	industry?	yes, 29 per group	yes for 1 and 2; no for control	yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx1	33 (27)	85	50	nd	30.7 ± 5.2	nd	nd	nd
Tx2	30 (25)	80	50	nd	31.3 ± 5.2	nd	nd	nd
Cx	30 (29)	79	49	nd	31.3 ± 7.4	nd	nd	nd
Total	81	81.4	50	nd	31.1	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx1	nd	nd	nd	nd	nd	nd	nd	no
Tx2	nd	nd	nd	nd	nd	nd	nd	no
Cx	nd	nd	nd	nd	nd	nd	nd	no
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx1	nd							
Tx2	nd							
Cx	nd							
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment1:	27	39.1 ± 23.8	11.7 ± 4.3	nd	nd	nd	nd	
Treatment2:	25	32.6 ± 22.0	10.8 ± 4.6	nd	nd	nd	nd	
Control:	29	34.3 ± 26.3	10.7 ± 4.6	nd	nd	nd	nd	
Total:	81	35.4	11.06	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>5						

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	mandibular advancement appliance (MAA)	custom made	
2	Oral appliance	manidibular non-advancement appliance (MNA)	custom made	
3				
Control	no treatment			
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	change in AHI	4 wk	
2	Sleepiness measures	change in Epworth	4 wk	daytime sleepiness
3	QoL	change in SF36	4 wk	
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx1												
		Tx2												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value	95%CI	P
Petri, 2008 Denmark 18482111	AHI		**Tx1**	MAA	4 wk	27	39.1	23.8	25	27.5	-14.1		<0.001	-13.1	(-26.6,0.2)	<0.05
			Tx2	MNA	4 wk	25	32.6	22	31.7	25	-0.9		0.69	0.1		
			Cx	no Tx	4 wk	29	34.3	26.3	33.3	25.3	-1		0.67			
	sleep stage 3	%	**Tx1**	MAA	4 wk	27	7	5	9.1	5.1	2.1		0.016	4.5		
			Tx2	MNA	4 wk	25	9.9	5.1	9.1	5.6	-0.8		0.57	1.6		
			Cx	no Tx	4 wk	29	10.3	6.9	7.9	5.5	-2.4		0.046	2.9	(0.1,5.7)	0.045
	sleep stage 4	%	**Tx1**	MAA	4 wk	27	10.2	10.5	12.4	9.5	2.2		0.28	2.7		
			Tx2	MNA	4 wk	25	9.6	10.3	13	9.6	3.4		0.043	3.9		
			Cx	no Tx	4 wk	29	9.5	8.3	9.0	10.3	-0.5		0.81	-1.2	(-6.6,4.2)	0.666
	REM sleep	%	**Tx1**	MAA	4 wk	27	18.4	5.6	18.7	4.7	0.3		0.79	-0.7		
			Tx2	MNA	4 wk	25	16.8	7.5	17.5	6.5	0.7		0.88	-0.3		
			Cx	no Tx	4 wk	29	17.5	6.2	18.5	6.8	1		0.36	-0.4	(-3.7,2.9)	0.817
	Epworth		**Tx1**	MAA	4 wk	27	11.7	4.3	8.4	4.3	-3.3		<0.001	-2.6		<0.05
			Tx2	MNA	4 wk	25	10.8	4.6	9.6	4.2	-1.2		0.05	-0.5		
			Cx	no Tx	4 wk	29	10.7	4.6	10	4.8	-0.7		0.39	-2.1	(-4.4,0.2)	0.08
	PCS (SF-36)		**Tx1**	MAA	4 wk	27	45.5	9.5	46.5	8	1		0.21	0.3		
			Tx2	MNA	4 wk	25	48.1	9.2	47.5	11.2	-0.6		0.40	-1.3		
			Cx	no Tx	4 wk	29	46.6	9.6	47.3	8.7	0.7		0.69			
	MCS (SF-36)		**Tx1**	MAA	4 wk	27	47.2	8.5	51.1	8	3.9		0.039	2.9		
			Tx2	MNA	4 wk	25	48.8	10	49.8	8.5	1		0.48	0		
			Cx	no Tx	4 wk	29	50.2	8.9	51.2	7.8	1		0.79			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper
Red highlights MAA vs MNA Estimated from reported data

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
Petri, 2008 Denmark 18482111	SF36 domains of vitality, general health, and mental health – see Table 2 in paper	Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
All	9	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			MAA	MNA	no Tx	
Petri, 2008 Denmark 18482111	adverse events led to discontinued intervention		4	2	0	
	intolerant to appliance		2	1		
	teeth loosening		1	1		
	temporomandibular joint pain		1			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	y	y	y	y	n	y	y	n
	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?		If a Crossover study, was the Washout period adequate?
	y	n	y	y	n	NA			
Reasons for drop-outs:	12 did not complete study (reasons not provided)								
Other Issues:	stated ITT, but results reported were for per protocol analysis even though sensitivity analysis including the missing values were shown								
Overall Quality (A, B, C)	**B**								

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Question 5
Oral vs Sham

A.

Author, Year	Deane, 2009			**Intervention 1**	Mandibular advancement splint (MAS)
PMID*	19480232	**RefID**	3217	**Intervention 2**	
Key Question(s)	5- Mandib v Mandib			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	Tongue stabilizing device (TSD)
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Inclusion criteria were age > 20 years, ≥ 2 symptoms of OSA (snoring, fragmented sleep, witnessed apneas, daytime sleepiness) and evidence of OSA on polysomnography with an apnea hypopnea index (AHI) > 10 per hour.	regular use of sedative medications, previous failure of an oral appliance for treatment of OSA, exaggerated gag reflex, edentulous patients, and < 10 teeth per jaw or evidence of periodontal disease.	nd	nd	n	Australia	Australian Society of Orthodontics Foundation for Research and Education	sample size of 21 subjects was required to give a 90% power to detect a 50% reduction in AHI (P = 0.05), based on the data from group's previous study	n	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**22**	59%	49.4	Nd	29.3	Nd	Nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	Nd	Nd	Nd	Nd	Nd	Nd	Nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	22	27.0	Nd	Nd	Nd	Nd	Nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	Nd	Nd	cessation of airflow ≥ 10 s with oxygen desaturation > 3% and/or associated with arousal..	reduction in amplitude of airflow > 50% of the baseline tidal volume for > 10 s with an accompanying oxygen desaturation of ≥ 3% and/or associated arousal	Nd	NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	MAS (Mandibular adjustment device)	Somnomed Ltd, Australia	custom-made 2-piece device with vertical extensions on the lower component and ramps on the upper component which induced a forward mandibular posture. non-titratable version of the device was used by not incorporating the usual adjustable screw mechanism. A protrusive bite was taken with a 4-mm vertical interincisal opening at 75% of the maximal comfortable protrusive range. 4 week acclimatization period.
2				
3				
Control	Oral appliance	TSD (Tongue stabilizing device)		preformed, non-adjustable silicon appliance constructed by injection molding. 4 week acclimatization period.
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	AHI	Baseline, 1 wk	
2	Sleep study measures	MinSaO2 %	Baseline, 1 wk	
3	Sleep study measures	Arousal Index	Baseline, 1 wk	
4	Sleep study measures	Sleep efficiency %	Baseline, 1 wk	
	Sleep study measures	REM %	Baseline, 1 wk	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	95% CI *	P
Deane, 2009 Australia 19480232	AHI	Number	**Tx**	MAS (Mandibular adjustment device)	1 wk	22	27	17	12	9	-15	Nd	0.000	-1	(-5.2,3.2)	NS 0.644
			Cx	TSD (Tongue stabilizing device)	1 wk	22	27	17	13	11	-14	Nd	0.002			
	MinSaO2 %	%	**Tx**	MAS (Mandibular adjustment device)	1 wk	22	84	7	87	5	3	Nd	Ns	-1	(-3.2,1.3)	NS 0.400
			Cx	TSD (Tongue stabilizing device)	1 wk	22	84	7	88	6	4	Nd	Ns			
	Arousal Index	Number	**Tx**	MAS (Mandibular adjustment device)	1 wk	22	33	16	21	9	-12	Nd	0.004	0	(-4.2,4.2)	NS 1.00
			Cx	TSD (Tongue stabilizing device)	1 wk	22	33	16	21	11	-12	Nd	0.001			
	Sleep efficiency %	%	**Tx**	MAS (Mandibular adjustment device)	1 wk	22	80	11	78	17	-2	Nd	Ns	-1	(-7.2,5.2)	NS 0.753
			Cx	TSD (Tongue stabilizing device)	1 wk	22	80	11	79	11	-1	Nd	Ns			
	REM %	%	**Tx**	MAS (Mandibular adjustment device)	1 wk	22	Nd	nd	18%	Nd	Nd	Nd	nd	nd	nd	nd
			Cx	TSD (Tongue stabilizing device)	1 wk	22	nd	Nd	17%	nd	nd	nd	Nd			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Both	19%	Two patients failed to complete the study for medical and work-related reasons, and 3 patients attended the first consultation, then subsequently withdrew for personal and time concerns unrelated to the nature of the devices.

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			MAS (Mandibular adjustment device)	TSD (Tongue stabilizing device)		
Deane, 2009 Australia 19480232	Jaw discomfort	1 wk	59.1%	Nd		
	Dry mouth	1 wk	50%	59.1%		
	Excess salivation	1 wk	Nd	86.4%		
	Soft tissue irritation	1 wk	nd	50%		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	y	y	n	y	n	y	NA	n	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	y	y	y	Y	NA	y			Y
Reasons for drop-outs:	Two patients failed to complete the study for medical and work-related reasons, and 3 patients attended the first consultation, then subsequently withdrew for personal and time concerns unrelated to the nature of the devices.									
Other Issues:	Baseline measurement of total sleep time did not add up to (REM + NREM) sleep time									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Hans ,1997			**Intervention 1**	MAD-A
PMID*	9155816	**RefID**	12330	**Intervention 2**	
Key Question(s)	5(Manibular)			**Intervention 3**	
Design †	Cross over			**Control**	Sham device
Extractor	NO			**Comments**	Individual patient data provided in article

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Age 25- 69 years RDI <30 History of loud snoring	Pregnant Prisoners Minors and persons with chronic illness other than OSAS Mentally disabled Edentulous Previous surgery to correct snoring Periodic leg movt Chronic insufficient sleep efficiency Narcolepsy CNS disease or psychiatric illness, unstable hypertension BP>195/105 Unstable ischemic heart disease		nd	n	USA	NIDR grant, NIH grant, grant from American association of orthodontists foundation	nd	n	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx	**24(17)**				29.5(4.2)			
Cx	24(17)				29.4(6.0)			
Total	24(17)	83	51.875(12.27)	nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	RDI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	17	35.6(28.4)	12.0(3.9)					
Control:	17	36.5(43.7)	12.5(5.7)					
Total:	17			nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Portable monitor (edentrance II digital recorder, edentech	RDI 30		nd	nd	snoring		

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	**Oral appliance**		Snore guard, dental sleep disorder prevention Inc.	Thermoplastic intraoral device, fitted in upper dentition by molding the softened plastic around the upper teeth. Caused mandibular protrusion of 6 to 8 mm and vertical opening 8mm
2				
3				
Control	Oral appliance		Sham device	Similar device to intervention, but designed to cause minimal increase in vertical opening 1mm and no protusion
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	**Sleep study measures**	RDI		Total number of apnea and hypopneas divided by total number of sleep hours
2		ESS		
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value	95% CI	P
Hans 1997 9155816 USA	RDI		**Tx**	MAD-A	2 weeks	17	35.6	28.4	21.1	21.4	-14.5			-24.8	(-45.0,-6.3)	<0.0045
			Cx	Sham device	2 weeks	17	36.5	43.7	46.8	46.9	10.3					
	ESS		**Tx**	MAD-A	2 weeks	17	12.0	3.9	8.2	4.0	-3.8			-3.3	(-6.4,-0.2) ***	NS
			Cx	Sham device	2 weeks	17	13.0	4.5	12.5	5.7	-0.5					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper
*** Estimated from reported SD's .our estimates does not match reported NS

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
both	29	"various reasons"

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	n	n	nd	n	y	n	y	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	y	n	n			y
Reasons for drop-outs:										
Other Issues:	Drop out 30%, no power analysis									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Johnston, 2002			**Intervention 1**	Mandibular advancement device
PMID*	12143089	**RefID**	4412	**Intervention 2**	
Key Question(s)	5- Positional vs Cx			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	Maxillary placebo appliance
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
->10 hourly desaturations (≥4% fall in SaO2)	-Concurrent serious illness, including pulmonary disease -Edentulous patients, those with inadequate number of sound teeth to support a MAA	nd	nd	n	Ireland	nd	80% power and significance level of 5% required sample size of 18 subjects	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**20**							
Cx	**20**							
Total	**20**	81%	55.1	Nd	31.6	Nd	Nd	Nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	Nd	Nd	Nd	Nd	Nd	Nd	Nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	20	31.9	30.7	Nd	Frequency = 3.8 out of 5, loudness 3.2 out of 5	Nd	Nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
Frequency of feeling unrefreshed = 3.45/5						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Edentrace II multi-channel recording system (Nellcor, Puritan and Bennett Inc, Eden Prairie MN, USA)	Hourly rate of apneas and hypopneas	Hourly rate of desaturation events	Apnea = complete cessation of oronasal airflow for at least 10 sec	Decrease in oronasal airflow of at least 50% combined with a desaturation event			

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	Mandibular advancement appliance	'Proform Dual Laminate', Dental Resources, Delano MN, USA	Bilaminate acrylic material with a soft fitting surface; mandible protruded by 75% of maximum protrusion with a 4 mm inter-incisal vertical clearance
2				
3				
Control	Oral appliance	Placebo appliance	Nd	Single arch upper anterior bite plane design on a dual laminate base constructed to produce approximately 1.5 mm of separation between the upper and lower posterior teeth
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description
For CPAP:	**Describe the frequency of the initial education follow-up**

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	AHI	Baseline, 4-6 wks	
2	Sleep study measures	ODI	Baseline, 4-6 wks	
3	Sleepiness measures	ESS	Baseline, 4-6 wks	
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Final test - control		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	95% CI	P
Johnston, 2002 Ireland 12143089	AHI	Events/hr	Tx	Mandibular advancement appliance	4-6 wks	20	31.93	21.18	22.86	22.84	-9.07			-14.82	(-25.77,-3.87)	0.011
			Cx	Placebo appliance	4-6 wks	20	31.93	21.18	37.68	24.86	5.75					
	ODI	Events/hr	Tx	Mandibular advancement appliance	4-6 wks	20	30.69	18.82	21.08	19.82	-9.61			-10.12	(-15.89,-4.35)	0.002
			Cx	Placebo appliance	4-6 wks	20	30.69	18.82	31.21	18.22	0.52					
	ESS	Events/hr	Tx	Mandibular advancement appliance	4-6 wks	18	13.9	6.39	11.61	6.73	-2.29			-0.94	(-3.32,1.43)	0.414
			Cx	Placebo appliance	4-6 wks	18	13.9	6.39	12.56	6.29	-1.34					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Mandibular advancement appliance	5	Unable to tolerate

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			Mandibular advancement appliance	Placebo appliance		
Johnston, 2002 Ireland 12143089	Excessive salivation	4-6 weeks	68%	Nd		
	Temporary occlusal changes in the morning	4-6 weeks	44%	Nd		
	Temporary TMJ discomfort on waking	4-6 weeks	42%	Nd		
	Persistant TMJ discomfort during day	4-6 weeks	5%	Nd		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Y	Nd	Nd	Y	nd	nd	N	Y	NA	NA	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	Y	N	Y	y	y	NA	Y	Y

Reasons for drop-outs:	One patient unable to tolerate mandibular advancement appliance
Other Issues:	No intention to treat analysis, even though patient in treatment arm withdrew because inability to tolerate device
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments
Washout period deemed as unnecessary based on previous studies

A.

Author, Year	Mehta, 2001			**Intervention 1**	Mandibular advancement splint
PMID*	11371418	**RefID**	5601	**Intervention 2**	
Key Question(s)	5- Mandib v Cx			**Intervention 3**	
Design †	Randomized cross-over			**Control**	Lower dental plate
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
-2+ symptoms of OSA (snoring, fragmented sleep, witnessed apneas, daytime sleepiness) -Evidence of OSA on polysomnography, with an apnea/hypopnea Index (AHI)>10/h	- evidence of periodontal disease, edentulism, an exaggerated gag reflex, or regular use of sedatives	≥10	nnd	N	australia	National Health and Medical Research Council of Australia, and the Australian Society for Orthodontists Research Foundation	Power calculated to be 96%	N	Y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**24**	79.2%	48	Nd	29.4	Nd	Nd	Nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	Nd	Nd	Nd	Nd	Nd	Nd	Nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	24	27	nd	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
MinSa(O2) = 85%						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	Mild OSA = AHI<20/hr; moderate = OSA 20 to 40/hr; severe = AHI > 40/hr	Nd	Cessation of airflow for at least 10 s with oxygen desaturation of more than 3% and/or associated with arousal.	Reduction in amplitude of airflow or thoracoabdominal wall movement of greater than 50% of the baseline measurement for more than 10 s with an accompanying oxygen desaturation of at least 3% (no time limit), and/or associated with arousal. These events were considered obstructive if they occurred in association with continued diaphragm EMG activity and thoracoabdominal wall movement.	Nd	NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	Mandibular advancement splint	Custom-made	-Upper and lower removable clear acrylic plates with full occlusal coverage that fitted onto both dental arches. The average thickness of each upper and lower appliance was between 1.5 and 2.0 mm. -Two acrylic flanges, one on either side of the palatal aspect of the molars of the upper plate. These flanges fitted into slots cut into the acrylic on the lingual sides of the lower plate in the molar region. This unique coupling mechanism prevents posterior movement of the mandible, while permitting free opening of the mouth. -Two 10-mm screws to enable incremental anterior advancement of the lower plate.
2				
3				
Control	Oral appliance	Lower dental plate alone	Nd	No protrusive effect on the mandible
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	REM %	1 wk	
2	Sleep study measures	Arousal index	1 wk	
3	Sleep study measures	Sleep efficiency	1 wk	
4	Sleep study measures	AHI	Baseline, 1 wk	
	Sleep study measures	Min SaO2 %	1 wk	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Final test - control		
							Value	SD/SE *	Value	SD/SE *	Value	SD/SE *	P	Value	95%CI*	P
Mehta, 2001 Australia 11371418	REM %	% of total sleep time	**Tx**	Mandibular advancement splint	1 wk	24	nd	Nd	21%	1%	nd	nd	Nd	5%	(4.6,5.4)	<0.005
			Cx	Lower dental plate	1 wk	24	nd	Nd	16%	1%	nd	nd	Nd			
	Arousal index	Events/hr	**Tx**	Mandibular advancement splint	1 wk	24	nd	Nd	27	2	nd	nd	Nd	-14	(-14.8,-13.2)	<0.0001
			Cx	Lower dental plate	1 wk	24	Nd	nd	41	2	nd	nd	Nd			
	Sleep efficiency	Time asleep/time in bed	**Tx**	Mandibular advancement splint	1 wk	24	nd	Nd	85	1	nd	nd	Nd	-2	(-2.4,-1.6)	NS
			Cx	Lower dental plate	1 wk	24	nd	Nd	87	1	nd	nd	Nd			
	AHI	Events/hr	**Tx**	Mandibular advancement splint	1 wk	24	27	17	14	2	-13	nd	Nd	-16	(-25.1,-6.9)	<0.0001
			Cx	Lower dental plate	1 wk	24	27	17	30	2	3	nd	Nd			
	Min SaO2 %	%	**Tx**	Mandibular advancement splint	1 wk	24	85%	8%	91%	1%	6%	nd	Nd	4%	(-2.4,-1.6)	<0.0001
			Cx	Lower dental plate	1 wk	24	85%	8%	87%	1%	2%	nd	nd			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
All	14.3	Excessive salivation, TMJ pain, unstable angina, time demands

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			Mandibular advancement device			
Mehta, 2001 Australia 11371418	Excessive salivation	1 wk	50%			
	Gum irritation	1 wk	20%			
	Mouth dryness	1 wk	46%			
	Jaw discomfort	1 wk	12.5%			
	Tooth grinding	1 wk	12.5%			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	N	Y	N	Y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Y	N	Y	Y	N	NA	y			y
Reasons for drop-outs:	Excessive salivation, TMJ pain, unstable angina, time demands									
Other Issues:										
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Naismith, 2005; Gotsopoulos 2002; Gotsopoulos 2004			**Intervention 1**	mandibular advancement splint (MAS)
PMID*	17564405; 12204875; 15453552	**RefID**	3631,4318,4317	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	inactive device
Extractor	SI			**Comments**	

* or Cochrane number

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	Exclusion	AHI Criteria to Dx OSA	Enrollment Years	Multicenter?	Country	Funding source	Power calculation? (specify outcome)	Blinding, patient	Blinding, outcome assessor
≥2 symptoms of OSA; AHI ≥10; >20 y/o; able to protrude mandible ≥3 mm	central sleep apnea; periodontal disease; insufficient teeth; exaggerated gag; use of narcotics, sedatives; psychoactive drugs; hx of head injury or psychiatric disorders		nd	no	Australia	industry	no	yes	yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?)	AFib/AFlutter, %	CVD †, % (specify)
Tx	**73**	81	48	nd	29 ± 4.7	nd	nd	nd
Cx	**73**	81	48	nd	29 ± 4.7	nd	nd	nd
Total	**73**	81	48	nd	29 ± 4.7	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	nd	nd	nd	no
Cx	nd	nd	nd	nd	nd	nd	nd	no
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx	nd							
Cx	nd							
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Including CVD, CAD, IHD, previous MI, previous stroke, etc.

‡ Motor vehicle accident.

** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	RDI
Treatment:	73		11 ± 5	nd	nd	nd	nd	27 ± 2
Control:	73		11 ± 5	nd	nd	nd	nd	27 ± 2
Total:	73		11 ± 5	nd	nd	nd	nd	27 ± 2
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	RDI
PSG		nd	nd	nd	nd	nd	≥5

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	mandibular advancement splint		
2				
3				
Control	Oral appliance	inactive device		
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Neuropsychological	Speed/vigilance	4 wk from beginning of assignment	Rozelle Test Battery
2		Attention/working memory	4 wk from beginning of assignment	Wechsler Digit Span
3		Verbal memory	4 wk from beginning of assignment	Rey Auditory Verbal Learning
4		Visual spatial functioning	4 wk from beginning of assignment	Wechsler Block Design
5		Executive functioning	4 wk from beginning of assignment	Trail Making Test
6	Sleepiness measures	Epworth	4 wk from beginning of assignment	
7	Psych scale	Total Mood Disturbance	4 wk from beginning of assignment	Profile of Mood States
8		Beck Depression Inventory	4 wk from beginning of assignment	BDI
9	Sleep study measures	AHI	4 wk from beginning of assignment	
10		sleep efficiency	4 wk from beginning of assignment	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Naismith, 2005 Australia 17564405		**Tx**												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Naismith, 2005 Australia 17564405	Speed/Vigilance Trails-A		**Tx**		4 wk from start of Tx/Cx	73	30	10.6	27.1	8.6	-2.9			0.2		NS
			Cx		4 wk from start of Tx/Cx	73	30	10.6	26.9	10.3	-3.1					
	Speed/Vigilance Choice Reaction time		**Tx**		4 wk from start of Tx/Cx	73	0.664	0.1	0.643	0.1	-0.021			-0.019		0.001†
			Cx		4 wk from start of Tx/Cx	73	0.664	0.1	0.662	0.1	-0.002					
	Attention/working memory Digit span backward		**Tx**		4 wk from start of Tx/Cx	73	8	2.9	8.1	2.8	0.1			0.1		NS
			Cx		4 wk from start of Tx/Cx	73	8	2.9	8.0	2.5	0					
	Verbal Memory RAVLT1 (/15)		**Tx**		4 wk from start of Tx/Cx	73	6.6	2.2	7.0	2.2	0.4			-0.5		NS
			Cx		4 wk from start of Tx/Cx	73	6.6	2.2	7.5	2.2	0.9					
	Visual spatial functioning Block Design		**Tx**		4 wk from start of Tx/Cx	73	34.2	9.4	36.4	9.8	2.2			-0.1		NS
			Cx		4 wk from start of Tx/Cx	73	34.2	9.4	36.5	9.9	2.3					
	Executive functioning Trails B		**Tx**		4 wk from start of Tx/Cx	73	70	30.4	65.2	25.9	-4.8			-0.7		NS
			Cx		4 wk from start of Tx/Cx	73	70	30.4	65.9	31.5	-4.1					

	AHI		**Tx**		4 wk from start of Tx/Cx	73	26.9	15.4	12.2	12.3	-14.7			-13.2		≤0.01
			Cx		4 wk from start of Tx/Cx	73	26.9	15.4	25.4	14.5	-1.5					
	Arousals	no./h	**Tx**		4 wk from start of Tx/Cx	73	35	13.5	25	13.9	-10			-8.1		≤0.01
			Cx		4 wk from start of Tx/Cx	73	35	13.5	33.1	12.8	-1.9					
	Sleep efficiency	%	**Tx**		4 wk from start of Tx/Cx	73	80.6	12	83.6	10.7	3			1.8		NS
			Cx		4 wk from start of Tx/Cx	73	80.6	12	81.8	12.9	1.2					
	Min SaO2	%	**Tx**		4 wk from start of Tx/Cx	73	85.7	5.6	88.7	5.3	3			2.3		≤0.01
			Cx		4 wk from start of Tx/Cx	73	85.7	5.6	86.4	4.7	0.7					
	TIME-REM	min/h	**Tx**		4 wk from start of Tx/Cx	73	66.2	29.4	67.8	29	1.6			5.1		NS
			Cx		4 wk from start of Tx/Cx	73	66.2	29.4	62.7	27.4	-3.5					
	Epworth		**Tx**		4 wk from start of Tx/Cx	73	10.9	4.8	7.1	4.5	-3.8			-2		≤0.01
			Cx		4 wk from start of Tx/Cx	73	10.9	4.8	9.1	5.1	-1.8					
	Total Mood Disturbance		**Tx**		4 wk from start of Tx/Cx	73	56.8	20.9	49.7	19.6	-7.1			-1.9		NS
			Cx		4 wk from start of Tx/Cx	73	56.8	20.9	51.6	22.4	-5.2					

	Beck Depression Inventory (BDI) Total score		**Tx**		4 wk from start of Tx/Cx	73	5.8	4	4.2	4.3	-1.6			-0.8		NS
			Cx		4 wk from start of Tx/Cx	73	5.8	4	5	4.3	-0.8					
	BDI cognitive		**Tx**				2.4	2.2	2.1	2.8	-0.3			-0.2		NS
			Cx				2.4	2.2	2.3	2.8	-0.1					
	BDI somatic		**Tx**				3.3	2.3	2.1	2.1	-1.2			-0.6		<0.05
			Cx				3.3	2.3	2.7	2.1	-0.6					
Gotsopoulos 2002	Multiple sleep latency test	min	**Tx**		4 wk from start of Tx/Cx	73			10.3	0.5						0.01
			Cx		4 wk from start of Tx/Cx	73			9.1	0.5						
Gotsopoulos 2004	SBP (24 h)		**Tx**		4 wk from start of Tx/Cx	61	127.3	1.3 (SE)	125.2	1.3 (SE)	-2.1			-1.5	0.7 (SE)	0.05
			Cx		4 wk from start of Tx/Cx	61	127.3	1.3	126.7	1.3	-0.6					
	DBP (24 h)		**Tx**			61	77.7	0.9 (SE)	76.4	0.9 (SE)	-1.3			-1.6	0.5 (SE)	0.001
			Cx			61	77.7	0.9	78	0.8	0.3					

†Bonferroni-adjusted significance level = 0.01

* Delete or correct the incorrect value/item. If change, highlight yellow.

** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	**Outcome**		**Intervention**	**Follow-up**	**Results**
Gotsopoulos 2004		**Tx**			Baseline age, sex, BMI, BP, AHI, measures of protrusion, and change in MinSaO2 between treatments were not independent predictors of BP treatment effects.
		Cx			

Comments on Results	See Table 4 in paper for complete results from neuropsychological measures.

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	y	y	n	y	NA	NA	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n					?
Reasons for drop-outs:										
Other Issues:	Unclear how many participants were originally randomized									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Petri, 2008			**Intervention 1**	mandibular advancement appliance (MAA)
PMID*	18482111	**RefID**	3702	**Intervention 2**	manidibular non-advancement appliance (MNA)
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	no intervention
Extractor	si			**Comments**	all pts offered CPAP but preferred oral appliances

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
AHI >5; >20 y/o; teeth okay to hold splint	severe somatic or psychiatric disease; periodontal disease; temporomandibular dysfunction; pregnancy	>5	nd	no	Denmark	industry?	yes, 29 per group	yes for 1 and 2; no for control	yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx1	33 (27)	85	50	nd	30.7 ± 5.2	nd	nd	nd
Tx2	30 (25)	80	50	nd	31.3 ± 5.2	nd	nd	nd
Cx	30 (29)	79	49	nd	31.3 ± 7.4	nd	nd	nd
Total	81	81.4	50	nd	31.1	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx1	nd	nd	nd	nd	nd	nd	nd	no
Tx2	nd	nd	nd	nd	nd	nd	nd	no
Cx	nd	nd	nd	nd	nd	nd	nd	no
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx1	nd							
Tx2	nd							
Cx	nd							
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment1:	27	39.1 ± 23.8	11.7 ± 4.3	nd	nd	nd	nd	
Treatment2:	25	32.6 ± 22.0	10.8 ± 4.6	nd	nd	nd	nd	
Control:	29	34.3 ± 26.3	10.7 ± 4.6	nd	nd	nd	nd	
Total:	81	35.4	11.06	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>5						

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	mandibular advancement appliance (MAA)	custom made	
2	Oral appliance	manidibular non-advancement appliance (MNA)	custom made	
3				
Control	no treatment			
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	change in AHI	4 wk	
2	Sleepiness measures	change in Epworth	4 wk	daytime sleepiness
3	QoL	change in SF36	4 wk	
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx1												
		Tx2												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value	95%CI	P
Petri, 2008 Denmark 18482111	AHI		**Tx1**	MAA	4 wk	27	39.1	23.8	25	27.5	-14.1		<0.001	-13.1	(-26.6,0.2)	<0.05
			Tx2	MNA	4 wk	25	32.6	22	31.7	25	-0.9		0.69	0.1		
			Cx	no Tx	4 wk	29	34.3	26.3	33.3	25.3	-1		0.67			
	sleep stage 3	%	**Tx1**	MAA	4 wk	27	7	5	9.1	5.1	2.1		0.016	4.5		
			Tx2	MNA	4 wk	25	9.9	5.1	9.1	5.6	-0.8		0.57	1.6		
			Cx	no Tx	4 wk	29	10.3	6.9	7.9	5.5	-2.4		0.046	2.9	(0.1,5.7)	0.045
	sleep stage 4	%	**Tx1**	MAA	4 wk	27	10.2	10.5	12.4	9.5	2.2		0.28	2.7		
			Tx2	MNA	4 wk	25	9.6	10.3	13	9.6	3.4		0.043	3.9		
			Cx	no Tx	4 wk	29	9.5	8.3	9.0	10.3	-0.5		0.81	-1.2	(-6.6,4.2)	0.666
	REM sleep	%	**Tx1**	MAA	4 wk	27	18.4	5.6	18.7	4.7	0.3		0.79	-0.7		
			Tx2	MNA	4 wk	25	16.8	7.5	17.5	6.5	0.7		0.88	-0.3		
			Cx	no Tx	4 wk	29	17.5	6.2	18.5	6.8	1		0.36	-0.4	(-3.7,2.9)	0.817
	Epworth		**Tx1**	MAA	4 wk	27	11.7	4.3	8.4	4.3	-3.3		<0.001	-2.6		<0.05
			Tx2	MNA	4 wk	25	10.8	4.6	9.6	4.2	-1.2		0.05	-0.5		
			Cx	no Tx	4 wk	29	10.7	4.6	10	4.8	-0.7		0.39	-2.1	(-4.4,0.2)	0.08
	PCS (SF-36)		**Tx1**	MAA	4 wk	27	45.5	9.5	46.5	8	1		0.21	0.3		
			Tx2	MNA	4 wk	25	48.1	9.2	47.5	11.2	-0.6		0.40	-1.3		
			Cx	no Tx	4 wk	29	46.6	9.6	47.3	8.7	0.7		0.69			
	MCS (SF-36)		**Tx1**	MAA	4 wk	27	47.2	8.5	51.1	8	3.9		0.039	2.9		
			Tx2	MNA	4 wk	25	48.8	10	49.8	8.5	1		0.48	0		
			Cx	no Tx	4 wk	29	50.2	8.9	51.2	7.8	1		0.79			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper
Red highlights MAA vs MNA Estimated from reported data

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
Petri, 2008 Denmark 18482111	SF36 domains of vitality, general health, and mental health – see Table 2 in paper	Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
All	9	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			MAA	MNA	no Tx	
Petri, 2008 Denmark 18482111	adverse events led to discontinued intervention		4	2	0	
	intolerant to appliance		2	1		
	teeth loosening		1	1		
	temporomandibular joint pain		1			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	y	y	y	y	n	y	y	n
	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?		If a Crossover study, was the Washout period adequate?
	y	n	y	y	n	NA			
Reasons for drop-outs:	12 did not complete study (reasons not provided)								
Other Issues:	stated ITT, but results reported were for per protocol analysis even though sensitivity analysis including the missing values were shown								
Overall Quality (A, B, C)	**B**								

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Clark, 1996			**Intervention 1**	Anterior mandibular positioning device
PMID*	8769497	**RefID**	5152	**Intervention 2**	
Key Question(s)	5(CPAP and Oral appliance)			**Intervention 3**	
Design †	Cross over			**Control**	CPAP
Extractor	NO			**Comments**	Issues with implementing cross over design only 6/21 patients had AMP after CPAP, the others had only CPAP. Number of patients analyzed not clear

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Previous OSAS diagnostic PSG 21-75yrs AHI>=15/hr Adequate nasal flow capacity determined by otolaryngologist General good health Minimum of 7mm protrusive jaw movement from a position of maximum intercuspation	Central sleep apnea More than one missing tooth per quadrant(excluding molars) Visual or clinical evidence of periodontal disease or dental caries TMJ disorder Previous nasal obstruction/allergies Use of psychoactive drugs daily, alcohol or narcotics Previous failed CPAP or dental device	AHI>=10	1991 to 1992	n	Israel	nd	n	n	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**23(21)**	100	47.1(8.07)	nd	28.07(3.77)	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	21	33.86(14.30)	nd	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>=10		>=10secs	>50% reduction in airflow	Excessive daytime sleepiness, loud snoring, restless sleep	separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	Anterior mandibular device		Two acrylic appliances placed into the two dental arches with the aid of Herbst attachments
2				
3				
Control	PAP	CPAP	Respironics, Murrysville, Pa	
For CPAP:		**How was the Pressure selected?**	manual	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	2 weeks	
2	Sleep study measure	Sleep efficiency	2 weeks	
3	Sleep study measure	Stage 3 and 4	2 weeks	
4	Sleep study measure	REM	2 weeks	
5	Sleepiness measure	Excessive daytime sleepiness	2 weeks	
6	Sleepiness measure	Daytime symptoms	2 weeks	
7	Sleep study	Min O_2	2 weeks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Clark, 1996 Israel 8769497	AHI		**Tx**	AMD	2weeks		33.86	14.30	19.94	12.75	-13.92		0.0001			
			Cx	CPAP	2weeks	21	33.86	14.30	11.15	3.93	-22.71		0.001			
	Sleep efficiency	%	**Tx**	AMD	2weeks		87.10	10.67	89.91	5.46						
			Cx	CPAP	2weeks		87.10	10.67	89.52	7.27						
	Stage 3 and 4	%	**Tx**	AMD	2weeks		12.41	7.81	13.39	7.96						
			Cx	CPAP	2weeks		12.41	7.81	15.24	5.59						
	REM	%	**Tx**	AMD	2weeks		5.90	5.78	20.88	7.52						
			Cx	CPAP	2weeks		5.90	5.78	20.67	6.73						
	Excessive daytime sleepiness		**Tx**	AMD	2weeks		2.4	0.7	1.6	0.6			0.0001			
			Cx	CPAP	2weeks		2.4	0.7	1.8	0.6			0.008			
	Daytime symptoms		**Tx**	AMD	2weeks		2.0	0.5	1.4	0.4						
			Cx	CPAP	2weeks		2.0	0.5	1.5	0.4						
	Min O_2		**Tx**	AMD	2weeks		84.30	6.77	90.20	4.36			0.0007			
			Cx	CPAP	2weeks		84.30	6.77	91.10	6.40			0.0003			

* Mean (1SD)91.10
Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	1/23	Intolerance to CPAP
AMD	1/23	AMP device induced TMJ pain

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	Y?(cross over not successfully implemented)		n	n	y		y	na	Y?	n

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	n	y	n	nd
Reasons for drop-outs:								
Other Issues:								
Overall Quality (A, B, C)		**C(n<30, no power calculation, failed cross over design)**						

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Engleman, 2002			**Intervention 1**	CPAP
PMID*	12231497	**RefID**	4233	**Intervention 2**	
Key Question(s)	5(CPAP and oral appliance)			**Intervention 3**	
Design †	Cross over			**Control**	Mandibular repositioning splint(MRS)
Extractor	NO			**Comments**	Patients with Sleep apnea/Hypopnea syndrome (SAHS)

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
New SAHS patients Daytime Sleepiness or sleepiness while driving 18-70yrs	<4 teeth in either arch Narcolepsy or periodic limb movement more than 10/hr Major medical illness Shift work Living >50 miles away from study location(Edinburgh)	>=5/hr	nd	n	UK	British Lung foundation fellowship grant Non industry	Y(Preferred treatment)	n	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**26(24)**		47(8)	nd		nd	nd	nd
Cx	**25(24)**		45(9)	nd		nd	nd	nd
Total	**51(48)**	75	46(9)	nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	9(12) (IQ decrement score)	7(5) (HADS depression score)	nd	n
Cx	nd	nd	nd	nd	4(12)	5(4)	nd	
Total	nd	nd	nd	nd			nd	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	patients had MRS individually manufactured and fitted to produce 80% of maximal comfortable mandibular protrusion with 2-4mm interdental clearance for 2 months till snoring was abolished							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

IQ(intelligence quotient), HADS (hospital anxiety and depression scale)

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	29	32(29)	15(3)	nd	nd	nd	nd	nd
Control:	19	30(21)	13(4)	nd	nd	nd	nd	nd
Total:		31(26)	14(4)	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG (assumed)	>=5/hr		nd	nd	Daytime Sleepiness or sleepiness while driving	split	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP		
2				
3				
Control	Oral appliance	MRS	Kombiplast hard/soft (or 1MEDL)	A flexible ethylene polystyrene material sealed in protrusion (or Less flexible, dual laminate material molded to fit interior contours of mouth and affixed with metal adams clasps that hold the mandible in protrusion)
For CPAP:		**How was the Pressure selected?**	Manual adjustment by staff till snoring was abolished	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Preference	Preferred treatment	8 weeks	
2	Sleepiness	MWT	8 weeks	
3	Sleepiness	ESS	8 weeks	
4	Sleepiness	FOSQ	8 weeks	
5	QOL	Health transition (SF 36)	8 weeks	
6	QOL	Physical component (SF 36)	8 weeks	
7	QOL	Mental component (SF 36)	8 weeks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Engleman, 2002 UK 12231497	Preferred treatment	**Tx**	CPAP	8weeks	25					0.194				
		Cx	MRS	8weeks	19									

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD	Value	SD/SE*	P	Value	SD/SE*	P
Engleman, 2002 UK 12231497	MWT	minutes	**Tx**	CPAP	8 weeks	48	nd	nd	24	12						0.460
			Cx	MRS	8 weeks	48	nd	nd	22	12						
	ESS		**Tx**	CPAP	8 weeks	48	15	3	8	5	-7			-6		<0.001
			Cx	MRS	8 weeks	48	13	4	12	5	-1					
	FOSQ		**Tx**	CPAP	8 weeks	48	10	3	14	2	4			3		0.001
			Cx	MRS	8 weeks	48	12	2	13	3	1					
	Health transition (SF 36)		**Tx**	CPAP	8 weeks	48	nd	nd	2.4	0.8						0.001
			Cx	MRS	8 weeks	48	nd	nd	2.9	0.8						
	Physical component (SF 36)		**Tx**	CPAP	8 weeks	48	40	11	47	10	7			11		0.023
			Cx	MRS	8 weeks	48	49	6	45	10	-4					
	Mental component (SF 36)		**Tx**	CPAP	8 weeks	48	42	12	52	10	10			7		0.008
			Cx	MRS	8 weeks	48	45	12	48	11	3					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	1/51	No reason and could not be contacted
CPAP	1/51	New job, not able to spare time for study
MRS	1/51	New job, not able to spare time for study

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

MRS	Frequency	CPAP	Frequency
Pain in teeth, gums, or jaw	33 (69%)	Sleep disruption	16 (33%)
MRS is removed or comes off in sleep	19 (40%)	Leaky or painful mask	11 (23%)
Sleep disruption	12 (25%)	Stuffy nose	8 (17%)
Excessive salivation	9 (19%)	Mask is removed in sleep	7 (15%)
Dental crown damaged	3 (6%)	Cold airstream	7 (15%)
		Noise/inconvenience	6 (13%)
		Dry upper airway	5 (10%)
Reported use ≤3 hours per night (second month)	10 (21%)	Reported use ≤3 hours per night (second month)	13 (27%)
No problems limiting use (second month)	13 (27%)	No problems limiting use (second month)	15 (31%)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	n	y	N(stated but did not analyze data from 3)	y	na	y	N (uncertain of actual duration of study, sample size)
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y		y	na			nd
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)		**B**								

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments:

A.

Author, Year	Ferguson 1996			**Intervention 1**	Oral mandibular device
PMID*	8625679	**RefID**	5258	**Intervention 2**	
Key Question(s)	5 (CPAP and oral)			**Intervention 3**	
Design †	Cross over			**Control**	CPAP
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
AHI 15-50 At least 10 teeth in each of the mandibular or maxillary arches	nd	>10	1991-1994	n	Canada		n	n	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**27(19)**	88	46.2(10.9)	nd	30.4(4.8)	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	Intranasal corticosteroids and or anticholinergic medication used to relieve any nasal symptoms							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	27	24.5(8.8)	nd	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, (neck circumference in cm)**		**Other characteristics**
nd						42.2 (3.1) Mean (SD)		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG			>= 10s	>50% decrease in thoracoabdominal amplitude for at least 10secs		Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	Mandibular advancement device	Snore-Guard	Acrylic polymer which advances the mandible
2				
3				
Control	PAP	CPAP	REMstar or Respironics or Tranquility plus machine	
For CPAP:		**How was the Pressure selected?**	nd	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	4months	
2	Sleep study measure	ODI	4months	
3	Sleep study measure	SaO_2 min	4months	
4	Sleep study measure	Sleep efficiency	4months	
5	Sleep study measure	REM	4months	
6		Treatment success	4months	Resolution of symptoms and reduction in AHI<=10/hr

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Ferguson 1996 Canada 8625679	Treatment success	**Tx**	MAD	4months	12	25	%	48						
		Cx	CPAP	4months	13	21	%	62						
	Treatment failure	**Tx**	MAD	4months	7	25	%	28						
		Cx	CPAP	4months	0	0	%	0						

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value	SD*	P
Ferguson 1996 Canada 8625679	AHI	No./hr	**Tx**	MAD	4months	19	19.7	13.8	9.7	7.3	-10		<0.005			
			Cx	CPAP	4months	20	17.6	13.2	3.6	1.7	-14		<0.005			
	Desaturations <90%	No.	**Tx**	MAD	4months	19	56.2	75.6	35.6	73.8	-20.6		NS			
			Cx	CPAP	4months	20	53.5	76.4	3.5	6.4	-50		<0.005			
	SaO_2 min	%	**Tx**	MAD	4months	19	83.0	7.4	83.8	7.3	0.8		NS			
			Cx	CPAP	4months	20	82.6	6.0	88.7	2.5	6.1		<0.05			
	Sleep efficiency	%	**Tx**	MAD	4months	19	88.0	5.4	86.5	10.6	-1.5		NS			
			Cx	CPAP	4months	20	87.8	7.7	88.1	7.3	0.3		NS			
	REM	%	**Tx**	MAD	4months	19	14.3	6.5	20.0	12.3	5.7		NS			
			Cx	CPAP	4months	20	16.5	8.2	16.1	6.1	-0.4		NS			

* Delete or correct the incorrect value/item. If change, highlight yellow. Data from 1996 Ferguson
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

Table 4—*Symptoms With and Without the OA and N-CPAP*

	Pre-OA, No. (%)	OA, No. (%)
Moderate to loud snoring*	25/25 (100)	6/25 (24)
Witnessed apneas*	21/25 (84)	2/25 (8)
Unrefreshing sleep†	20/25 (80)	12/25 (48)
Excessive daytime sleepiness/ fatigue*	21/25 (84)	10/25 (40)
Sleepiness while driving†	11/25 (44)	4/25 (16)
	Pre-N-CPAP, No. (%)	**N-CPAP, No. (%)**
Moderate to loud snoring*	21/21 (100)	0/21 (0)
Witnessed apneas*	17/21 (81)	1/21 (5)
Unrefreshing sleep†	21/21 (100)	6/21 (29)
Excessive daytime sleepiness/ fatigue*	18/21 (86)	5/21 (24)
Sleepiness while driving†	6/21 (29)	1/21 (5)

*$p<0.005$.
†$p<0.05$.

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			MAD			
Ferguson 1996 Canada 8625679	Severe jaw discomfort		1/25			
	Compliance failures(unable to wear device)		6/25			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	n	n	nd	n	y	na	y	n

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	n	y	n	y
Reasons for drop-outs:								
Other Issues:								
Overall Quality (A, B, C)	**B**							

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

A.

Author, Year	Gagnadoux, 2009			**Intervention 1**	Mandibular advancement device (MAd)
PMID*	19324954	**RefID**	160	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	CPAP
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
-age 18-70 -newly diagnosed by PSG -AHI 10-60 -2+ symptoms of OSA	-previous treatment -BMI ≥ 35 -coexisting sleep disorder -inadequate dental structure or TMJ contradicting Mad treatment -unstable medical illness -severe sleepiness	nd	Nd	Y	France	Programme Hospitalier de Recherche Clinique, ANTADIR, and the Etablissement Public, Chancellerie de Paris	A sample size of 60 patients was calculated to detect a 1 SD difference in AHI between the two treatments with a power of 99% and a significance level of 5% (two-sided)	n	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**59 (59)**	61%	50.3	Nd	26.7	Nd	Nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	Nd	Nd	Nd	Nd	Nd	Nd	Nd	nd
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	59	34.2	10.6	Nd	Nd	Nd	Nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
Maximum mandibular advancement = 9.5 mm								

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	3%	Cessation of airflow for ≥ 10 sec	50% reduction of airflow or a 50% reduction of airflow accompanied by a 3% decrease in SaO2	nd	Split	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	Mandibular advancement device	AMC; Artech Medical, Pantin,France	Adjustable bi-bloc acrylic oral appliance. Maximum mandibular adjustment (MA) while awake was determined for each patient on three consecutive voluntary manoeuvres. MA titration was performed during PSG after 1 week of acclimatisation to MAd at 50% of the maximum MA.
2				
3				
Control	PAP	CPAP (fixed)	Sullivan S6 Elite; Resmed, Bella Vista, NSW, Australia	Patients were then treated at the manually titrated pressure with CPAP device equipped with a microprocessor and pressure monitor, providing a precise index of daily use by measuring the time spent with the mask on.
For CPAP:		**How was the Pressure selected?**	CPAP titration was conducted during PSG according to authors' standard procedure	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	AHI	Baseline, 2 mo	
2	Sleep study measures	ODI 3%	Baseline, 2 mo	
3	Sleepiness measures	ESS	Baseline, 2 mo	
4	Sleepiness measures	OSLER test	Baseline, 2 mo	objective vigilance test, complete tasks that involve high levels of concentration
5	Sleepiness measures	Trail Making Test A	Baseline, 2 mo	neuropsychological test of visual attention and task switching--requires a subject to connect-the-dots of 25 consecutive targets, all numbers
6	Sleepiness measures	Trail Making Test B	Baseline, 2 mo	neuropsychological test of visual attention and task switching--requires a subject to connect-the-dots of 25 consecutive targets, numbers and letters
7	Compliance	Hours per night	2 mo	number of hours of daily use
8	Compliance	Nights on treatment %	2 mo	% nights on which treatment was used.
9	Harms	Mean side-effects score	2 mo	six common side-effects of CPAP (congested, drippy or irritated nose, skin lesion, irritated eyes and dry mouth) and MAd (jaw pain, tooth pain, muscle stiffness, dry mouth, hypersalivation and occlusal change), score from 0-18
10	QoI	Health related quality of life	Baseline, 2 mo	Evaluated using Nottingham Health Profile
11	Sleep study measures	Treatment response	2 mo	Complete response was defined by a ≥50% reduction in AHI to <5 events/h, partial response by a ≥50% reduction in the AHI but with AHI remaining ≥5 events/h, and treatment failure by <50% reduction in AHI.

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Gagnadoux, 2009 France 19324954	Complete response (≥50% reduction in AHI to <5 events/hr)	**Tx**	Mandibular advancement device	2 mo	12	28	nd	nd	nd	nd	nd	nd	nd	nd
		Cx	CPAP		20	28	nd	nd	nd	nd	nd	nd	nd	nd
	Partial response (a ≥50% reduction in the AHI but with AHI remaining ≥5 events/h)	**Tx**	Mandibular advancement device	2 mo	14	28	nd	nd	nd	nd	nd	nd	nd	nd
		Cx	CPAP		7	28	nd	nd	nd	nd	nd	nd	nd	nd
	Treatment failure (<50% reduction in AHI)	**Tx**	Mandibular advancement device	2 mo	2	28	nd	nd	nd	nd	nd	nd	nd	nd
		Cx	CPAP		1	28	nd	nd	nd	nd	nd	nd	nd	nd

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			(final test – control)*		
							Value	SD	Value	SD	Value	SD	P	Value	SD	P
Gagnadoux, 2009 France 19324954	AHI	Events/hr	**Tx**	Mandibular advancement device	2 mo	28	34.2	13.0	6	nd	28.2	Nd	nd	4	Nd	0.001
			Cx	CPAP		28	34.2	13.0	2	nd	32.2	nd	Nd			
	ODI 3%	Events/hr	**Tx**	Mandibular advancement device	2 mo	28	nd	Nd	6.3	Nd	nd	nd	Nd	4.6	nd	0.001
			Cx	CPAP		28	nd	nd	1.7	nd	Nd	Nd	nd			
	ESS	scale	**Tx**	Mandibular advancement device	2 mo	28	10.6	4.5	7.7	4.0	-2.9	nd	<0.001	nd	nd	Nd
			Cx	CPAP		28	10.6	4.5	8.2	3.9	-2.4	nd	<0.001	nd	nd	nd
	OSLER test-sleep latency	sec	**Tx**	Mandibular advancement device	2 mo	28	2094	674	2312	322	218	Nd	<0.05	nd	nd	Nd
			Cx	CPAP		28	2094	674	2300	391	206	nd	<0.05	nd	nd	nd
	OSLER test-errors n	number	**Tx**	Mandibular advancement device	2 mo	28	12.5	17.9	4.3	7.5	-8.2	Nd	<0.05	nd	nd	Nd
			Cx	CPAP		28	12.5	17.9	8.7	19.8	-3.8	nd	<0.01	nd	nd	nd
	Trail making test A	Nd	**Tx**	Mandibular advancement device	2 mo	28	36.4	10.9	32.5	9.6	-3.9	Nd	<0.001	nd	nd	Nd
			Cx	CPAP		28	36.4	10.9	30.1	8.9	-6.3	nd	<0.05	nd	nd	nd
	Trail making test B	Nd	**Tx**	Mandibular advancement device	2 mo	28	79.3	26.2	73.4	33.0	-5.9	Nd	<0.001	nd	nd	Nd
			Cx	CPAP		28	79.3	26.2	68.5	22.2	-10.8	nd	nd	nd	nd	nd
	Mean side-effects score	Nd	**Tx**	Mandibular advancement device	2 mo	28	NA	NA	3.2	3.1	NA	NA	NA	0.0	Nd	0.8
			Cx	CPAP		28	NA	NA	3.2	3.4	NA	NA	NA			
	Reported compliance-hrs/night	Hrs/night	**Tx**	Mandibular advancement device	2 mo	28	NA	NA	7.0	Nd	NA	NA	NA	nd	Nd	<0.01

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			(final test – control)*		
							Value	SD	Value	SD	Value	SD	P	Value	SD	P
			Cx	CPAP		28	NA	NA	6.0	Nd	NA	NA	NA	nd	Nd	
	Reported compliance-nights on treatment %	%	**Tx**	Mandibular advancement device	2 mo	28	NA	NA	98%	Nd	NA	NA	NA	Nd	nd	<0.01
			Cx	CPAP		28	NA	NA	90%	nd	NA	NA	NA	nd	nd	
	Physical mobility	Score	**Tx**	Mandibular advancement device	2 mo	28	9.9	nd	5.3	nd	-4.6	nd	nd	-2.6	nd	nd
			Cx	CPAP		28	9.9	nd	7.9	nd	-2	nd	nd			
	Social isolation	Score	**Tx**	Mandibular advancement device	2 mo	28	7.9	nd	4.4	nd	-3.5	nd	nd	-1.7	nd	nd
			Cx	CPAP		28	7.9	nd	6.1	nd	-1.8	nd	nd			
	Pain	Score	**Tx**	Mandibular advancement device	2 mo	28	16.3	nd	8.3	nd	-8	nd	nd	-3.8	nd	nd
			Cx	CPAP		28	16.3	nd	12.1	nd	-4.2	nd	nd			
	Emotional reaction	Score	**Tx**	Mandibular advancement device	2 mo	28	16.7	nd	8.1	nd	-8.6	nd	nd	-3.3	nd	nd
			Cx	CPAP		28	16.7	nd	11.4	nd	-5.3	nd	nd			
	Energy	Score	**Tx**	Mandibular advancement device	2 mo	28	30.1	nd	18.5	nd	-11.6	nd	nd	0.9	nd	nd
			Cx	CPAP		28	30.1	nd	17.6	nd	-12.5	nd	nd			
	Sleep	score	**Tx**	Mandibular advancement device	2 mo	28	29.0	nd	16.2	nd	-12.8	nd	nd	-10	nd	nd
			Cx	CPAP		28	29.0	nd	26.2	nd	-2.8	nd	nd			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
Gagnadoux, 2009 France 19324954	Nd (mean side effects score in outcome)					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Y	Y	Nd	Y	N	Nd	N	Y	N	N	Y
	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?			If a Crossover study, was the Washout period adequate?
	Y	N	Y	Y	Y	Y	n			y
Reasons for drop-outs:	Nd									
Other Issues:	May not have sufficient N for power, no analysis of different treatment centers									
Overall Quality (A, B, C)	B									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Hoekema, 2008 Hoekema, 2007			**Intervention 1**	Oral appliance
PMID*	3371 3375	**RefID**	18719218 17081222	**Intervention 2**	CPAP
Key Question(s)	KQ 5 CPAP v Oral			**Intervention 3**	
Design †	RCT			**Control**	
Extractor	EMB			**Comments**	Block randomization Trial designed and analyzed as a non-inferiority study

* or Cochrane number

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA AHI ≥5 ≥20 yo PMID 17081222: GRISS completed at baseline (see outcomes); Men only	Previous CPAP, oral appliance, or UPPP Clearly reversible morphological airway abnormality Endocrine dysfunction (not including DM) Severe cardiac or pulmonary disease Periodic limb movement index >25/hr Psychological condition precluding informed consent Extensive periodontal disease or tooth decay Active TMJ disease or bruxism Restrictions in mouth opening (<25 mm) or mandible advancement (<5 mm) <8 teeth in upper or lower jaw	≥5	2002-2005	No	Netherlands	Netherlands Organization for Health Research and Development.	**Analyzed as non-inferiority Power: ≥46 participants/intervention (Effective treatment)**	No (not possible)	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx Oral	**51 (51)**	84%	49±9.5		32.3±6.1	76% 151/93		0 (by eligibility)
Cx CPAP	**52 (52)**	94%	49±9.5		33.3±5.8	81% 152/92		
Total				nd		>140/90 or antihypertensive	nd	
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx		39%						
Cx		33%						
Total	nd		nd	nd	nd	nd	nd	No
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	None (no CPAP, oral appliance, or UPPP)							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Tx Oral	51	≤30: 49% >30: 51% 39.4±30.8	12.9±5.6					
Cx CPAP	52	≤30: 48% >30: 52% 40.3±27.6	14.2±5.6					
Total:				nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
none						nd		none

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥5		nd (AASM 1999)	nd (AASM 1999)	daytime sleepiness (implied)	Split	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance		Thornton Adjustable Positioner type 1 Airway Management, Inc., Dallas	Positions mandible in a forward and downward position. Patient can adjust in 0.2 mm increments. Advanced until symptoms abate or until discomfort
2	PAP	CPAP	Breas PV10 Molnlycke, Sweden	
3				
Control				
For CPAP:		**How was the Pressure selected?**	During afternoon nap	
NOTE		PSG done at 8 wks and CPAP or oral appliance adjusted if AHI still ≥5, then 4 more wk treatment. Adjustments continued q 4 wk with PSG as tolerated		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
All	Conservative measure advice: avoid depressants (eg, EtOH, sleep medications), 7-8 hr sleep, cease smoking, lose weight	
For CPAP:	**Describe the frequency of the initial education follow-up**	Detailed instructions by a skilled nursing consultant, then trial of 2 wk then return for check-up, then adjustment at 8 wk and q 4 wk as necessary

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	Effective Treatment	Final review	AHI<5 or >50% reduction to an AHI<20 without symptoms Home PSG
	Sleep study measure	AHI<5		(sensitivity analysis of "Effective treatment")
	Sleep study measure	AHI<10		Excludes those with AHI<10 at baseline.
2	QoL	SF-36		
3	Sleepiness measure	ESS		
4	Sleepiness measure	Functional outcomes of sleep questionnaire		Weaver TE, Laizner AM, Evans LK, Maislin G, Chugh DK, Lyon K, et al. (1997). An instrument to measure functional status outcomes for disorders of excessive sleepiness. Sleep 20:835-843. Total score range 5-20
	Psychiatric scale	Hospital anxiety and depression scale		Zigmond AS, Snaith RP (1983). The hospital anxiety and depression scale. Acta Psychiatr Scand 67:361-370. Range 0-21
	Compliance	Non-Adherent Night/wk; hr/night		Discontinued treatment for any reason Nights/wk and hr/night of use, by questionnaire (not by CPAP device measurement, to minimize bias)
	Miscellaneous	Golombok Rust Inventory of Sexual Satisfaction		(PMID 17081222)

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

GRISS

The GRISS is a self-report questionnaire that measures the most common psychosexual complaints. It has separate forms for men and women, each consisting of 28 items. The male questionnaire yields seven subscale scores, reflecting sexual function in the following areas: impotence, premature ejaculation, sensuality, avoidance, satisfaction, frequency, and communication. The reliability of the GRISS and its predictive validity for the identification of sexual dysfunction within a sexological population have been found to be satisfactory in English and Dutch samples [18,26,27]. In addition, the subscales were found to be independent of social desirability [18]. Each questionnaire was anonymized to guarantee the patient's privacy.

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Hoekema, 2008	Effective Tx (Total Population)	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	39	51	RD	-6.2%	-21.7, 9.4					
Netherlands		**Cx**	CPAP	Mean 86 d Median 63 d IQR 60-88 d	43	52								
18719218														
	Effective Tx (AHI≤30)	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	21	25	RD	+4.0%	-17.7, 25.4					
		Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	20	25								
	Effective Tx (AHI>30)	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	18	26	RD	-16.0%	-37.1, 6.8					
		Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	23	27								
	AHI<5	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	29	51	RD	-20.0%	-36.6, -1.9					
	(also data for baseline AHI<>30)	**Cx**	CPAP	Mean 86 d Median 63 d IQR 60-88 d	40	52								
	AHI<10	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	31	44		-4.5%	-22.6, 13.9					
	(also data for baseline AHI<>30)	**Cx**	CPAP	Mean 86 d Median 63 d IQR 60-88 d	33	44								
	Non-Adherent	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	2	49								
		Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	5	50								

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference Final (Test – Control)		
							Value	SD	Value	SD/SE*	Value	SD/SE*	P	Value	95% CI	P
Hoekema, 2008	Sleep efficiency	% Time in Bed	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/47 (b/f)	88.3	9.7	86.1	8.1	-1.8			0.00	-0.40, 0.40	
Netherlands			**Cx**	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/47 (b/f)	85.5	15.5	86.2	10.0	+0.7					
18719218																
	AHI	/hr	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/47 (b/f)	39.4	30.8	7.8 (median 2.2)	14.4 (IQR 0, 9.5)	-31.6					0.006
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/47 (b/f)	40.3	27.6	2.4 (median 0)	4.2 (IQR 0, 3.0)	-37.9					
	Min O_2 sat	%	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/47 (b/f)	78.0	8.5	87.7	6.3				-0.33	-0.73, 0.08	
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/47 (b/f)	77.9	9.9	89.7	5.8						
	Sleep stage 3&4	% TST	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/47 (b/f)	13.7	9.0	20.4	7.7				-0.18	-0.58, 0.23	
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/47 (b/f)	13.0	11.5	21.8	8.0						
	REM	% TST	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/47 (b/f)	21.0	7.8	26.5	6.7				0.39	-0.03, 0.79	
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/47 (b/f)	19.2	7.4	24.1	5.7						
	ESS		**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/49 (b/f)	12.9	5.6	6.9 (median 7.0)	5.5 (IQR 2.0, 9.5)						0.53
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/50 (b/f)	14.2	5.6	5.9 (median 6.0)	4.8 (IQR 3.8, 12.0)						
Hoekema, 2008	FOSQ (Total score†)		**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/49 (b/f)	13.7	3.1	16.6	2.8				-0.05	-0.44, 0.34	

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference Final (Test – Control)		
							Value	SD	Value	SD/SE*	Value	SD/SE*	P	Value	95% CI	P
Netherlands			**Cx**	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/50 (b/f)	13.9	3.7	16.7	3.1						
18719218																
	Hospital anxiety scale		**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/49 (b/f)	5.6 (median 4)	3.8 (IQR 3, 8)	4.5 (median 3)	3.6 (IQR 2, 6.5)						0.81
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/50 (b/f)	5.4 (median 5)	3.6 (IQR 3, 8)	4.3 (median 3.5)	3.4 (IQR 1.8, 7)						
	Hospital depression scale		**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/49 (b/f)	5.8 (median 5)	3.8 (IQR 3, 8)	3.8 (median 2)	3.7 (IQR 1, 7)						0.25
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/50 (b/f)	7.1 (median 75)	4.3 (IQR 4, 10)	4.8 (median 3)	4.5 (IQR 1, 8.5)						
	SF 36 Phys Fxn†		**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/49 (b/f)	71.8	23.3	78.8	21.5				-0.09	-0.48, 0.31	
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/50 (b/f)	68.9	24.2	80.6	18.5						
	SF 36 Mental Health†		**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/49 (b/f)	70.9	17.8	77.5	16.5				+0.15	-0.24, 0.55	
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/50 (b/f)	68.2	17.6	75.0	16.2						
	Treatment usage/wk	noc/wk	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	49	6.7	1.0								
	(Also categorical data reported)		**Cx**	CPAP	Mean 86 d Median 63 d IQR 60-88 d	50	6.7	0.8								
	Treatment usage/noc	hr/noc	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	49	6.9	1.0								

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference Final (Test – Control)		
							Value	SD	Value	SD/SE*	Value	SD/SE*	P	Value	95% CI	P
	(Also categorical data reported)		**Cx**	CPAP	Mean 86 d Median 63 d IQR 60-88 d	50	6.5	1.6								
Hoekema, 2007	GRISS Erectile Dysfunction†	Range 4-20	**Tx**	Oral appliance	Median 82 d IQR 69-103 d	20	7.9	3.5	7.9	4.0	0		NS			NS
Netherlands			**Cx**	CPAP	Median 76 d IQR 63-109 d	27	9.5	4.2	8.6	3.0	-0.9		NS			
17081222																
	GRISS Sexual dissatisfaction†	Range 4-20	**Tx**	Oral appliance	Median 82 d IQR 69-103 d	20	8.5	3.9	8.8	4.0	+0.3		NS			NS
			Cx	CPAP	Median 76 d IQR 63-109 d	27	10.2	4.3	10.5	4.3	+0.3		NS			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper
† Data for (other) subcomponents also reported, not extracted

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Oral appliance	2/51 (4%)	Loss to follow up
CPAP	2/52 (4%)	Loss to follow up

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes) SEE ABOVE FOR SUBGROUPS BASED ON BASELINE AHI

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	Yes	Yes	No (not possible)	Yes	Yes	Yes	NA	NA	Yes
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Yes	No	Yes	Yes	Yes	Yes	NA			NA
Reasons for drop-outs:	Loss to followup									
Other Issues:	Performed only final analyses in parallel design RCT (not net changes). Difficult to interpret.									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Randerath, 2002			**Intervention 1**	Intraoral sleep apnea device (ISAD)
PMID*	12171833	**RefID**	4698	**Intervention 2**	
Key Question(s)	5(CPAP and oral appliance)			**Intervention 3**	
Design †	Cross over			**Control**	CPAP
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSAS AHI 5-30/hr	TMJ disorders Bruxism Gaps in dentition that did not allow oral fitting of device	nd	1999	n	Germany	nd	nd	n	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**20(20)**	80	56.5(12)	nd	31.2(6.4)	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	none							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	20	17.5(7.7)	nd	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG			Reduction in effort of 50% for at least 10s or decrease o_2 sat of at least 4%			Nd(implied Same night)	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	Intraoral sleep apnea device	IST, Hinz, Herne	Thermoplastic parts attached to the upper and lower jaws that advance and depress the mandible and tongue with a slight vertical clockwise rotation.
2				
3				
Control	PAP	CPAP	Max II, MAP	
For CPAP:		**How was the Pressure selected?**	Pressure increased manually in incremental steps till respiratory disturbances minimized and arousals reduced to <=5/hr	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	6 weeks	
2	Sleep study measure	SaO_2 min	6 weeks	
3	Sleep study measure	Stage 3 and 4	6 weeks	
4	Sleep study measure	REM	6 weeks	
5	Sleep study measure	Arousals	6 weeks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD	Value	SD	P	Value	SD*	P
Randerath, 2002 Germany 12171833	AHI		Tx	ISAD	6 weeks	20	17.5	7.7	13.8	11.1	-3.7		NS	10.6		0.01
			Cx	CPAP	6 weeks	20	17.5	7.7	3.2	2.9	-14.3		<0.01			
	SaO_2 min	%	Tx	ISAD	6 weeks	20	54.5	25.9	85.3	3.1	30.8		NS	-3.7		<0.05
			Cx	CPAP	6 weeks	20	54.5	25.9	89	3.4	34.5		<0.01			
	Stage 3 and 4	% TST	Tx	ISAD	6 weeks	20	14.2	10.6	14.1	10.8	-0.1		NS	-2.1		NS
			Cx	CPAP	6 weeks	20	14.2	10.6	16.2	9.1	2		NS			
	REM	% TST	Tx	ISAD	6 weeks	20	15.1	5.9	14.8	7.3	-0.3		NS	-0.5		NS
			Cx	CPAP	6 weeks	20	15.1	5.9	15.3	6.8	0.2		NS			
	Arousals	/hr TST	Tx	ISAD	6 weeks	20	21.8	9.9	17	5.1	-4.8		<0.05	2.9		NS
			Cx	CPAP	6 weeks	20	21.8	9.9	14.1	5.1	-7.7		NS			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD *	Value	SD*	Value	SD*	P	Value	SD*	P
AHI<10	Randerath, 2002 Germany 12171833	AHI		**Tx**	ISAD	6 weeks	4	~7.5		~5.5				NS			NS
				Cx	CPAP	6 weeks	4	~7.5		~3.2				NS			
AHI 10 - <20		AHI		**Tx**	ISAD	6 weeks	10	~16		~11				NS			<0.05
				Cx	CPAP	6 weeks	10	~16		~3				<0.01			
AHI>=20		AHI		**Tx**	ISAD	6 weeks	6	~27		~24				NS			<0.01
				Cx	CPAP	6 weeks	6	~27		~3				<0.01			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
BMI<27	Randerath, 2002 Germany 12171833	AHI		**Tx**	ISAD	6 weeks	6	~16		~17				NS			nd
				Cx	CPAP	6 weeks	6	~16		~3				NS			
BMI 27 to <30.5		AHI		**Tx**	ISAD	6 weeks	7	~19		~15				NS			nd
				Cx	CPAP	6 weeks	7	~19		~3				<0.05			
BMI >=30.5		AHI		**Tx**	ISAD	6 weeks	7	~16		~8				<0.05			nd
				Cx	CPAP	6 weeks	7	~16		~3				<0.01			

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			ISAD			
Randerath, 2002 Germany 12171833	Sensation of pressure on face		8/20			
	Sensation of pressure on mouth		2/20			
	Early morning discomfort in mouth and TMJ		8/20			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	n	nd	y	y	na	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	y	y	n	nd
Reasons for drop-outs:								
Other Issues:	No power calculation, no data on blinding outcome assessor, no data on washout period							
Overall Quality (A, B, C)	**B**							

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Skinner, 2004			**Intervention 1**	Cervicomandibular support collar
PMID*	14718430	**RefID**	4811	**Intervention 2**	
Key Question(s)	5- CPAP v Mandib			**Intervention 3**	
Design †	Randomized cross-over			**Control**	Auto-titrating nCPAP
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
mild-to-moderately severe OSA and apnea-hypopnea index (AHI) of 10 to 60/h of total sleep time.	medical history of cardiovascular, neurologic, or psychological disorders affecting sleep; coexisting sleep disorders; and known cervical or temporomandibular joint dysfunction and/or pain	nd	Nd	N	New Zealand	University of Otago School of Physiotherapy and the Otago Respiratory Research Trust.	nd	N	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**10**	80	48.6	Nd	34.1	Nd	Nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	Nd	Nd	Nd	Nd	Nd	Nd	Nd	no
	Treatments used (prior to trial, including surgery)							
Tx	Nd							
Cx	nd							
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	10	29.4	12.2	Nd	Nd	Nd	Nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
Nd						Nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	Nd	Nd	cessation of airflow lasting at least 10 s	Changes in thoracoabdominal movements were used to score hypopneas, given that the thermistor is unable to quantify the reduction in airflow, or to distinguish between obstructive and central events. A reduction in any of these signals by ≥50% from a rolling baseline, and persisting for ≥10 s, or a reduction in thoracoabdominalmovement with an accompanying oxygen desaturation of at least 3% and/or associated with an arousal, defined the significant respiratory events	Nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Positional therapy	Cervicomandibular support collar	Symmetric Designs; Salt Spring Island, BC, Canada	The collar comprised a fabric-covered, semicircular acrylic and latex ring, which was molded to fit under the mandible and rest on the upper third of the manubrium sterni. It was held in place by a fabric-covered foam strap with self-adhesive attachments. A chin piece supported the lower jaw in the closed position with the teeth held in light occlusion, and an anterior support tube was attached between the mandible and sternal portions to provide rigid support and prevent neck flexion beyond the NHP.
2				
3				
Control	CPAP	Autotitrating nCPAP	Autoset T, Sullivan; ResMed Ltd; North Ryde, NSW, Australia	
For CPAP:		**How was the Pressure selected?**	Minimum CPAP pressure was set at 4 cm H2O, and maximum CPAP pressure was set at 20 cm H2O. The Autoset T permits automatic titration of the CPAP required to maintain airway patency while asleep.	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	AHI	Baseline, 1 month	
2	Sleep study measures	ESS	Baseline, 1 month	
3	Sleep study measures	FOSQ	Baseline, 1 month	
4	Physical scale	SF-36 physical	Baseline, 1 month	
5	Psych scale	SF-36 mental	Baseline, 1 month	
6	General symptom scales	SQ	Baseline, 1 month	Scottish National Sleep Laboratory symptom questionnaire
7	Sleep study measures	Arousal frequency	Baseline, 1 month	
8	Sleep study measures	Min SaO2	Baseline, 1 month	
9	Sleep study measures	Sleep efficiency %	Baseline, 1 month	
10	Sleep study measures	Slow-wave sleep %	Baseline, 1 month	
11	Sleep study measures	REM sleep %	Baseline, 1 month	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD	Value	SD	P	Value	SD/SE*	P
	AHI		**Tx**	Cervicomandibular support collar	1 mo	10	29.4	13.4	26.9	17.2	-2.5	15.1	NS	16.9	nd	0.001
			Cx	Autotitrating nCPAP			29.4	13.4	9.9	8.0	-19.4	11.5	<0.001			
	ESS		**Tx**	Cervicomandibular support collar	1 mo	10	13.2	4.9	9.4	5.5	-3.8	nd	nd	-1.9	Nd	0.215
			Cx	Autotitrating nCPAP			13.2	4.9	11.3	4.6	-1.9					
	FOSQ		**Tx**	Cervicomandibular support collar	1 mo	10	12.2	3.1	12.7	3.1	0.5	nd	nd	-0.1	Nd	0.854
			Cx	Autotitrating nCPAP			12.2	3.1	12.8	2.7	0.6					
	SF-36 physical		**Tx**	Cervicomandibular support collar	1 mo	10	45.3	10.4	47.2	10.0	1.9	nd	nd	3	Nd	0.177
			Cx	Autotitrating nCPAP			45.3	10.4	44.2	9/7	-1.1					
	SF-36 mental		**Tx**	Cervicomandibular support collar	1 mo	10	43.8	50.5	50.5	10.5	6.7	nd	nd	-2.1	Nd	0.189
			Cx	Autotitrating nCPAP			43.8	50.5	52.6	8.6	8.8					
	SQ %		**Tx**	Cervicomandibular support collar	1 mo	10	59.7	11.9	39.3	23.4	-20.4	nd	nd	-4.2	Nd	0.513
			Cx	Autotitrating nCPAP			59.7	11.9	43.5	19.1	-16.2					
	Arousal Frequency		**Tx**	Cervicomandibular support collar	1 mo	10	27.7	9.0	31.7	22.8	4	nd	nd	15.2	Nd	0.072
			Cx	Autotitrating nCPAP			27.7	9.0	16.5	5.9	-11.2					
	Min SaO2		**Tx**	Cervicomandibular support collar	1 mo	10	84.3	4.4	81.0	12.0	-3.3	nd	nd	-9.8	Nd	0.076
			Cx	Autotitrating nCPAP			84.3	4.4	90.8	3.0	6.5					
	Sleep efficiency %		**Tx**	Cervicomandibular support collar	1 mo	10	81.9	7.9	78.6	11.8	-3.3	nd	nd	0.2	Nd	0.974
			Cx	Autotitrating nCPAP			81.9	7.9	78.4	11.6	-3.5					
	Slow-wave sleep %		**Tx**	Cervicomandibular support collar	1 mo	10	20.4	8.2	20.1	13.4	-0.3	nd	nd	-3.9	Nd	0.296
			Cx	Autotitrating nCPAP			20.4	8.2	24.0	8.9	3.6					
	REM sleep %		**Tx**	Cervicomandibular support collar	1 mo	10	20.4	4.6	19.7	5.1	-0.7	nd	nd	-0.7	Nd	0.819
			Cx	Autotitrating nCPAP			20.4	4.6	20.4	8.0	0	nd	nd			

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD	Value	SD	P	Value	SD/SE*	P

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
	Adverse effects score	Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
all	0	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			Cervicomandibular support collar	Autotitrating nCPAP		
Skinner, 2004 New Zealand 14718430	Adverse effect scale (19 self-reported questions scored 0-3)	1 mo	6.7	6.5		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Y	Nd	nd	y	n	Nd	Y	Y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Y	N	Y	Y	N	Y	n			n
Reasons for drop-outs:	No dropouts									
Other Issues:	Study stopped after 10 patients (originally planned for 20) because treatment didn't show objective benefit. Washout deemed unlikely to change outcome because of lack of benefit from treatment.									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Tan, 2002			**Intervention 1**	CPAP
PMID*	12143088	**RefID**	4873	**Intervention 2**	
Key Question(s)	5 (CPAP and oral appliance)			**Intervention 3**	
Design †	Cross over			**Control**	MAS(mandibular advancement splint)
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA Mild or moderate OSA (AHI <50) >18 years Adequate dentition to support retention of oral appliance No temporomandibular joint dysfunction No medical contraindication	Significant heart disease (MI in last 3 years, angina, uncontrolled hypertension) COPD Regular hypnotic use Epilepsy Arterial o2 sat <60% Language barrier		nd	y	UK		nd	n	Y?(done in a random order with all patient identification removed)
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**24(21)**	83	50.9(10.1)		31.9(6.8)			
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total								
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	24	22.2(9.6)	13.4(4.6)					
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG							

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	nCPAP	Respironics Inc and Resmed Uk ltd	
2				
3				
Control	Oral appliance	MAS	Soft MAS (and Erkodent Gmbh, semi rigid MAS)	One piece vaccum formed appliance for first 10 subjects (and two part semi rigid silensor for others)
For CPAP:		**How was the Pressure selected?**	Manual titration till OSA abolished	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measure	ESS	2 months	
2	Sleep study measure	AHI	2 months	
3	Sleep study measure	ODI	2 months	
4	Sleep study measure	Arousals	2 months	
5	Sleep study measure	Sleep efficiency	2 months	
6	Sleep study measure	REM sleep	2 months	
7	QOL	General health	2months	
8		Daytime sleepiness		

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD	Value	SD	P	Value	SD/SE*	P
Tan, 2002 UK 12143088	ESS		Tx	nCPAP	2 months	24	13.4	4.6	8.1	4.1	-5.3			-0.9		NS
			Cx	MAS	2 months	24	13.4	4.6	9.0	5.1	-4.4					
	AHI		Tx	nCPAP	2 months	24	22.2	9.6	3.1	2.8	-19.1			-4.9		NS
			Cx	MAS	2 months	24	22.2	9.6	8.0	10.9	-14.2					
	ODI	%	Tx	nCPAP	2 months	24	7.1	2.7	3.3	1.6	-3.8			-1.5		NS
			Cx	MAS	2 months	24	7.1	2.7	4.8	2.7	-2.3					
	Arousals	/hr	Tx	nCPAP	2 months	24	19.3	9.6	9.8	6.6	-9.5			-1.8		NS
			Cx	MAS	2 months	24	19.3	9.6	11.6	5.6	-7.7					
	Sleep efficiency	%	Tx	nCPAP	2 months	24	81.6	10.4	87.2	8.1	5.6			4		NS
			Cx	MAS	2 months	24	81.6	10.4	83.2	8.1	1.6					
	REM sleep	%	Tx	nCPAP	2 months	24	12.7	5.8	18.5	6.1	5.8			4.7		NS
			Cx	MAS	2 months	24	12.7	5.8	13.8	5.6	1.1					
	General health		Tx	nCPAP	2 months	24	17.4	7.5	6.5	5.9	-10.9		<0.001	-3.7		NS
			Cx	MAS	2 months	24	17.4	7.5	10.2	9.9	-7.2		<0.001			
	Daytime sleepiness		Tx	nCPAP	2 months	24	10.0	7.3	5.2	5.1	-4.8		<0.001	-2.5		NS
			Cx	MAS	2 months	24	10.0	7.3	7.7	7.0	-2.3		NS			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
nCPAP	2/24	Did not tolerate CPAP but completed the other arm. Included in analysis
MAS	1/24	Did not tolerate MAS but included in analysis

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			MAS			
Tan, 2002 UK 12143088	Jaw discomfort	Early morning	12/24			
	Nasal stuffiness	nd	nd			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y		y	n	Y?	y	y	n	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y		y	n	y
Reasons for drop-outs:								
Other Issues:								
Overall Quality (A, B, C)	**B**							

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Question 5
CPAP vs Oral

A.

Author, Year	Clark, 1996			**Intervention 1**	Anterior mandibular positioning device
PMID*	8769497	**RefID**	5152	**Intervention 2**	
Key Question(s)	5(CPAP and Oral appliance)			**Intervention 3**	
Design †	Cross over			**Control**	CPAP
Extractor	NO			**Comments**	Issues with implementing cross over design only 6/21 patients had AMP after CPAP, the others had only CPAP. Number of patients analyzed not clear

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Previous OSAS diagnostic PSG 21-75yrs AHI>=15/hr Adequate nasal flow capacity determined by otolaryngologist General good health Minimum of 7mm protrusive jaw movement from a position of maximum intercuspation	Central sleep apnea More than one missing tooth per quadrant(excluding molars) Visual or clinical evidence of periodontal disease or dental caries TMJ disorder Previous nasal obstruction/allergies Use of psychoactive drugs daily, alcohol or narcotics Previous failed CPAP or dental device	AHI>=10	1991 to 1992	n	Israel	nd	n	n	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx								
Cx								
Total	23(21)	100	47.1(8.07)	nd	28.07(3.77)	nd	nd	nd
	NIDDM, %	Smokers, % (define)	GERD, %	MVA ‡ etc, %	Cognitive Function **	Depression, %	Other Comorbidities, % (specify)	Is this a Special Population? (which?)
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	21	33.86(14.30)	nd	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>=10		>=10secs	>50% reduction in airflow	Excessive daytime sleepiness, loud snoring, restless sleep	separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	Anterior mandibular device		Two acrylic appliances placed into the two dental arches with the aid of Herbst attachments
2				
3				
Control	PAP	CPAP	Respironics, Murrysville, Pa	
For CPAP:		**How was the Pressure selected?**	manual	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	2 weeks	
2	Sleep study measure	Sleep efficiency	2 weeks	
3	Sleep study measure	Stage 3 and 4	2 weeks	
4	Sleep study measure	REM	2 weeks	
5	Sleepiness measure	Excessive daytime sleepiness	2 weeks	
6	Sleepiness measure	Daytime symptoms	2 weeks	
7	Sleep study	Min O_2	2 weeks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Clark, 1996 Israel 8769497	AHI		Tx	AMD	2weeks		33.86	14.30	19.94	12.75	-13.92		0.0001			
			Cx	CPAP	2weeks	21	33.86	14.30	11.15	3.93	-22.71		0.001			
	Sleep efficiency	%	Tx	AMD	2weeks		87.10	10.67	89.91	5.46						
			Cx	CPAP	2weeks		87.10	10.67	89.52	7.27						
	Stage 3 and 4	%	Tx	AMD	2weeks		12.41	7.81	13.39	7.96						
			Cx	CPAP	2weeks		12.41	7.81	15.24	5.59						
	REM	%	Tx	AMD	2weeks		5.90	5.78	20.88	7.52						
			Cx	CPAP	2weeks		5.90	5.78	20.67	6.73						
	Excessive daytime sleepiness		Tx	AMD	2weeks		2.4	0.7	1.6	0.6			0.0001			
			Cx	CPAP	2weeks		2.4	0.7	1.8	0.6			0.008			
	Daytime symptoms		Tx	AMD	2weeks		2.0	0.5	1.4	0.4						
			Cx	CPAP	2weeks		2.0	0.5	1.5	0.4						
	Min O_2		Tx	AMD	2weeks		84.30	6.77	90.20	4.36			0.0007			
			Cx	CPAP	2weeks		84.30	6.77	91.10	6.40			0.0003			

* Mean (1SD)91.10
Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	1/23	Intolerance to CPAP
AMD	1/23	AMP device induced TMJ pain

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	Y?(cross over not successfully implemented)		n	n	y		y	na	Y?	n

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	n	y	n	nd
Reasons for drop-outs:								
Other Issues:								
Overall Quality (A, B, C)		**C(n<30, no power calculation, failed cross over design)**						

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Engleman, 2002			**Intervention 1**	CPAP
PMID*	12231497	**RefID**	4233	**Intervention 2**	
Key Question(s)	5(CPAP and oral appliance)			**Intervention 3**	
Design †	Cross over			**Control**	Mandibular repositioning splint(MRS)
Extractor	NO			**Comments**	Patients with Sleep apnea/Hypopnea syndrome (SAHS)

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
New SAHS patients Daytime Sleepiness or sleepiness while driving 18-70yrs	<4 teeth in either arch Narcolepsy or periodic limb movement more than 10/hr Major medical illness Shift work Living >50 miles away from study location(Edinburgh)	>=5/hr	nd	n	UK	British Lung foundation fellowship grant Non industry	Y(Preferred treatment)	n	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**26(24)**		47(8)	nd		nd	nd	nd
Cx	**25(24)**		45(9)	nd		nd	nd	nd
Total	**51(48)**	75	46(9)	nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	9(12) (IQ decrement score)	7(5) (HADS depression score)	nd	n
Cx	nd	nd	nd	nd	4(12)	5(4)	nd	
Total	nd	nd	nd	nd			nd	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	patients had MRS individually manufactured and fitted to produce 80% of maximal comfortable mandibular protrusion with 2-4mm interdental clearance for 2 months till snoring was abolished							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

IQ(intelligence quotient), HADS (hospital anxiety and depression scale)

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	29	32(29)	15(3)	nd	nd	nd	nd	nd
Control:	19	30(21)	13(4)	nd	nd	nd	nd	nd
Total:		31(26)	14(4)	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG (assumed)	>=5/hr		nd	nd	Daytime Sleepiness or sleepiness while driving	split	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP		
2				
3				
Control	Oral appliance	MRS	Kombiplast hard/soft (or 1MEDL)	A flexible ethylene polystyrene material sealed in protrusion (or Less flexible, dual laminate material molded to fit interior contours of mouth and affixed with metal adams clasps that hold the mandible in protrusion)
For CPAP:		**How was the Pressure selected?**	Manual adjustment by staff till snoring was abolished	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Preference	Preferred treatment	8 weeks	
2	Sleepiness	MWT	8 weeks	
3	Sleepiness	ESS	8 weeks	
4	Sleepiness	FOSQ	8 weeks	
5	QOL	Health transition (SF 36)	8 weeks	
6	QOL	Physical component (SF 36)	8 weeks	
7	QOL	Mental component (SF 36)	8 weeks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Engleman, 2002 UK 12231497	Preferred treatment	**Tx**	CPAP	8weeks	25					0.194				
		Cx	MRS	8weeks	19									

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD	Value	SD/SE*	P	Value	SD/SE*	P
Engleman, 2002 UK 12231497	MWT	minutes	**Tx**	CPAP	8 weeks	48	nd	nd	24	12						0.460
			Cx	MRS	8 weeks	48	nd	nd	22	12						
	ESS		**Tx**	CPAP	8 weeks	48	15	3	8	5	-7			-6		<0.001
			Cx	MRS	8 weeks	48	13	4	12	5	-1					
	FOSQ		**Tx**	CPAP	8 weeks	48	10	3	14	2	4			3		0.001
			Cx	MRS	8 weeks	48	12	2	13	3	1					
	Health transition (SF 36)		**Tx**	CPAP	8 weeks	48	nd	nd	2.4	0.8						0.001
			Cx	MRS	8 weeks	48	nd	nd	2.9	0.8						
	Physical component (SF 36)		**Tx**	CPAP	8 weeks	48	40	11	47	10	7			11		0.023
			Cx	MRS	8 weeks	48	49	6	45	10	-4					
	Mental component (SF 36)		**Tx**	CPAP	8 weeks	48	42	12	52	10	10			7		0.008
			Cx	MRS	8 weeks	48	45	12	48	11	3					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	1/51	No reason and could not be contacted
CPAP	1/51	New job, not able to spare time for study
MRS	1/51	New job, not able to spare time for study

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

MRS	Frequency	CPAP	Frequency
Pain in teeth, gums, or jaw	33 (69%)	Sleep disruption	16 (33%)
MRS is removed or comes off in sleep	19 (40%)	Leaky or painful mask	11 (23%)
Sleep disruption	12 (25%)	Stuffy nose	8 (17%)
Excessive salivation	9 (19%)	Mask is removed in sleep	7 (15%)
Dental crown damaged	3 (6%)	Cold airstream	7 (15%)
		Noise/inconvenience	6 (13%)
		Dry upper airway	5 (10%)
Reported use ≤3 hours per night (second month)	10 (21%)	Reported use ≤3 hours per night (second month)	13 (27%)
No problems limiting use (second month)	13 (27%)	No problems limiting use (second month)	15 (31%)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	n	y	N(stated but did not analyze data from 3)	y	na	y	N (uncertain of actual duration of study, sample size)
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y		y	na			nd
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)		**B**								

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments:

A.

Author, Year	Ferguson 1996			**Intervention 1**	Oral mandibular device
PMID*	8625679	**RefID**	5258	**Intervention 2**	
Key Question(s)	5 (CPAP and oral)			**Intervention 3**	
Design †	Cross over			**Control**	CPAP
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
AHI 15-50 At least 10 teeth in each of the mandibular or maxillary arches	nd	>10	1991-1994	n	Canada		n	n	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**27(19)**	88	46.2(10.9)	nd	30.4(4.8)	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	Intranasal corticosteroids and or anticholinergic medication used to relieve any nasal symptoms							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	27	24.5(8.8)	nd	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, (neck circumference in cm)**		**Other characteristics**
nd						42.2 (3.1) Mean (SD)		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG			>= 10s	>50% decrease in thoracoabdominal amplitude for at least 10secs		Separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	Mandibular advancement device	Snore-Guard	Acrylic polymer which advances the mandible
2				
3				
Control	PAP	CPAP	REMstar or Respironics or Tranquility plus machine	
For CPAP:		**How was the Pressure selected?**	nd	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	4months	
2	Sleep study measure	ODI	4months	
3	Sleep study measure	SaO_2 min	4months	
4	Sleep study measure	Sleep efficiency	4months	
5	Sleep study measure	REM	4months	
6		Treatment success	4months	Resolution of symptoms and reduction in AHI<=10/hr

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Ferguson 1996 Canada 8625679	Treatment success	**Tx**	MAD	4months	12	25	%	48						
		Cx	CPAP	4months	13	21	%	62						
	Treatment failure	**Tx**	MAD	4months	7	25	%	28						
		Cx	CPAP	4months	0	0	%	0						

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value	SD*	P
Ferguson 1996 Canada 8625679	AHI	No./hr	**Tx**	MAD	4months	19	19.7	13.8	9.7	7.3	-10		<0.005			
			Cx	CPAP	4months	20	17.6	13.2	3.6	1.7	-14		<0.005			
	Desaturations <90%	No.	**Tx**	MAD	4months	19	56.2	75.6	35.6	73.8	-20.6		NS			
			Cx	CPAP	4months	20	53.5	76.4	3.5	6.4	-50		<0.005			
	SaO_2 min	%	**Tx**	MAD	4months	19	83.0	7.4	83.8	7.3	0.8		NS			
			Cx	CPAP	4months	20	82.6	6.0	88.7	2.5	6.1		<0.05			
	Sleep efficiency	%	**Tx**	MAD	4months	19	88.0	5.4	86.5	10.6	-1.5		NS			
			Cx	CPAP	4months	20	87.8	7.7	88.1	7.3	0.3		NS			
	REM	%	**Tx**	MAD	4months	19	14.3	6.5	20.0	12.3	5.7		NS			
			Cx	CPAP	4months	20	16.5	8.2	16.1	6.1	-0.4		NS			

* Delete or correct the incorrect value/item. If change, highlight yellow. Data from 1996 Ferguson
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

Table 4—*Symptoms With and Without the OA and N-CPAP*

	Pre-OA, No. (%)	OA, No. (%)
Moderate to loud snoring*	25/25 (100)	6/25 (24)
Witnessed apneas*	21/25 (84)	2/25 (8)
Unrefreshing sleep†	20/25 (80)	12/25 (48)
Excessive daytime sleepiness/ fatigue*	21/25 (84)	10/25 (40)
Sleepiness while driving†	11/25 (44)	4/25 (16)
	Pre-N-CPAP, No. (%)	N-CPAP, No. (%)
Moderate to loud snoring*	21/21 (100)	0/21 (0)
Witnessed apneas*	17/21 (81)	1/21 (5)
Unrefreshing sleep†	21/21 (100)	6/21 (29)
Excessive daytime sleepiness/ fatigue*	18/21 (86)	5/21 (24)
Sleepiness while driving†	6/21 (29)	1/21 (5)

*$p<0.005$.
†$p<0.05$.

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			MAD			
Ferguson 1996 Canada 8625679	Severe jaw discomfort		1/25			
	Compliance failures(unable to wear device)		6/25			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	n	n	nd	n	y	na	y	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	y	n			y
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

A.

Author, Year	Gagnadoux, 2009			**Intervention 1**	Mandibular advancement device (MAd)
PMID*	19324954	**RefID**	160	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	CPAP
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
-age 18-70 -newly diagnosed by PSG -AHI 10-60 -2+ symptoms of OSA	-previous treatment -BMI ≥ 35 -coexisting sleep disorder -inadequate dental structure or TMJ contradicting Mad treatment -unstable medical illness -severe sleepiness	nd	Nd	Y	France	Programme Hospitalier de Recherche Clinique, ANTADIR, and the Etablissement Public, Chancellerie de Paris	A sample size of 60 patients was calculated to detect a 1 SD difference in AHI between the two treatments with a power of 99% and a significance level of 5% (two-sided)	n	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**59 (59)**	61%	50.3	Nd	26.7	Nd	Nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	Nd	Nd	Nd	Nd	Nd	Nd	Nd	nd
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	59	34.2	10.6	Nd	Nd	Nd	Nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
Maximum mandibular advancement = 9.5 mm								

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	3%	Cessation of airflow for ≥ 10 sec	50% reduction of airflow or a 50% reduction of airflow accompanied by a 3% decrease in SaO2	nd	Split	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	Mandibular advancement device	AMC; Artech Medical, Pantin,France	Adjustable bi-bloc acrylic oral appliance. Maximum mandibular adjustment (MA) while awake was determined for each patient on three consecutive voluntary manoeuvres. MA titration was performed during PSG after 1 week of acclimatisation to MAd at 50% of the maximum MA.
2				
3				
Control	PAP	CPAP (fixed)	Sullivan S6 Elite; Resmed, Bella Vista, NSW, Australia	Patients were then treated at the manually titrated pressure with CPAP device equipped with a microprocessor and pressure monitor, providing a precise index of daily use by measuring the time spent with the mask on.
For CPAP:		**How was the Pressure selected?**	CPAP titration was conducted during PSG according to authors' standard procedure	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	AHI	Baseline, 2 mo	
2	Sleep study measures	ODI 3%	Baseline, 2 mo	
3	Sleepiness measures	ESS	Baseline, 2 mo	
4	Sleepiness measures	OSLER test	Baseline, 2 mo	objective vigilance test, complete tasks that involve high levels of concentration
5	Sleepiness measures	Trail Making Test A	Baseline, 2 mo	neuropsychological test of visual attention and task switching--requires a subject to connect-the-dots of 25 consecutive targets, all numbers
6	Sleepiness measures	Trail Making Test B	Baseline, 2 mo	neuropsychological test of visual attention and task switching--requires a subject to connect-the-dots of 25 consecutive targets, numbers and letters
7	Compliance	Hours per night	2 mo	number of hours of daily use
8	Compliance	Nights on treatment %	2 mo	% nights on which treatment was used.
9	Harms	Mean side-effects score	2 mo	six common side-effects of CPAP (congested, drippy or irritated nose, skin lesion, irritated eyes and dry mouth) and MAd (jaw pain, tooth pain, muscle stiffness, dry mouth, hypersalivation and occlusal change), score from 0-18
10	QoI	Health related quality of life	Baseline, 2 mo	Evaluated using Nottingham Health Profile
11	Sleep study measures	Treatment response	2 mo	Complete response was defined by a ≥50% reduction in AHI to <5 events/h, partial response by a ≥50% reduction in the AHI but with AHI remaining ≥5 events/h, and treatment failure by <50% reduction in AHI.

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Gagnadoux, 2009 France 19324954	Complete response (≥50% reduction in AHI to <5 events/hr)	**Tx**	Mandibular advancement device	2 mo	12	28	nd	nd	nd	nd	nd	nd	nd	nd
		Cx	CPAP		20	28	nd	nd	nd	nd	nd	nd	nd	nd
	Partial response (a ≥50% reduction in the AHI but with AHI remaining ≥5 events/h)	**Tx**	Mandibular advancement device	2 mo	14	28	nd	nd	nd	nd	nd	nd	nd	nd
		Cx	CPAP		7	28	nd	nd	nd	nd	nd	nd	nd	nd
	Treatment failure (<50% reduction in AHI)	**Tx**	Mandibular advancement device	2 mo	2	28	nd	nd	nd	nd	nd	nd	nd	nd
		Cx	CPAP		1	28	nd	nd	nd	nd	nd	nd	nd	nd

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			(final test – control)*		
							Value	SD	Value	SD	Value	SD	P	Value	SD	P
Gagnadoux, 2009 France 19324954	AHI	Events/hr	**Tx**	Mandibular advancement device	2 mo	28	34.2	13.0	6	nd	28.2	Nd	nd	4	Nd	0.001
			Cx	CPAP		28	34.2	13.0	2	nd	32.2	nd	Nd			
	ODI 3%	Events/hr	**Tx**	Mandibular advancement device	2 mo	28	nd	Nd	6.3	Nd	nd	nd	Nd	4.6	nd	0.001
			Cx	CPAP		28	nd	nd	1.7	nd	Nd	Nd	nd			
	ESS	scale	**Tx**	Mandibular advancement device	2 mo	28	10.6	4.5	7.7	4.0	-2.9	nd	<0.001	nd	nd	Nd
			Cx	CPAP		28	10.6	4.5	8.2	3.9	-2.4	nd	<0.001	nd	nd	nd
	OSLER test-sleep latency	sec	**Tx**	Mandibular advancement device	2 mo	28	2094	674	2312	322	218	Nd	<0.05	nd	nd	Nd
			Cx	CPAP		28	2094	674	2300	391	206	nd	<0.05	nd	nd	nd
	OSLER test-errors n	number	**Tx**	Mandibular advancement device	2 mo	28	12.5	17.9	4.3	7.5	-8.2	Nd	<0.05	nd	nd	Nd
			Cx	CPAP		28	12.5	17.9	8.7	19.8	-3.8	nd	<0.01	nd	nd	nd
	Trail making test A	Nd	**Tx**	Mandibular advancement device	2 mo	28	36.4	10.9	32.5	9.6	-3.9	Nd	<0.001	nd	nd	Nd
			Cx	CPAP		28	36.4	10.9	30.1	8.9	-6.3	nd	<0.05	nd	nd	nd
	Trail making test B	Nd	**Tx**	Mandibular advancement device	2 mo	28	79.3	26.2	73.4	33.0	-5.9	Nd	<0.001	nd	nd	Nd
			Cx	CPAP		28	79.3	26.2	68.5	22.2	-10.8	nd	nd	nd	nd	nd
	Mean side-effects score	Nd	**Tx**	Mandibular advancement device	2 mo	28	NA	NA	3.2	3.1	NA	NA	NA	0.0	Nd	0.8
			Cx	CPAP		28	NA	NA	3.2	3.4	NA	NA	NA			
	Reported compliance-hrs/night	Hrs/night	**Tx**	Mandibular advancement device	2 mo	28	NA	NA	7.0	Nd	NA	NA	NA	nd	Nd	<0.01

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			(final test – control)*		
							Value	SD	Value	SD	Value	SD	P	Value	SD	P
			Cx	CPAP		28	NA	NA	6.0	Nd	NA	NA	NA	nd	Nd	
	Reported compliance-nights on treatment %	%	**Tx**	Mandibular advancement device	2 mo	28	NA	NA	98%	Nd	NA	NA	NA	Nd	nd	<0.01
			Cx	CPAP		28	NA	NA	90%	nd	NA	NA	NA	nd	nd	
	Physical mobility	Score	**Tx**	Mandibular advancement device	2 mo	28	9.9	nd	5.3	nd	-4.6	nd	nd	-2.6	nd	nd
			Cx	CPAP		28	9.9	nd	7.9	nd	-2	nd	nd			
	Social isolation	Score	**Tx**	Mandibular advancement device	2 mo	28	7.9	nd	4.4	nd	-3.5	nd	nd	-1.7	nd	nd
			Cx	CPAP		28	7.9	nd	6.1	nd	-1.8	nd	nd			
	Pain	Score	**Tx**	Mandibular advancement device	2 mo	28	16.3	nd	8.3	nd	-8	nd	nd	-3.8	nd	nd
			Cx	CPAP		28	16.3	nd	12.1	nd	-4.2	nd	nd			
	Emotional reaction	Score	**Tx**	Mandibular advancement device	2 mo	28	16.7	nd	8.1	nd	-8.6	nd	nd	-3.3	nd	nd
			Cx	CPAP		28	16.7	nd	11.4	nd	-5.3	nd	nd			
	Energy	Score	**Tx**	Mandibular advancement device	2 mo	28	30.1	nd	18.5	nd	-11.6	nd	nd	0.9	nd	nd
			Cx	CPAP		28	30.1	nd	17.6	nd	-12.5	nd	nd			
	Sleep	score	**Tx**	Mandibular advancement device	2 mo	28	29.0	nd	16.2	nd	-12.8	nd	nd	-10	nd	nd
			Cx	CPAP		28	29.0	nd	26.2	nd	-2.8	nd	nd			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
Gagnadoux, 2009 France 19324954	Nd (mean side effects score in outcome)					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Y	Y	Nd	Y	N	Nd	N	Y	N	N	Y
	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?			If a Crossover study, was the Washout period adequate?
	Y	N	Y	Y	Y	Y	n			y
Reasons for drop-outs:	Nd									
Other Issues:	May not have sufficient N for power, no analysis of different treatment centers									
Overall Quality (A, B, C)	B									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Hoekema, 2008 Hoekema, 2007			**Intervention 1**	Oral appliance
PMID*	3371 3375	**RefID**	18719218 17081222	**Intervention 2**	CPAP
Key Question(s)	KQ 5 CPAP v Oral			**Intervention 3**	
Design †	RCT			**Control**	
Extractor	EMB			**Comments**	Block randomization Trial designed and analyzed as a non-inferiority study

* or Cochrane number

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA AHI ≥5 ≥20 yo PMID 17081222: GRISS completed at baseline (see outcomes); Men only	Previous CPAP, oral appliance, or UPPP Clearly reversible morphological airway abnormality Endocrine dysfunction (not including DM) Severe cardiac or pulmonary disease Periodic limb movement index >25/hr Psychological condition precluding informed consent Extensive periodontal disease or tooth decay Active TMJ disease or bruxism Restrictions in mouth opening (<25 mm) or mandible advancement (<5 mm) <8 teeth in upper or lower jaw	≥5	2002-2005	No	Netherlands	Netherlands Organization for Health Research and Development.	**Analyzed as non-inferiority** **Power: ≥46 participants/intervention (Effective treatment)**	No (not possible)	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx Oral	**51 (51)**	84%	49±9.5		32.3±6.1	76% 151/93		0 (by eligibility)
Cx CPAP	**52 (52)**	94%	49±9.5		33.3±5.8	81% 152/92		
Total				nd		>140/90 or antihypertensive	nd	
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx		39%						
Cx		33%						
Total	nd		nd	nd	nd	nd	nd	No
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	None (no CPAP, oral appliance, or UPPP)							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Tx Oral	51	≤30: 49% >30: 51% 39.4±30.8	12.9±5.6					
Cx CPAP	52	≤30: 48% >30: 52% 40.3±27.6	14.2±5.6					
Total:				nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
none						nd		none

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥5		nd (AASM 1999)	nd (AASM 1999)	daytime sleepiness (implied)	Split	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance		Thornton Adjustable Positioner type 1 Airway Management, Inc., Dallas	Positions mandible in a forward and downward position. Patient can adjust in 0.2 mm increments. Advanced until symptoms abate or until discomfort
2	PAP	CPAP	Breas PV10 Molnlycke, Sweden	
3				
Control				
For CPAP:		**How was the Pressure selected?**	During afternoon nap	
NOTE		PSG done at 8 wks and CPAP or oral appliance adjusted if AHI still ≥5, then 4 more wk treatment. Adjustments continued q 4 wk with PSG as tolerated		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
All	Conservative measure advice: avoid depressants (eg, EtOH, sleep medications), 7-8 hr sleep, cease smoking, lose weight	
For CPAP:	**Describe the frequency of the initial education follow-up**	Detailed instructions by a skilled nursing consultant, then trial of 2 wk then return for check-up, then adjustment at 8 wk and q 4 wk as necessary

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	Effective Treatment	Final review	AHI<5 or >50% reduction to an AHI<20 without symptoms Home PSG
	Sleep study measure	AHI<5		(sensitivity analysis of "Effective treatment")
	Sleep study measure	AHI<10		Excludes those with AHI<10 at baseline.
2	QoL	SF-36		
3	Sleepiness measure	ESS		
4	Sleepiness measure	Functional outcomes of sleep questionnaire		Weaver TE, Laizner AM, Evans LK, Maislin G, Chugh DK, Lyon K, et al. (1997). An instrument to measure functional status outcomes for disorders of excessive sleepiness. Sleep 20:835-843. Total score range 5-20
	Psychiatric scale	Hospital anxiety and depression scale		Zigmond AS, Snaith RP (1983). The hospital anxiety and depression scale. Acta Psychiatr Scand 67:361-370. Range 0-21
	Compliance	Non-Adherent Night/wk; hr/night		Discontinued treatment for any reason Nights/wk and hr/night of use, by questionnaire (not by CPAP device measurement, to minimize bias)
	Miscellaneous	Golombok Rust Inventory of Sexual Satisfaction		(PMID 17081222)

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

GRISS

The GRISS is a self-report questionnaire that measures the most common psychosexual complaints. It has separate forms for men and women, each consisting of 28 items. The male questionnaire yields seven subscale scores, reflecting sexual function in the following areas: impotence, premature ejaculation, sensuality, avoidance, satisfaction, frequency, and communication. The reliability of the GRISS and its predictive validity for the identification of sexual dysfunction within a sexological population have been found to be satisfactory in English and Dutch samples [18,26,27]. In addition, the subscales were found to be independent of social desirability [18]. Each questionnaire was anonymized to guarantee the patient's privacy.

I. RESULTS (dichotomized or categorical outcomes)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Hoekema, 2008	Effective Tx (Total Population)	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	39	51	RD	-6.2%	-21.7, 9.4					
Netherlands		**Cx**	CPAP	Mean 86 d Median 63 d IQR 60-88 d	43	52								
18719218														
	Effective Tx (AHI≤30)	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	21	25	RD	+4.0%	-17.7, 25.4					
		Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	20	25								
	Effective Tx (AHI>30)	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	18	26	RD	-16.0%	-37.1, 6.8					
		Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	23	27								
	AHI<5	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	29	51	RD	-20.0%	-36.6, -1.9					
	(also data for baseline AHI<>30)	**Cx**	CPAP	Mean 86 d Median 63 d IQR 60-88 d	40	52								
	AHI<10	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	31	44		-4.5%	-22.6, 13.9					
	(also data for baseline AHI<>30)	**Cx**	CPAP	Mean 86 d Median 63 d IQR 60-88 d	33	44								
	Non-Adherent	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	2	49								
		Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	5	50								

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference Final (Test – Control)		
							Value	SD	Value	SD/SE*	Value	SD/SE*	P	Value	95% CI	P
Hoekema, 2008	Sleep efficiency	% Time in Bed	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/47 (b/f)	88.3	9.7	86.1	8.1	-1.8			0.00	-0.40, 0.40	
Netherlands			**Cx**	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/47 (b/f)	85.5	15.5	86.2	10.0	+0.7					
18719218																
	AHI	/hr	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/47 (b/f)	39.4	30.8	7.8 (median 2.2)	14.4 (IQR 0, 9.5)	-31.6					0.006
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/47 (b/f)	40.3	27.6	2.4 (median 0)	4.2 (IQR 0, 3.0)	-37.9					
	Min O_2 sat	%	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/47 (b/f)	78.0	8.5	87.7	6.3				-0.33	-0.73, 0.08	
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/47 (b/f)	77.9	9.9	89.7	5.8						
	Sleep stage 3&4	% TST	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/47 (b/f)	13.7	9.0	20.4	7.7				-0.18	-0.58, 0.23	
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/47 (b/f)	13.0	11.5	21.8	8.0						
	REM	% TST	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/47 (b/f)	21.0	7.8	26.5	6.7				0.39	-0.03, 0.79	
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/47 (b/f)	19.2	7.4	24.1	5.7						
	ESS		**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/49 (b/f)	12.9	5.6	6.9 (median 7.0)	5.5 (IQR 2.0, 9.5)						0.53
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/50 (b/f)	14.2	5.6	5.9 (median 6.0)	4.8 (IQR 3.8, 12.0)						

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference Final (Test – Control)		
							Value	SD	Value	SD/SE*	Value	SD/SE*	P	Value	95% CI	P
Hoekema, 2008	FOSQ (Total score†)		**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/49 (b/f)	13.7	3.1	16.6	2.8				-0.05	-0.44, 0.34	
Netherlands			**Cx**	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/50 (b/f)	13.9	3.7	16.7	3.1						
18719218																
	Hospital anxiety scale		**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/49 (b/f)	5.6 (median 4)	3.8 (IQR 3, 8)	4.5 (median 3)	3.6 (IQR 2, 6.5)						0.81
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/50 (b/f)	5.4 (median 5)	3.6 (IQR 3, 8)	4.3 (median 3.5)	3.4 (IQR 1.8, 7)						
	Hospital depression scale		**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/49 (b/f)	5.8 (median 5)	3.8 (IQR 3, 8)	3.8 (median 2)	3.7 (IQR 1, 7)						0.25
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/50 (b/f)	7.1 (median 75)	4.3 (IQR 4, 10)	4.8 (median 3)	4.5 (IQR 1, 8.5)						
	SF 36 Phys Fxn†		**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/49 (b/f)	71.8	23.3	78.8	21.5				-0.09	-0.48, 0.31	
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/50 (b/f)	68.9	24.2	80.6	18.5						
	SF 36 Mental Health†		**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	51/49 (b/f)	70.9	17.8	77.5	16.5				+0.15	-0.24, 0.55	
			Cx	CPAP	Mean 86 d Median 63 d IQR 60-88 d	52/50 (b/f)	68.2	17.6	75.0	16.2						
	Treatment usage/wk	noc/wk	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	49	6.7	1.0								
	(Also categorical data reported)		**Cx**	CPAP	Mean 86 d Median 63 d IQR 60-88 d	50	6.7	0.8								

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference Final (Test – Control)		
							Value	SD	Value	SD/SE*	Value	SD/SE*	P	Value	95% CI	P
	Treatment usage/noc	hr/noc	**Tx**	Oral appliance	Mean 78 d Median 68 d IQR 60-96 d	49	6.9	1.0								
	(Also categorical data reported)		**Cx**	CPAP	Mean 86 d Median 63 d IQR 60-88 d	50	6.5	1.6								
Hoekema, 2007	GRISS Erectile Dysfunction†	Range 4-20	**Tx**	Oral appliance	Median 82 d IQR 69-103 d	20	7.9	3.5	7.9	4.0	0		NS			NS
Netherlands			**Cx**	CPAP	Median 76 d IQR 63-109 d	27	9.5	4.2	8.6	3.0	-0.9		NS			
17081222																
	GRISS Sexual dissatisfaction†	Range 4-20	**Tx**	Oral appliance	Median 82 d IQR 69-103 d	20	8.5	3.9	8.8	4.0	+0.3		NS			NS
			Cx	CPAP	Median 76 d IQR 63-109 d	27	10.2	4.3	10.5	4.3	+0.3		NS			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper
† Data for (other) subcomponents also reported, not extracted

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Oral appliance	2/51 (4%)	Loss to follow up
CPAP	2/52 (4%)	Loss to follow up

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes) SEE ABOVE FOR SUBGROUPS BASED ON BASELINE AHI

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	Yes	Yes	No (not possible)	Yes	Yes	Yes	NA	NA	Yes
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Yes	No	Yes	Yes	Yes	Yes	NA			NA
Reasons for drop-outs:	Loss to followup									
Other Issues:	Performed only final analyses in parallel design RCT (not net changes). Difficult to interpret.									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Randerath, 2002			**Intervention 1**	Intraoral sleep apnea device (ISAD)
PMID*	12171833	**RefID**	4698	**Intervention 2**	
Key Question(s)	5(CPAP and oral appliance)			**Intervention 3**	
Design †	Cross over			**Control**	CPAP
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSAS AHI 5-30/hr	TMJ disorders Bruxism Gaps in dentition that did not allow oral fitting of device	nd	1999	n	Germany	nd	nd	n	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**20(20)**	80	56.5(12)	nd	31.2(6.4)	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	none							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	20	17.5(7.7)	nd	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG			Reduction in effort of 50% for at least 10s or decrease o_2 sat of at least 4%			Nd(implied Same night)	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	Intraoral sleep apnea device	IST, Hinz, Herne	Thermoplastic parts attached to the upper and lower jaws that advance and depress the mandible and tongue with a slight vertical clockwise rotation.
2				
3				
Control	PAP	CPAP	Max II, MAP	
For CPAP:		**How was the Pressure selected?**	Pressure increased manually in incremental steps till respiratory disturbances minimized and arousals reduced to <=5/hr	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	6 weeks	
2	Sleep study measure	SaO_2 min	6 weeks	
3	Sleep study measure	Stage 3 and 4	6 weeks	
4	Sleep study measure	REM	6 weeks	
5	Sleep study measure	Arousals	6 weeks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD	Value	SD	P	Value	SD*	P
Randerath, 2002 Germany 12171833	AHI		Tx	ISAD	6 weeks	20	17.5	7.7	13.8	11.1	-3.7		NS	10.6		0.01
			Cx	CPAP	6 weeks	20	17.5	7.7	3.2	2.9	-14.3		<0.01			
	SaO_2 min	%	Tx	ISAD	6 weeks	20	54.5	25.9	85.3	3.1	30.8		NS	-3.7		<0.05
			Cx	CPAP	6 weeks	20	54.5	25.9	89	3.4	34.5		<0.01			
	Stage 3 and 4	% TST	Tx	ISAD	6 weeks	20	14.2	10.6	14.1	10.8	-0.1		NS	-2.1		NS
			Cx	CPAP	6 weeks	20	14.2	10.6	16.2	9.1	2		NS			
	REM	% TST	Tx	ISAD	6 weeks	20	15.1	5.9	14.8	7.3	-0.3		NS	-0.5		NS
			Cx	CPAP	6 weeks	20	15.1	5.9	15.3	6.8	0.2		NS			
	Arousals	/hr TST	Tx	ISAD	6 weeks	20	21.8	9.9	17	5.1	-4.8		<0.05	2.9		NS
			Cx	CPAP	6 weeks	20	21.8	9.9	14.1	5.1	-7.7		NS			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD *	Value	SD*	Value	SD*	P	Value	SD*	P
AHI<10	Randerath, 2002 Germany 12171833	AHI		**Tx**	ISAD	6 weeks	4	~7.5		~5.5				NS			NS
				Cx	CPAP	6 weeks	4	~7.5		~3.2				NS			
AHI 10 - <20		AHI		**Tx**	ISAD	6 weeks	10	~16		~11				NS			<0.05
				Cx	CPAP	6 weeks	10	~16		~3				<0.01			
AHI>=20		AHI		**Tx**	ISAD	6 weeks	6	~27		~24				NS			<0.01
				Cx	CPAP	6 weeks	6	~27		~3				<0.01			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
BMI<27	Randerath, 2002 Germany 12171833	AHI		**Tx**	ISAD	6 weeks	6	~16		~17				NS			nd
				Cx	CPAP	6 weeks	6	~16		~3				NS			
BMI 27 to <30.5		AHI		**Tx**	ISAD	6 weeks	7	~19		~15				NS			nd
				Cx	CPAP	6 weeks	7	~19		~3				<0.05			
BMI >=30.5		AHI		**Tx**	ISAD	6 weeks	7	~16		~8				<0.05			nd
				Cx	CPAP	6 weeks	7	~16		~3				<0.01			

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			ISAD			
Randerath, 2002 Germany 12171833	Sensation of pressure on face		8/20			
	Sensation of pressure on mouth		2/20			
	Early morning discomfort in mouth and TMJ		8/20			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	n	nd	y	y	na	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	y	y	n	nd
Reasons for drop-outs:								
Other Issues:	No power calculation, no data on blinding outcome assessor, no data on washout period							
Overall Quality (A, B, C)	**B**							

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Skinner, 2004			**Intervention 1**	Cervicomandibular support collar
PMID*	14718430	**RefID**	4811	**Intervention 2**	
Key Question(s)	5- CPAP v Mandib			**Intervention 3**	
Design †	Randomized cross-over			**Control**	Auto-titrating nCPAP
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
mild-to-moderately severe OSA and apnea-hypopnea index (AHI) of 10 to 60/h of total sleep time.	medical history of cardiovascular, neurologic, or psychological disorders affecting sleep; coexisting sleep disorders; and known cervical or temporomandibular joint dysfunction and/or pain	nd	Nd	N	New Zealand	University of Otago School of Physiotherapy and the Otago Respiratory Research Trust.	nd	N	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**10**	80	48.6	Nd	34.1	Nd	Nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	Nd	Nd	Nd	Nd	Nd	Nd	Nd	no
	Treatments used (prior to trial, including surgery)							
Tx	Nd							
Cx	nd							
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	10	29.4	12.2	Nd	Nd	Nd	Nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
Nd						Nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	Nd	Nd	cessation of airflow lasting at least 10 s	Changes in thoracoabdominal movements were used to score hypopneas, given that the thermistor is unable to quantify the reduction in airflow, or to distinguish between obstructive and central events. A reduction in any of these signals by ≥50% from a rolling baseline, and persisting for ≥10 s, or a reduction in thoracoabdominalmovement with an accompanying oxygen desaturation of at least 3% and/or associated with an arousal, defined the significant respiratory events	Nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Positional therapy	Cervicomandibular support collar	Symmetric Designs; Salt Spring Island, BC, Canada	The collar comprised a fabric-covered, semicircular acrylic and latex ring, which was molded to fit under the mandible and rest on the upper third of the manubrium sterni. It was held in place by a fabric-covered foam strap with self-adhesive attachments. A chin piece supported the lower jaw in the closed position with the teeth held in light occlusion, and an anterior support tube was attached between the mandible and sternal portions to provide rigid support and prevent neck flexion beyond the NHP.
2				
3				
Control	CPAP	Autotitrating nCPAP	Autoset T, Sullivan; ResMed Ltd; North Ryde, NSW, Australia	
For CPAP:		**How was the Pressure selected?**	Minimum CPAP pressure was set at 4 cm H2O, and maximum CPAP pressure was set at 20 cm H2O. The Autoset T permits automatic titration of the CPAP required to maintain airway patency while asleep.	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	AHI	Baseline, 1 month	
2	Sleep study measures	ESS	Baseline, 1 month	
3	Sleep study measures	FOSQ	Baseline, 1 month	
4	Physical scale	SF-36 physical	Baseline, 1 month	
5	Psych scale	SF-36 mental	Baseline, 1 month	
6	General symptom scales	SQ	Baseline, 1 month	Scottish National Sleep Laboratory symptom questionnaire
7	Sleep study measures	Arousal frequency	Baseline, 1 month	
8	Sleep study measures	Min SaO2	Baseline, 1 month	
9	Sleep study measures	Sleep efficiency %	Baseline, 1 month	
10	Sleep study measures	Slow-wave sleep %	Baseline, 1 month	
11	Sleep study measures	REM sleep %	Baseline, 1 month	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD	Value	SD	P	Value	SD/SE*	P
	AHI		**Tx**	Cervicomandibular support collar	1 mo	10	29.4	13.4	26.9	17.2	-2.5	15.1	NS	16.9	nd	0.001
			Cx	Autotitrating nCPAP			29.4	13.4	9.9	8.0	-19.4	11.5	<0.001			
	ESS		**Tx**	Cervicomandibular support collar	1 mo	10	13.2	4.9	9.4	5.5	-3.8	nd	nd	-1.9	Nd	0.215
			Cx	Autotitrating nCPAP			13.2	4.9	11.3	4.6	-1.9					
	FOSQ		**Tx**	Cervicomandibular support collar	1 mo	10	12.2	3.1	12.7	3.1	0.5	nd	nd	-0.1	Nd	0.854
			Cx	Autotitrating nCPAP			12.2	3.1	12.8	2.7	0.6					
	SF-36 physical		**Tx**	Cervicomandibular support collar	1 mo	10	45.3	10.4	47.2	10.0	1.9	nd	nd	3	Nd	0.177
			Cx	Autotitrating nCPAP			45.3	10.4	44.2	9/7	-1.1					
	SF-36 mental		**Tx**	Cervicomandibular support collar	1 mo	10	43.8	50.5	50.5	10.5	6.7	nd	nd	-2.1	Nd	0.189
			Cx	Autotitrating nCPAP			43.8	50.5	52.6	8.6	8.8					
	SQ %		**Tx**	Cervicomandibular support collar	1 mo	10	59.7	11.9	39.3	23.4	-20.4	nd	nd	-4.2	Nd	0.513
			Cx	Autotitrating nCPAP			59.7	11.9	43.5	19.1	-16.2					
	Arousal Frequency		**Tx**	Cervicomandibular support collar	1 mo	10	27.7	9.0	31.7	22.8	4	nd	nd	15.2	Nd	0.072
			Cx	Autotitrating nCPAP			27.7	9.0	16.5	5.9	-11.2					
	Min SaO2		**Tx**	Cervicomandibular support collar	1 mo	10	84.3	4.4	81.0	12.0	-3.3	nd	nd	-9.8	Nd	0.076
			Cx	Autotitrating nCPAP			84.3	4.4	90.8	3.0	6.5					
	Sleep efficiency %		**Tx**	Cervicomandibular support collar	1 mo	10	81.9	7.9	78.6	11.8	-3.3	nd	nd	0.2	Nd	0.974
			Cx	Autotitrating nCPAP			81.9	7.9	78.4	11.6	-3.5					
	Slow-wave sleep %		**Tx**	Cervicomandibular support collar	1 mo	10	20.4	8.2	20.1	13.4	-0.3	nd	nd	-3.9	Nd	0.296
			Cx	Autotitrating nCPAP			20.4	8.2	24.0	8.9	3.6					
	REM sleep %		**Tx**	Cervicomandibular support collar	1 mo	10	20.4	4.6	19.7	5.1	-0.7	nd	nd	-0.7	Nd	0.819
			Cx	Autotitrating nCPAP			20.4	4.6	20.4	8.0	0	nd	nd			

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD	Value	SD	P	Value	SD/SE*	P

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
	Adverse effects score	Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
all	0	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			Cervicomandibular support collar	Autotitrating nCPAP		
Skinner, 2004 New Zealand 14718430	Adverse effect scale (19 self-reported questions scored 0-3)	1 mo	6.7	6.5		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Y	Nd	nd	y	n	Nd	Y	Y	NA	NA	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	Y	N	Y	Y	N	Y	n	n

Reasons for drop-outs:	No dropouts
Other Issues:	Study stopped after 10 patients (originally planned for 20) because treatment didn't show objective benefit. Washout deemed unlikely to change outcome because of lack of benefit from treatment.
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Tan, 2002			**Intervention 1**	CPAP
PMID*	12143088	**RefID**	4873	**Intervention 2**	
Key Question(s)	5 (CPAP and oral appliance)			**Intervention 3**	
Design †	Cross over			**Control**	MAS(mandibular advancement splint)
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA Mild or moderate OSA (AHI <50) >18 years Adequate dentition to support retention of oral appliance No temporomandibular joint dysfunction No medical contraindication	Significant heart disease (MI in last 3 years, angina, uncontrolled hypertension) COPD Regular hypnotic use Epilepsy Arterial o2 sat <60% Language barrier		nd	y	UK		nd	n	Y?(done in a random order with all patient identification removed)
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**24(21)**	83	50.9(10.1)		31.9(6.8)			
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total								
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	24	22.2(9.6)	13.4(4.6)					
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG							

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	nCPAP	Respironics Inc and Resmed Uk ltd	
2				
3				
Control	Oral appliance	MAS	Soft MAS (and Erkodent Gmbh, semi rigid MAS)	One piece vaccum formed appliance for first 10 subjects (and two part semi rigid silensor for others)
For CPAP:		**How was the Pressure selected?**	Manual titration till OSA abolished	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measure	ESS	2 months	
2	Sleep study measure	AHI	2 months	
3	Sleep study measure	ODI	2 months	
4	Sleep study measure	Arousals	2 months	
5	Sleep study measure	Sleep efficiency	2 months	
6	Sleep study measure	REM sleep	2 months	
7	QOL	General health	2months	
8		Daytime sleepiness		

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD	Value	SD	P	Value	SD/SE*	P
Tan, 2002 UK 12143088	ESS		**Tx**	nCPAP	2 months	24	13.4	4.6	8.1	4.1	-5.3			-0.9		NS
			Cx	MAS	2 months	24	13.4	4.6	9.0	5.1	-4.4					
	AHI		**Tx**	nCPAP	2 months	24	22.2	9.6	3.1	2.8	-19.1			-4.9		NS
			Cx	MAS	2 months	24	22.2	9.6	8.0	10.9	-14.2					
	ODI	%	**Tx**	nCPAP	2 months	24	7.1	2.7	3.3	1.6	-3.8			-1.5		NS
			Cx	MAS	2 months	24	7.1	2.7	4.8	2.7	-2.3					
	Arousals	/hr	**Tx**	nCPAP	2 months	24	19.3	9.6	9.8	6.6	-9.5			-1.8		NS
			Cx	MAS	2 months	24	19.3	9.6	11.6	5.6	-7.7					
	Sleep efficiency	%	**Tx**	nCPAP	2 months	24	81.6	10.4	87.2	8.1	5.6			4		NS
			Cx	MAS	2 months	24	81.6	10.4	83.2	8.1	1.6					
	REM sleep	%	**Tx**	nCPAP	2 months	24	12.7	5.8	18.5	6.1	5.8			4.7		NS
			Cx	MAS	2 months	24	12.7	5.8	13.8	5.6	1.1					
	General health		**Tx**	nCPAP	2 months	24	17.4	7.5	6.5	5.9	-10.9		<0.001	-3.7		NS
			Cx	MAS	2 months	24	17.4	7.5	10.2	9.9	-7.2		<0.001			
	Daytime sleepiness		**Tx**	nCPAP	2 months	24	10.0	7.3	5.2	5.1	-4.8		<0.001	-2.5		NS
			Cx	MAS	2 months	24	10.0	7.3	7.7	7.0	-2.3		NS			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
nCPAP	2/24	Did not tolerate CPAP but completed the other arm. Included in analysis
MAS	1/24	Did not tolerate MAS but included in analysis

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			MAS			
Tan, 2002 UK 12143088	Jaw discomfort	Early morning	12/24			
	Nasal stuffiness	nd	nd			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y		y	n	Y?	y	y	n	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y		y	n	y
Reasons for drop-outs:								
Other Issues:								
Overall Quality (A, B, C)	**B**							

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Question 5
Oral vs Oral

A.

Author, Year	Campbell, 2009			**Intervention 1**	MAS 70% protrusion of mandible (Objective)
PMID*	18989715	**RefID**	3128	**Intervention 2**	
Key Question(s)	5(mandibular)			**Intervention 3**	
Design †	RCT			**Control**	MAS 70% protrusion of mandible(subjective)
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA AHI10-40 BMI<35 At least 2 of Subjective daytime sleepiness ESS>8/24, habitual snoring, observed choking during sleep, morning headaches or complaint of poor sleep quality	Significant co morbidity Co existing sleep disorder Regular use of sedatives or narcotics Dental factors preventing effective therapy (<8 teeth per arch), exaggerated gag reflex, inability to tolerate MAS at initial fitting	>5	nd	n	New Zealand	nd	Nd(but they say AHI is primary endpoint)	n	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**?(12)**		49.8(12.6)		27.1(3.9)			
Cx	**?(16)**		48.1(10.6)		28.0(3.0)			
Total	**30(28)**	86		nd		nd	**nd**	**nd**
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	**nd**	**nd**	**nd**	**nd**	**nd**	**nd**	**nd**	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	12	26.5(12.0)	11.0(5.3)					
Control:	16	25.4(7.4)	11.6(4.7)					
Total:	28			nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>5		10-secs	3 % decline in o2 saturation	Excessive sleepiness, snoring, choking, morning headaches		

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	MAS		Full occlusal splint made from heat cured acrylic using hard/soft bilaminar process and the MDSA® hook attachment Objective Patients used the device for first three weeks without titration, and then adviced on how to titrate device for the next 3 weeks adjusting for OSA sympts and comfort
2				
3				
Control	**Oral appliance**	MAS		Full occlusal splint made from heat cured acrylic using hard/soft bilaminar process and the MDSA® hook attachment Subjective: patients used the device for 6 weeks straight, titrating (ant and posteriorly)
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	6 weeks	
2	Sleep study measure	AHI	6 weeks	**AHI >50% reduction in AHI but still remains >5/h**
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Campbell, 2009 18989715 New Zealand	AHI<5	**Tx**	Objective	12	3.9	12	%	33		**NS(0.53)**				
		Cx	subjective	16	1.92	16		12.5						
	Improvement %(AHI >50% reduction in AHI but still remains >5/h	**Tx**	Objective	12	5.04	12	%	42		NS(0.53)				
		Cx	subjective	16	8.96	16		56.25						
	Failure percent(AHI decreased by <50%)	**Tx**	Objective	12	3	12	%	25		nd				
		Cx	subjective	16	4.96	16		31.25						

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Campbell, 2009 18989715 New Zealand	AHI(mean , range)		Tx	Objective	6 weeks	12	26.6	12	11.7	10	-14.9		<0.001	-3.8 (-11.4,3.9		0.333
			Cx	subjective	6 weeks	16	25.4	7.4	14.3	10	-11.1		0.0002			
	ESS		Tx	Objective	6 weeks	12	11.0	5.3	9.5	5.1	-1.5		NS	2.3(-1.4,6.0)		nd
			Cx	subjective	6 weeks	16	11.6	4.7	7.8	4.5	-3.8		0.003			
	Arousal index		Tx	Objective	6 weeks	12	33.6	10	24.2	7.6	-9.4		0.004	0.5(-7.3,8.3)		0.900
			Cx	subjective	6 weeks	16	32.1	13.3	22.2	10.1	-9.9		0.008			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			Objective	Subjective		
Campbell, 2009 18989715 New Zealand	Sore teeth gums	6 weeks	0	6.3		
	Jaw pain	6 weeks	0	0		
	Dry mouth	6 weeks	8.3	6.3		
	Excess saliva	6 weeks	8.3	6.3		
	Ejection of the MAS	6 weeks	0	6.3		
	Difficulty breathing	6 weeks	0	0		
	choking	6 weeks	0	0		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	n	nd	n	y	na	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	n	na	na	na
Reasons for drop-outs:								
Other Issues:								
Overall Quality (A, B, C)		**B**						

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Dort, 2008			**Intervention 1**	Suction tongue-retaining device
PMID*	18461376	**RefID**	3238	**Intervention 2**	
Key Question(s)	5- Mandib vs Cx			**Intervention 3**	
Design †	RCT			**Control**	Non-suction tongue-retaining device
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
For appliance-naïve subjects- mild to moderate sleep disordered breathing: -primary snoring, -RDI<5 events per hour or mild to moderate OSA (RDI<30 events per hour) For those with severe OSA (RDI≥ 30 events per hour): -Failure of CPAP therapy	-unable to protrude the tongue 10 mm beyond the anterior teeth -unable to travel to the clinic for the necessary visits or if craniofacial abnormalities were present	RDI>5/hr	nd	n	Canada	Alberta Heritage Fund for Medical Research	Nd	N	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx	**32**							
Cx	**32**							
Total	**32**	**69%**	48	Nd	29.4	Nd	Nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	32							
Control:	32							
Total:	32	nd	12.4	nd	Snoring index = 214.7	Nd	Nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
RDI = 15.5								

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Nd	Nd	Nd	Nd	Nd	Nd	nd	-mild to moderate OSA (RDI<30 events per hour) -severe OSA (RDI≥ 30 events per hour):

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance			Fabricated by vacuum molding a single piece of dental mouth guard material, ethyl vinyl acetate. The active suction device was designed to allow suction formation on the tip of the tongue when placed in the mouth.
2				
3				
Control	Oral appliance			Appeared similar to the S device but was designed so that no suction could be developed on the tongue. Lack of suction was achieved through the design of the bulb.
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	RDI	Baseline, 1 wk	Assessed by portable monitor measured oxygen saturation; algorithm calculates RDI
2	Sleep study measures	Snoring index	Baseline, 1 wk	Average of the frequency of snores per hour over the period of portable monitoring
3	Sleepiness measures	ESS	Baseline, 1 wk	
4	General symptom scales	SAQLI	Baseline, 1 wk	Calgary Sleep Apnea Quality-of-Life Index

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE *	Value	SD/SE *	Value	SD/SE *	P	Value	95% CI	P
Dort, 2008 Canada 18461376	RDI	Events/hr	**Tx**	Suction tongue-retaining device	1 wk	32	15.5	17.6	8.9	7.6	-6.6		0.006	-4.9	(-8.9,-0.85)	0.019
			Cx	Non-suction tongue-retaining device	1 wk	32	15.5	17.6	13.5	15.4	-2.0		0.391			
	Snoring index	Snores/hr	**Tx**	Suction tongue-retaining device	1 wk	32	214.7	162.7	132.9	178.7	-81.8		0.027	-59	(-170,55))	0.298
			Cx	Non-suction tongue-retaining device	1 wk	32	214.7	162.7	191.0	262.1	-23.7		0.145			
	ESS		**Tx**	Suction tongue-retaining device	1 wk	32	12.4	4.5	10.9	4.4	-1.5		0.025	0.65	(-0.47, 1.8)	0.247
			Cx	Non-suction tongue-retaining device	1 wk	32	12.4	4.5	10.3	4.9	-2.1					
	SAQLI		**Tx**	Suction tongue-retaining device	1 wk	32	3.9	1.2	4.2	1.4	0.3		0.149	0.28	(-0.93,0.31)	0.286
			Cx	Non-suction tongue-retaining device	1 wk	32	3.9	1.2	3.9	1.5	0.0		0.909			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
nd		

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
Dort, 2008 Canada 18461376	Excessive saliva,	Nd				
	Tender oral mucosa and tongue	nd				

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Y	Y	N	Y	n	nd	nd	y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Y	N	Y	y	N	NA	N			y
Reasons for drop-outs:	Nd									
Other Issues:	Methodology section is sparse, little information on statistical analysis, no mention of reasons for dropout or intent-to-treat									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Kato, 2000			**Intervention 1**	OA2
PMID*	10767241	**RefID**	5450	**Intervention 2**	OA4
Key Question(s)	5(mandibular)			**Intervention 3**	OA6
Design †	RCT			**Control**	No OA
Extractor	NO			**Comments**	Paper specified total number of subjects required, not number per group. Baseline data for total group only, no baseline data per intervention

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Symptoms suggestive of sleep disordered breathing (excessive daytime sleepiness, loud snoring, and witnessed repetitive apneas	Inadequate anchoring of teeth (too few teeth) TMJ dysfunction History of UPPP	nd	nd	n	Japan	nd	nd	**nd**	**nd**
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**37**		49(27.1-66.6)	nd	28.7(23.0-40.0)	**nd**	**nd**	**nd**
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	**nd**	**nd**	**nd**	**nd**	**nd**	**nd**	**nd**	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Median (ragne) If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Baseline ODI
Treatment:								
Control:								
Total:	37	nd	nd	nd	nd	nd	nd	26(11.2-72.0)
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Nocturnal oximetry		4% decline in O_2 saturation	nd	nd			

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	OA 2	Erkodur; Erkodent Inc.; Pfalzgrafenweiler	clear acrylic resin and 1-mm polyethylene plate made in plastic models with 2 mm mandibular advancement
2	Oral appliance	OA 4	Erkodur; Erkodent Inc.; Pfalzgrafenweiler	clear acrylic resin and 1-mm polyethylene plate made in plastic models with 4 mm mandibular advancement
3	Oral appliance	OA 6	Erkodur; Erkodent Inc.; Pfalzgrafenweiler	clear acrylic resin and 1-mm polyethylene plate made in plastic models with 6 mm mandibular advancement
Control	No treatment	No oral appliance		No Oral appliance
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	ODI	8 nights	
2	Sleep study measures	Mean min O2 sat	8 nights	
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							median	95% CI*	median	95% CI*	median	95% CI*	P	median	95% CI*	P
Kato 2000 Japan 10767241	ODI		**Tx**	OA2	8 nights	nd	nd	nd	17.3	2.6-70.1						<0.05 (test vs control)
			Tx2	OA4	8 nights	nd	nd	nd	14.7	2.9-58.9						<0.05 (test vs control)
			Tx3	OA6	8 nights	nd	nd	nd	10.8	2.3-48.6						<0.05 (test vs control)
			Cx	No OA	8 nights	nd	nd	nd	26	11.2-72.0						
	Mean min O2 sat	%	**Tx**	OA2	8 nights	nd	nd	nd	89.2	80.0-92.6						<0.05 (test vs control)
			Tx 2	OA4	8 nights	nd	nd	nd	89.5	78.1-93.4						<0.05 (test vs control)
			Tx 3	OA6	8 nights	nd	nd	nd	89.6	81.3-92.6						<0.05 (test vs control)
			Cx	No OA	8 nights	nd	nd	nd	87.2	78.0-91.8						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
both	13	2 desired UPP, 1 preferred nCPAP, 1 lost weight and felt better, and 2 failed to construct their OA before completion of the study protocol

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Y	nd	nd	y	nd	nd	n		n		n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y		n	y	n	na	na			na
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Vanderveken 2008			**Intervention 1**	**MADcm**
PMID*	17673699	**RefID**	3918	**Intervention 2**	
Key Question(s)	5 (Mandibular)			**Intervention 3**	
Design †	Cross over			**Control**	MAD_{tp}
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSAS AHI≤40	Insufficient teeth to support the device Periodontal problems including teeth mobility Active TMJ dysfunction Limited maximum protrusive capacity (<6mm)	>5	2003-2004	n	Belgium		n	n	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**38(35)**	84	49(9)		28(4)	**nd**	**nd**	**nd**
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	**nd**	**nd**	**nd**	**nd**	**nd**	**nd**	**nd**	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	8 patients had a history of unsuccessful UPPP							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	23	13(11)	8(5)	nd	**nd**	**nd**	**nd**	**nd**
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	5	nd	10secs		Snoring, Excessive sleepiness		

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	MAD_{cm}	(Ivoclar, Vivadent AG; Schaan, Liechtenstein	Mono bloc splint, made of soft SR Ivo-cap elastomer which provides full occlusal coverage of both dental arches
2				
3				
Control	**Oral appliance**	MAD_{tp}	SomnoGuard Plus	Mono bloc splint, made from polymeric material which allowed for adjustment and advancement
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	*Description*	
For CPAP:	***Describe the frequency of the initial education follow-up***	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	4 months	
2	Sleep study measure	Mins Sao2	4 months	
3	Sleep study measure	Sleep efficiency	4 months	
4		VAS snoring	4 months	
5	Sleepiness measure	ESS	4 months	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value	SD*	P
Vanderveken, 2008 1763699	AHI		Tx	MAD_{cm}	4 months	23	14	12	6	8	-8		<0.01	-5		NS
			Cx	MAD_{tp}	4 months	23	14	12	11	9	-3		NS			
	Mins Sao2	%	Tx	MAD_{cm}	4 months	23	83	7	82	8	-1		NS	0		NS
			Cx	MAD_{tp}	4 months	23	83	7	82	6	-1		NS			
	Sleep efficiency	%	Tx	MAD_{cm}	4 months	23	78	11	80	11	2		NS	-1		NS
			Cx	MAD_{tp}	4 months	23	78	11	81	12	3		NS			
	VAS snoring (0-10)		Tx	MAD_{cm}	4 months	23	8	2	2	3	-6		<0.01	-2		<0.05
			Cx	MAD_{tp}	4 months	23	8	2	4	3	-4		<0.01			
	ESS 0-24)		Tx	MAD_{cm}	4 months	23	7	5	5	4	-2		NS	0		NS
			Cx	MAD_{tp}	4 months	23	7	5	5	4	-2		NS			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
Vanderveken 2008 1763699 Belgium	compliance	**Tx**	MAD_{cm}	4 months	Patients used this device on average for 6.4 nights per week (92%) and for 6.3 hr per nights (92%). 19 out of 23 patients who completed both arms preferred the custom made device. (P<0.00001)
		Cx	MAD_{tp}	4 months	Patients used this device for 4.5 nights per week (65%) and 4.6 hours per night (63%)

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Vanderveken 2008 1763699 Belgium	3/38	One patient discontinued because of a significant decrease in symptoms after weight loss and reduction of alcohol consumption, one patient experienced a complaint of increasing headache, one patient withdrew consent for socio economic reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)/ compliance failures

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			MAD cm	MAD tp		
Vanderveken 2008 1763699 Belgium	Lack of device retention	4 months	-	8		
	Pain from TMJ or teeth	4 months	2	1		
	Sleeping problems	4 months	-	1		
	Discomfort at night	4 months	-	1		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	y	y	n	y	n	y	na	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	y	na	n	y

Reasons for drop-outs:	
Other Issues:	
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Walker Engstrom 2003			**Intervention 1**	50% mandibular advancement
PMID*	14569523	**RefID**	4934	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	75% mandibular advancement
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Confirmed OSA AHI ≥ 20 Age 20-65 yrs sufficient number of teeth to anchor an appliance	Pronounced dental malocclusion Severe cardiovascular, neurological or respiratory disease mental illness, drug abuse, significant nasal obstruction	>10	1998-2000	n	Sweden	govt	n	Assumed n	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**42(37)**		50.4		30.5(1.4)			
Cx	**42(40)**		54.3		30.2(1.2)			
Total	**84(77)**	100		nd		**nd**	**nd**	**nd**
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	**nd**	**nd**	**nd**	**nd**	**nd**	**nd**	**nd**	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	42	47.0(5.1)	11.7(3.1)					
Control:	42	50.4(4.7)	11.5(3.1)					
Total:	84			nd	**nd**	**nd**	**nd**	**nd**
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±95% CI. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥ 10	number of episodes of o2 desat. of at least 4% per hour of sleep	10secs	**4% decline in O_2 saturation**			

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	**Oral appliance**	50% MAD		One piece appliance made from heat- cured acrylic polymer and advanced the mandible by 50% of the patient's maximum protrusive capacity (mean (95% CI) mandibular advancement 5.0mm (4.8, 5.3)).
2				
3				
Control	Oral appliance	75% MAD		**One piece appliance made from heat- cured acrylic polymer and advanced the mandible by 75% of the patients maximum protrusive capacity. (mean (95% CI) mandibular advancement 7.2mm (6.7,7.6)).**
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	AHI	6 months	
2	Sleep study measures	ODI	6 months	
3	Sleep study measures	ESS	6 months	
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	95 CI*	Value	95 CI*	Value	95 CI*	P	Value	95 CI*	P
Walker Engstrom 2003 14569523 Sweden	AHI		Tx	50% MA	6 months	37	47.0	5.1	17.4	5.7	-29.6		<0.001	5.2	(2.7,7.6) ***	NS
			Cx	75% MA	6 months	40	50.4	4.7	15.6	6.2	-34.8		<0.001			
	ODI		Tx	50% MA	6 months	37	44.6	5.9	18.0	6.0	-26.6		<0.001	4		NS
			Cx	75% MA	6 months	40	49.7	5.6	19.1	7.0	-30.6		<0.001			
	ESS		Tx	50% MA	6 months	37	11.7	3.1	8.6	2.8	-3.1		<0.001	0.9	(-0.4,2.2)	NS
			Cx	75% MA	6 months	40	11.5	3.1	7.5	2.6	-4		<0.001			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper
***** Estimated from reported data. Our estimate does not match with reported NS**

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
75% MAD	2/42	could not tolerate
	1/42	Moved out of area
	1/42	Could not achieve sleep registration
50% MAD	2/42	could not tolerate
	1/42	Moved out of area
	1/42	Chose UPPP

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	n	y	n	y	Mentioned but not applied	y	n	y	y
	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?			If a Crossover study, was the Washout period adequate?
	y	n	y	y		na	na			na
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)		B								

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments: data of number of patients with symptoms from stomatographic system not extracted

Key Question 5
Oral vs Surgery

A.

Author, Year	Walker-Engstrom 2002, 2000; Wilhelmsson, 1999			**Intervention 1**	Mandibular advancement device
PMID*	11888954; 11012871; 10445069	**RefID**	12941; 12942; 1070	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	UPPP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
suspected OSA; AI >5 but <25	<20 y/o or >65 y/o, mental illness, drug abuse, significant nasal obstruction, insufficient teeth to anchor appliance, pronounced dental malocclusion, severe CVD, neurologic, and respiratory disease	apnea index only >5	nd	no	Sweden	govt	yes; 35 pts in each group	no	yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**49 (41)**	nd	49.3	nd	26.9	nd	nd	nd
Cx	**46 (43)**	nd	51	nd	27.1	nd	nd	nd
Total	**95 (84)**	100	50.2	nd	27	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	nd	nd	nd	no
Cx	nd	nd	nd	nd	nd	nd	nd	no
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx	nd							
Cx	nd							
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	41	18.2 (95%CI 15.7-20.8)	nd	nd	nd	nd	nd	
Control:	43	20.4 (95%CI 17.4-23.3)	nd	nd	nd	nd	nd	
Total:	84	19.3	nd	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>5 (?)		no flow ≥10 s	50%↓ in flow with ↓O_2 sat of ≥4%			

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	dental appliance		custom made; used at night only; advanced the mandible by 50% of the maximum protrusive capacity
2				
3				
Control	Surgery	UPPP		Fujita procedure; tonsillectomy, resection of excess fat and mucosa of the soft palate, including the uvula
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	AHI	6 mo; 12 mo; 4 yr	
2		success rate	12 mo; 4 yr	% of pts with a decrease in AI or AHI of ≥50%
3	QoL	MSE-P		
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Wilhelmsson 1999 Sweden 10445069	success rate (AHI)	**Tx**	MAD	12 mo	30	37	%	81		<0.05				
		Cx	UPPP	12 mo	26	43		60						
Walker-Engstrom 2002 Sweden 11888954	success rate (AHI)	**Tx**	MAD	4 yr	23	32	%	72		<0.01 (diff at 4 yr)				
		Cx	UPPP	4 yr	14	40		35						

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	CI*	Value	CI*	Value	CI*	P	Value	SD/SE*	P
Wilhelmsson 1999 Sweden 10445069	AHI		**Tx**	MAD	6 mo	41					11.3	8.7-13.9	<0.001	-0.4		
			Cx	UPPP	6 mo	43					11.7	8.9-14.5	<0.001			
Wilhelmsson 1999 Sweden 10445069	AHI		**Tx**	MAD	12 mo	37					12.4	9-15.8	<0.001	2.4		
			Cx	UPPP	12 mo	43					10	6.5-13.5	<0.001			
Walker-Engstrom 2002 Sweden 11888954	AHI		**Tx**	MAD	4 yr	32	17.9	15-20.8	7.2	4.6-9.8	-10.7		<0.001	-5		<0.001 (btw group final values, not net diff)
			Cx	UPPP	4 yr	40	19.9	16.9-22.9	14.2	10.8-17.6	-5.7		<0.01			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Walker-Engstrom 2000 Sweden 11012871	MSE-P	contentment	12 mo	MAD	37	UPPP	43	UPPP	Final diff	6.3	100	0	<0.05
	MSE-P	vitality						0					
	MSE-P	sleep						0					

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
MAD at 1 yr	18% (8/45)	epilepsy (1); maxillofacial cancer (1); recurrent apthous ulcer due to allergy to acrylic polymer (1); uncomfortable (2); no improvement (3)
MAD at 4 yr	29% (13/45)	uncomfortable (2 more); moved (2, but 1 still using MAD); no improvement (1 more)
UPPP at 1 yr	0% (0/43)	
UPPP at 4 yr	8% (3/43)	death from a non-apnea related cause (1); withdrew for medical reasons other than OSA (2)

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			UPPP	MAD		
Walker-Engstrom 2002 Sweden 11888954	death	4 yr	1/43			
	allergic reaction	1 yr		1/45		
	lost teeth	4 yr		3/45		
	occlusion problem with TMJ apin	4 yr		1/45		
	fibrotic narrowing (asymptomatic)	4 yr	1/43			
	nasopharynx regurgitation	4 yr	8%			
	difficulty swallowing	4 yr	10%			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	n	nd	y	n	y	n	y	n	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	y	y	y	n	NA				
Reasons for drop-outs:	see above									
Other Issues:	randomization by closed-envelope system drawn sequentially; claimed "ITT" analysis but looks like it is per protocol analysis									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Question 5
Positional vs Control

A.

Author, Year	Cartwright, 1991			**Intervention 1**	Tongue retaining device
PMID*	1798889	**RefID**	4126	**Intervention 2**	Posture alarm
Key Question(s)	KQ5 Positional			**Intervention 3**	Tongue retaining device plus posture alarm
Design †	RCT			**Control**	
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Sleep apnea Male Positionality of SA	nd	≥12.5	nd	No	US	Gov't	nd	No	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**% Ideal Body Weight**	**SBP>104**	**DBP>100**	**AFib/AFlutter, %**	**CVD †, % (specify)**
TRD	**15 (15)**		50		1.20	27%	13%		
PA	**15 (15)**		49		1.35	40%	47%		
TRD+PA	**15 (15)**		46		1.31	20%	13%		
Cx	**15 (15)**		50		1.28	20%	27%		
Total	**60 (60)**	100		nd				nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**		**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx									
Cx									
Total	nd	nd	nd	nd	nd	nd		nd	No
	Treatments used (prior to trial, including surgery)								
Tx									
Cx									
Total	nd								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Side AHI	Back AHI	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
TRD	15	27.36±17.64	7.95±9.70	50.79±19.33						
PA	15	33.25±21.30	9.73±9.74	62.53±30.05						
TRD+PA	15	30.70±14.54	13.95±13.04	63.90±25.59						
Cx	15	26.69±13.31	7.72±8.86	87.29±59.72						
Total:					nd	nd	nd	nd	nd	

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify) "Nasal pathology scale (0-8)" ‡		Other characteristics
	TRD	4.40	
	PA	3.40	
	TRD+PA	3.73	
	Cx	4.47	

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

‡ Right and left nasal airway were rated as normal, mildly, moderately, or severely obstructed. This was converted to a scale of 0-8.

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	12.5		nd	nd	nd	NA	Positionalality (not defined)

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	Tongue retaining device (TRD)		nd
2	Positional therapy	Posture alarm (PA)		Auditory beep if supine >15 seconds
3	Combination	TRD + PA		
Control	No additional intervention			
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.

If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description
Good health habits for sleep apnea	Weight loss, exercise, no evening alcohol, sleep on side
Weekly phone call	
For CPAP:	**Describe the frequency of the initial education follow-up**

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study	AHI	8 wk	
2	Sleep study	AHI (categorical)		<5.5
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Cartwright, 1991	AHI <5.5	Tx	TRD	8 wk	9	15								
US		Tx	PA		8	15								
1798889		Tx	TRD+PA		11	15								
		Cx	Cx		9	15								

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ (Δ test – Δ control)*		
							Value	SD	Value	SD	Value		P Final v Final	Value	SD/SE*	P
Cartwright, 1991	AHI (total)		Tx	TRD	8 wk	15	27.36	17.64	11.38	15.05	-15.98		0.01 (t=2.85, df=14)	+0.80		
US			Tx	PA		15	33.25	21.30	20.83	29.25	-12.42		0.08 (t=1.88, df=14)	+4.36		
1798889			Tx	TRD+PA		15	30.70	14.54	7.87	12.27	-22.83		<0.001 (t=5.24, df=14)	-6.05		
			Cx	Cx		15	26.69	13.31	7.72 †	9.91	-16.78		<0.01 (t="524"†, df=14)			
										ANOVA NS						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper
† 6.28, P<0.001 based on reported raw data. But mean = 7.66 (not 7.72

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	Also data for "Side AHI" and "Back" AHI

Pearson (r) correlations of 5 variables with total AHI. (see D for definition of nasal patency)

TABLE 8. *The relation of five factors to posttreatment total A + HI*

	All cases	TRD	PA	Both	HH
A + HI pre (severity)	0.378**	0.095	0.527*	0.172	0.524*
A + HI lateral	0.369**	0.555*	0.464	0.172	0.777**
Initial weight	0.289*	0.098	0.270	0.491*	0.246
Weight change	0.107	0.045	0.010	−0.584*	0.010
Nasal patency	0.021	0.573*	−0.145	−0.210	0.303

* $p < 0.05$.
** $p < 0.01$.

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	No	Yes	No	nd	Yes (all)	No Comparison of final values, but pt-level data reported	NA	Yes	No (some results numbers are wrong)

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	No ("Positionality" not clear)	No	No (TRD?)	Yes	No	NA	NA	NA

Reasons for drop-outs:	NA
Other Issues:	
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Question 5
Positional vs PAP

A.

Author, Year	Jokic, 1999			**Intervention 1**	Positional treatment
PMID*	10084491	**RefID**	5431	**Intervention 2**	
Key Question(s)	5- Positional treatment vs CPAP			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	CPAP
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Positional OSA- -AHI during supine sleep that was two or more times the AHI during sleep in the lateral position. -AHI in the lateral position < 15, during a minimum duration of 1 h sleep in the lateral position on overnight polysomnography, and including at least one rapid eye movement (REM) period. -Subjective daytime somnolence.	other conditions that might interfere with sleep (respiratory infections, uncontrolled allergies, heart failure, narcolepsy, periodic leg movements) were excluded from the study	Nd	nd	N	Canada	Health Services Utilisation and Research Commission of Saskatchewan; The Saskatchewan Lung Association	N	N	Y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx								
Cx								
Total	**14 (13)**	nd	51	Nd	30	Nd	Nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	Nd	Nd	Nd	Nd	Nd	Nd	Nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	Nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	13	17.9	13	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	Nd	Nd	Nd	Nd	Nd	Split	Definition of positional OSA given, see inclusion criteria

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Positional therapy	Positional therapy	Foam made by Canada Games Company Limited; Toronto, Ontario, Canada	2 weeks of tx; backpack with a soft ball inside, positioned to prevent the subjects from sleeping supine. The size of the ball in the backpack was 10x5.5 inches and it was made of semirigid synthetic foam
2				
3				
Control	PAP	Nasal CPAP	Nd	2 weeks of tx
For CPAP:		**How was the Pressure selected?**	CPAP was initiated at 4 cm H2O and was titrated upwards in 2-cm H2O increments to eliminate gross obstructive apneas and hypopneas, and then 1-cm H2O adjustments were made with sleep stage and position until the minimum CPAP necessary to eliminate respiratory arousals (obstructive apneas, hypopneas, and repetitive snoring-associated arousals) had been carefully defined both in non-REM and REM sleep.	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
no		
For CPAP:	**Describe the frequency of the initial education follow-up**	4 hr initial familiarization period

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	Slow wave sleep	2 wks	Stage 3+stage 4 sleep
2	Sleep study measures	AHI	Baseline, 2 wks	
3	Sleep study measures	REM sleep, % total sleep time	2 wks	
4	Sleep study measures	Sleep efficiency	2 wks	Total sleep time divided by total recorded time
5	Sleep study measures	Arousal index	Baseline, 2 wks	
6	Sleepiness measures	MWT (Maintenance of Wakefulness Test)	2 wks	
7	Sleepiness measures	ESS	Baseline, 2 wks	
8	Cognitive scale	Wechsler memory scale	Baseline, 2 wks	Memory test
9	Cognitive scale	Purdue pegboard	Baseline, 2 wks	Dexterity test
10	Cognitive scale	Trail-making test	Baseline, 2 wks	Visual attention and task-switching test
11	Cognitive scale	Symbol digit modalities	Baseline, 2 wks	Cognitive impairment test
12	Cognitive scale	Consonant trigram	Baseline, 2 wks	Working memory test
13	Cognitive scale	Concentration endurance test	Baseline, 2 wks	Attention and concentration test
14	Psych scale	Nottingham health profile	2 wks	Quality of life questionnaire
15	Psych scale	Hospital anxiety and depression scale	2 wks	
16	Psych scale	UWIST adjective checklist	2 wks	Mood questionnaire
17	General symptom scale	General health questionnaire	2 wks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Test final-control final		
							Value	SD/SE*	Value	SE*	Value	SD/SE*	P	Value	95% CI	P
Jokic, 1999 Canada 10084491	Slow wave sleep, % of total sleep time	%	**Tx**	Positional therapy	2 wk	13	nd	Nd	20	1.9	Nd	Nd	Nd	-2	Nd	0.31
			Cx	CPAP	2 wk	13	nd	nd	22	3.1	Nd	nd	nd			
	REM sleep, % total sleep time	%	**Tx**	Positional therapy	2 wk	13	nd	Nd	24	1.5	Nd	Nd	Nd	-2	Nd	0.71
			Cx	CPAP	2 wk	13	nd	nd	26	2.8	Nd	nd	nd			
	Sleep efficiency	%	**Tx**	Positional therapy	2 wk	13	nd	Nd	82	2.1	nd	Nd	nd	-2	Nd	0.51
			Cx	CPAP	2 wk	13	nd	nd	84	2.5	nd	nd	nd			
	AHI	Events/hr	**Tx**	Positional therapy	2 wk	13	17.9	Nd	9.5	1.9	-8.4	Nd	Nd	6.1	(2, 10.2)	0.007
			Cx	CPAP	2 wk	13	17.9	nd	3.4	0.5	-14.5	nd	nd			
	Arousal index	Events/hr	**Tx**	Positional therapy	2 wk	13	24.5	Nd	19.5	nd	-5.0	Nd	Nd	4.5	(-0.7, 9.4)	0.08
			Cx	CPAP	2 wk	13	24.5	Nd	15.0	nd	-9.5	nd	Nd			
	ESS	Scale (median)	**Tx**	Positional therapy	2 wk	13	13.4	Nd	9.5	nd	-3.5	Nd	0.04	Median diff = 1.5	(-2.9, 0.8)	0.2
			Cx	CPAP	2 wk	13	13.4	nd	8.75	nd	-4.65	nd	0.009			
	MWT	Minute	**Tx**	Positional therapy	2 wk	13	Nd	Nd	31.2	2.2	Nd	Nd	nd	-1.7	(-1.9, 5.3)	0.32
			Cx	CPAP	2 wk	13	nd	nd	32.9	1.7	nd	nd	Nd			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Jokic, 1999 Canada 10084491	Wechsler memory scale	All	2 wk	Positional therapy	13	CPAP	13	0					
	Purdue pegboard	All	2 wk	Positional therapy	13	CPAP	13	0					
	Trail-making test	All	2 wk	Positional therapy	13	CPAP	13	0					
	Symbol digit modalities	All	2 wk	Positional therapy	13	CPAP	13	0					
	Consonant trigram	All	2 wk	Positional therapy	13	CPAP	13	0					
	Concentration endurance test	All	2 wk	Positional therapy	13	CPAP	13	0					
	Nottingham health profile	Energy (5 other subscales not significant)	2 wk	Positional therapy	13	CPAP	13	CPAP	Final difference	1			0.04
	Hospital anxiety and depression scale	All	2 wk	Positional therapy	13	CPAP	13	0					
	UWIST adjective checklist	All	2 wk	Positional therapy	13	CPAP	13	0					
	General health questionnaire	All	2 wk	Positional therapy	13	CPAP	13	0					

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Both	7%	Finished study, excluded from analysis because found to have idiopathic hypersomnolence

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
Jokic, 1999 Canada 10084491	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	Nd	Y	N	y	Y	Y	NA	NA	Y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Y	n	Y	N	Y	Y	Y			n
Reasons for drop-outs:	One patient finished study, excluded from analysis because found to have idiopathic hypersomnolence									
Other Issues:	Power									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Skinner, 2004			**Intervention 1**	Shoulder-head elevation pillow (SHEP)
PMID*	15611894	**RefID**	4810	**Intervention 2**	
Key Question(s)	5(CPAP and Position)			**Intervention 3**	
Design †	Cross over			**Control**	nCPAP
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSAHS AHI 10-60	History of cardiovascular, neurological or psychological disorders affecting sleep Cervical, shoulder or thoracic wall abnormalities Chronic pain Previous intervention for OSA such as Uvulopalatopharyngoplasty Daytime symptoms of OSA	>10	nd	n	New zealand	University and Research Trust fund	N(though they say AHI is primary outcome measure)	n	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**14(14)**	85	54(10)	nd	34(7)	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	14	27(12)	11.9(4.6)	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Portable home based sleep monitor (Embletta PDS)	10-60		>=10secs	>=50% reduction in thoracoabdominal movement	nil	split	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Positional therapy	Shoulder head elevation pillow (SHEP)	Sammons® Preston, Bolingbrook, IL, USA	Standardized foam wedge to keep angulated at 60 degrees with a polyester filled tri pillow to keep the patient lying in an upright position with head and neck in a neutral position
2				
3				
Control	PAP	nCPAP	Autoset ® Sullivan, REsMEd	
For CPAP:		**How was the Pressure selected?**	auto titrated	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	1month	
2	Sleepiness measure	ESS	1month	
3	Sleepiness measure	FOS Q	1month	
4	Sleepiness measure	SF-36 (physical)	1month	
5	Sleepiness measure	SF-36(mental)	1month	
6		Treatment success	1month	AHI <10
7	Harms	Adverse events	1month	
	Compliance	Self reported compliance time	1 month	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Skinner 2004 New Zealand 15611894	Treatment success	**Tx**	SHEP	1month	4	14								
		Cx	nCPAP	1 month	12	14								

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Skinner 2004 New Zealand 15611894	AHI		**Tx**	SHEP	1 month	14	27	12	21	17	-6			16		0.008
			Cx	nCPAP	1 month	13	27	12	5	3	-22					
	ESS		**Tx**	SHEP	1 month	14	11.9	4.6	10.2	5.0	-1.7			0.7		0.686
			Cx	nCPAP	1 month	14	11.9	4.6	9.5	4.0	-2.4					
	FOS Q		**Tx**	SHEP	1 month	14	12.1	1.9	13.2	1.8	1.1			-0.3		0.927
			Cx	nCPAP	1 month	14	12.1	1.9	13.5	1.7	1.4					
	SF-36 (physical)		**Tx**	SHEP	1 month	14	42.6	11.3	44.6	8.9	2			-0.2		0.743
			Cx	nCPAP	1 month	14	42.6	11.3	44.8	9.9	2.2					
	SF-36(mental)		**Tx**	SHEP	1 month	14	47.9	12.3	47.2	12.0	-0.7			-1.9		0.309
			Cx	nCPAP	1 month	14	47.9	12.3	49.1	11.1	1.2					
	Adverse events		**Tx**	SHEP	1 month	14			5.6	4.1	5.6			-2.3		0.164
			Cx	nCPAP	1 month	14			7.9	3.4	7.9					
	Self reported compliance time		**Tx**	SHEP	1 month	14			6.3	1.6	6.3			1.9		0.026
			Cx	nCPAP	1 month	14			4.4	2.1	4.4					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
nCPAP	7%	Completed study, but declined to use home monitor at end of nCPAP treatment period

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	Back discomfort	1 month	SHEP			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	n	nd	y	y	n	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	y	y	n	y

Reasons for drop-outs:	
Other Issues:	
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Skinner, 2008			**Intervention 1**	Thoracic anti-spine band (TASB)
PMID*	18713092	**RefID**	3818	**Intervention 2**	
Key Question(s)	5(CPAP and positional)			**Intervention 3**	
Design †	Cross over			**Control**	Nasal CPAP
Extractor	NO			**Comments**	Equivalence trial

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSAH AHI >5 Time in supine position during baseline study >50mins Time spent in supine position =10 to 90% of total study time AHI in supine was at least 2 times greater than AHI in other positions Maximum AHI in other positions was 10/hr	Known thoracic pathology Previous intervention for OSA Other conditions affecting sleep	>5	nd	n	New Zealand	University	Y(AHI and TASB)	n	Nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**20(20)**	nd	55.9(9.8)	nd	30.7(5.1)	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	Y?(positional OSAHS see inclusion criteria)
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	20							
Control:	20							
Total:	20	22.7(12.0)	13.6(50.5)	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, (neck circumference, cm)**		**Other characteristics**
						41.9(4.7)		

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Home sleep monitoring using nine channel portal digital recording device	>5		>=10secs	>=50% reduction in thoraco abdominal movement	nd	separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Positional therapy	Thoracic anti-spine band (TASB)	Collar and cuff, Gordon's limited, New Zealand plus 25mm Velcro	Cotton stockings worn around the thorax with a polystyrene out pouching ball in the midline of the back .This helps to prevent the patient from sleeping supine. Only one head pillow allowed.
2				
3				
Control	PAP	CPAP	Auto set T suvillan ResMed S6 Elite	
For CPAP:		**How was the Pressure selected?**	Autotiratied	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
	All subjects were instructed to sleep in lateral position if roused during the night while on TASB	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	1 month	
2	Sleepiness measure	ESS	1 month	
3	QOL	SF-36 physical	1 month	
4	QOL	SF 36 mental	1 month	
5	Harms	Adverse effects from device	1 month	
6		Treatment success	1 month	AHI <=10/hr
7	Compliance	Diary reported compliance time	1 month	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Skinner , 2008 New Zealand 18713092	Treatment success	**Tx**	TASB	1 month	13	18	%	81		0.0004				
		Cx	nCPAP	1 month	16	18	%	89						

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD *	Value	SD *	Value	SD/SE*	P	Value	SD/SE*	P
Skinner , 2008 New Zealand 18713092	AHI	/hr	**Tx**	TASB	1 month	20	22.7	12.0	12.0	14.5	-10.7	nd	nd	7.1	nd	0.02
			Cx	nCPAP	1 month	20	22.7	12.0	4.9	3.9	-17.8					
	ESS		**Tx**	TASB	1 month	20	13.6	50.5	11.6	5.8	-2			1.2		NS
			Cx	nCPAP	1 month	20	13.6	50.5	10.4	4.1	-3.2					
	SF-36 physical		**Tx**	TASB	1 month	20	45.9	10.3	44.5	11.0	-1.4			-0.1		NS
			Cx	nCPAP	1 month	20	45.9	10.3	44.6	10.6	-1.3					
	SF 36 mental		**Tx**	TASB	1 month	20	42.4	12.0	50.3	9.5	7.9			0.6		NS
			Cx	nCPAP	1 month	20	42.4	12.0	49.7	8.5	7.3					
	Adverse effects from device		**Tx**	TASB	1 month	20			4.8	5.5						0.003
			Cx	nCPAP	1 month	20			8.4	3.9						
	Diary reported compliance time	Hr/night	**Tx**	TASB	1 month	20			7.4	1.6						0.0001
			Cx	nCPAP	1 month	20			4.9	1.9						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
	0	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	n	nd	y	y	na	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	N	n	y	y		y	y	y
Reasons for drop-outs:								
Other Issues:								
Overall Quality (A, B, C)		**B**						

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Question 5
Bariatric Surgery

A.

Author, Year	Grunstein, 2007			**Intervention 1**	Weight loss surgery
PMID*	17580591	**RefID**	3327	**Intervention 2**	
Key Question(s)	KQ 5 Bariatric vs Cx			**Intervention 3**	
Design †	NRCS, prospective			**Control**	Conservatively treated
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Age 37-60 y BMI ≥38 (women), 34 (men) Subgroup: sleep apnea	Severe illness, EtOH or drug abuse, previous bariatric surgery	none	<Sept 1998	Yes	Sweden	Non-industry	none	No	No
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):					Matched by sex and 18 other variables: age, height, weight, hip circumference, waist/hip ratio, SBP, cholesterol, Tg, smoking, DM, menopause, 6 psychological parameters. Pts in surgery group slightly younger, higher prevalence of HTN, DM, Smoking				

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**1729 (1592) w/ & w/o SA**	30	47	nd	42.2±4.4	78% 146/91	nd	nd
Cx	**1748 (1431) w/ & w/o SA**	30	48		40.1±4.6	61% 138/85		
Total			P<0.001		P<0.001	P<0.001		
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	19	24	nd	nd	nd	nd		Morbidly obese, eligible for bariatric surgery (self-selected).
Cx	16	21						
Total	P=0.048	P=0.03						
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	1592*24.0%=382	NA	nd	nd	nd	nd	unknown	
Control:	1431*21.8=312							
Total:								
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Questionnaire	no	no	none	NA	?		8-item sleep questionnaire validated against PSG in a subsample. "subjects were asked whether a partner or another family member had observed frequent pauses in breathing during sleep."

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡		Description
1	Surgical weight loss	Bariatric surgery	Self-selected	Gastric bypass, Vertical banded gastroplasty, Gastric banding
2				
3				
Control	Control	Routine obesity management	Self-selected	dietary advice, physical training, low calorie diets, behavior modification (no drugs)
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	"Sleep study" measure	Persistence of sleep apnea	2 y	Repeat questionnaire
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw				
Grunstein, 2007	Persistence of sleep apnea	Tx	Bariatric surgery	2 y	~107 (382*27.9%)	~382 (1592*24.0%)	OR	0.16	0.10, 0.23	<0.001				
Sweden		Cx	Other weight loss		~222 (312*71.3%)	~312 (1431*21.8%)								
17580591														

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
			Tx													
			Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Surgery	7.9%	nd
Usual care	18.1%	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			Bariatric surgery			
	Perioperative mortality		0.21%			
	Other surgical complications*		13%			

* Bleeding, Embolus or thrombosis, wound complications, deep infections, pulmonary, and other complications

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
No	NA	NA	Yes	No	No	No	Matching not successful	No	No. Unclear numbers
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**			
	Yes	Yes. Self-selected treatment	Yes	No	NA	NA			

Reasons for drop-outs:	nd
Other Issues:	Despite matching, dissimilar groups without statistical adjustment. Definition of SA inadequate. Numbers of patients with SA and persistent SA unclear
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention for quality to be A
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Question 5
Weight Loss

A.

Author, Year	Foster, 2009			**Intervention 1**	Behavioral weight loss program- intensive lifestyle intervention (ILI)
PMID*	19786682	**RefID**	3282	**Intervention 2**	
Key Question(s)	Wt loss v Cx			**Intervention 3**	
Design †	RCT			**Control**	diabetes support and education (DSE)
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Age 45-75, BMI ≥25 (≥27 if taking insulin), physician verified type 2 diabetes, a hemoglobin A1c level of less than 11%, and a blood pressure reading of less than 160/100 mm Hg.	previous surgical or current medical treatment for OSA.	nd	nd	Y	USA	NIH National Heart, Lung and Blood Institute, NIH National Institute of Diabetes and Digestive and Kidney Diseases	Nd	n	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**125 (125)**							
Cx	**139 (139)**							
Total	**264**	41.9	61.2	Nd	36.7	Nd	Nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	100%	nd	nd	nd	nd	nd	nd	diabetics
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	125							
Control:	139							
Total:	264	23.2	Nd	Nd	Nd	Nd	Nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	Nd	nd	decrease in the nasal pressure airflow signal to 10% or less of baseline for 10 seconds or more.	30% or more reduction from baseline in thoracoabdominal movement or airflow lasting 10 seconds or more with 4% or more oxygen desaturation. The absence of respiratory-related nasal pressure fluctuations for 10 seconds or more in the presence of fluctuations in the oronasal thermistor signal was also scored as hypopnea.	Nd	NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Weight loss program	intensive lifestyle intervention (ILI)	NA	Group behavioral weight loss program developed specifically for obese patients with type 2 diabetes. Participants were prescribed portion-controlled diets that included using liquid meal replacements, frozen food entrees, and snack bars for the first 4 months (with reduced use from months 5-12). The prescribed energy intake was 1200 to 1500 kcal/d if the patients weighed less than 113.6 kg or 1500 to 1800 kcal/d if the patients weighed 113.6 kg or more, with 30% or less calories from fat. The physical activity prescription was 175 min/wk of moderate-intensity activity such as brisk walking/
2				
3				
Control	other	diabetes support and education (DSE)	NA	3 group sessions over a 1-year period. These sessions focused on diet, physical activity, and social support as they related to effective diabetes management.
For CPAP:		**How was the Pressure selected?**	NA	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Physical scale	Hemoglobin A1c %	Baseline, 1 yr	
2	Sleep study measures	AHI	Baseline, 1 yr	
3	Sleep study measures	Oxygen desaturation index >4%	Baseline, 1 yr	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE *	Value	SD/SE *	Value	SD/SE *	P	Value	95% CI	P
Foster, 2009 United States 19786682	Hemoglobin A1c %	%	**Tx**	intensive lifestyle intervention (ILI)	1 yr	139	7.1	0.9			-0.7	0.1				<0.001
			Cx	diabetes support and education (DSE)	1 yr	125	7.3	1.1			-0.2	0.1				
	AHI	Events/hr	**Tx**	intensive lifestyle intervention (ILI)	1 yr	139	22.9	18.0			-5.4	1.5		-9.7	-13.6, -5.7	<0.001
			Cx	diabetes support and education (DSE)	1 yr	125	23.5	15.0			4.2	1.4				
	Oxygen desaturation index >4%	Events/hr	**Tx**	intensive lifestyle intervention (ILI)	1 yr	139	18.6	16.1			-5.5	1.4				<0.001
			Cx	diabetes support and education (DSE)	1 yr	125	20.2	13.7			1.2	1.3				

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Behavioral weight loss program- intensive lifestyle intervention (ILI)	17.6 (didn't complete full intervention)	nd
diabetes support and education (DSE)	16.5 (didn't complete full intervention)	nd

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Y	Y	Nd	Y	N	Y	nd	y	y	y	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Y	N	Y	Y	N	NA	NA			NA
Reasons for drop-outs:	nd									
Other Issues:	Questionable if outcome data included all initial participants, and if so, how data was imputed.									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Johansson, 2009			**Intervention 1**	Low energy diet
PMID*	19959590	**RefID**	179	**Intervention 2**	
Key Question(s)	5- Wt loss v Cx			**Intervention 3**	
Design †	RCT			**Control**	Usual diet
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
men with AHI ≥15 treated with continuous positive airway pressure for a minimum of six months, aged 30-65 years, BMI 30-40.	those with contraindications for very low energy diets (1.9-3.4 MJ/day) according to the SCOOP-VLED report, type 1 or type 2 diabetes, current use of a weight loss drug, previous bariatric surgery, or recent angina pectoris or atrial fibrillation.	Nd	Feb-April 2009	n	sweden	Cambridge Manufacturing Company Limited and Novo Nordisk Scandinavia AB	80% power with an α level of 5% to detect a difference in AHI of 15 events an hour between groups using a two sided independent Student's t test. Assumed a standard deviation of the within group AHI difference of 18 events per hour based on two previous studies.17 18 This resulted in a required sample size of 24 patients in each group.	n	n
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**30(30)**	100	47.5	nd	34.4	Nd	Nd	Nd
Cx	**33(33)**	100	49.9	nd	34.8	nd	nd	nd
Total	**66**							
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	Nd	nd	Nd	nd	Nd	nd	Nd	No
Cx	nd	Nd	nd	Nd	nd	Nd	nd	no
Total								
	Treatments used (prior to trial, including surgery)							
Tx	Nd							
Cx	Nd							
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	30	37	9	Nd	nd	Nd	nd	
Control:	33	37	7	nd	Nd	nd	Nd	
Total:	66							
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Nd	Nd	Nd	Complete cessation of airflow ≥10 sec	Reduction in airflow ≥10 sec	Nd	NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Weight loss program	Low energy diet	Cambridge Diet, Cambridge, Northants, UK	seven week very low energy diet using a standard 2.3 MJ/day liquid energy intake protocol followed by two weeks of gradual introduction of normal food to reach 6.3 MJ/day at week 9
2				
3				
Control	No treatment	Usual diet	NA	instructed to adhere to their usual diet
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	AHI	Baseline, 9 wk	
2	Sleep study measures	Oxygen desaturation ≥4%	Baseline, 9 wk	
3	Sleep study measures	Nadir of arterial oxygen saturation %	Baseline, 9 wk	
4	Sleepiness measures	ESS	Baseline, 9 wk	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	95%CI	P
Johansson, 2009 Sweden 19959590	AHI	Number	Tx	Low energy diet	9 wk	30	37	17	12	Nd	-25	17	Nd	-23	(-30 to -15)	<0.001
			Cx	Usual diet	9 wk	33	37	14	35	Nd	-2	11	Nd			
	Oxygen desaturation ≥4%	Events/hr	Tx	Low energy diet	9 wk	30	26	15	7	Nd	-19	14	Nd	-18	(-24 to -12)	<0.001
			Cx	Usual diet	9 wk	33	25	14	24	Nd	-1	9	Nd			
	Nadir of arterial oxygen saturation %	%	Tx	Low energy diet	9 wk	30	82	6	87	Nd	5	6	Nd	5	(2 to 7)	0.002
			Cx	Usual diet	9 wk	33	82	5	82	Nd	0	5	Nd			
	ESS	number	Tx	Low energy diet	9 wk	30	9	5	6	Nd	-3	5	Nd	-4	(-6 to -2)	<0.001
			Cx	Usual diet	9 wk	33	7	5	8	Nd	1	3	Nd			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Usual diet	6%	Dissatisfied with treatment allocation

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			Low energy diet	Usual diet		
Johansson, 2009 Sweden 19959590	Constipation	9 wk	10%	Nd		
	Elevated alanine aminotransferase concentrations	9 wk	20%	Nd		
	Dizziness	9 wk	3%	Nd		
	Gout	9 wk	3%	Nd		
	Dry lips	9 wk	3%	Nd		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Y	Y	y	y	n	n	y	y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Y	N	Y	Y	Y	NA	NA			NA
Reasons for drop-outs:	Dissatisfied with treatment allocation									
Other Issues:										
Overall Quality (A, B, C)	**A**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Kemppainen 2008 / Tuomilehto 2009			**Intervention 1**	Lifestyle intervention with 12 wk Very Low Calorie Diet weight reduction program
PMID*	18702908 /19011153	**RefID**	3452 / 3899	**Intervention 2**	
Key Question(s)	5 (Wt loss vs Cx)			**Intervention 3**	
Design †	RCT			**Control**	Single general dietary and Exercise counseling session
Extractor	DM			**Comments**	**Both Kemppainen 2008 and Tuomilehto 2009 were conducted by the same investigators with the same inclusion and exclusion criteria, and by all appearances, were started at the same time. It looks likely, though not certain, that they are both from the same trial (Kemppainen – ENT symptoms so maybe they are the patients referred from ENT & Tuomilehto - sleep quality, patients from respiratory medicine & ENT together).**

* or Cochrane number

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
18-65 yrs; BMI, 28–40 kg/m^2; AHI 5-15 events/hour	nd (**Tuomilehto**: Active treatment of OSA ; pregnancy; those with chronic kidney, thyroid, or liver disease)	5-15	Started Fall 2004 – nd (**Tuomilehto**: Oct 2004 – Dec 2006)	No	Finland	Hospital and Foundation Grants	Yes (Total volume 0-5 cm from nostril in acoustic rhinometry); **Tuomilehto:** Yes (Prevalence of Mild OSA)	No	nd **Tuomilehto:** Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Author, Year Country PMID	Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?)	AFib/AFlutter, %	CVD †, % (specify)
Kemppainen 2008 Finland 18702908	**Tx**	**26 (26)**	81	51 ± 8.3		33 ± 3.3			
	Cx	**26 (26)**	77	49 ± 8.9		32 ± 3.1			
	Total	**81 (81)**			?Caucasian		nd	nd	nd
Tuomilehto 2009 Finland 19011153	**Tx**	**40 (40)**	73	51.8 ± 9.0		33.4 ± 2.8			
	Cx	**41 (41)**	74	50.9 ± 8.6		31.4 ± 2.7			
	Total	**81 (81)**			?Caucasian		nd	nd	nd
		NIDDM, %	**Smokers, % (smokers)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Kemppainen 2008 Finland 18702908	**Tx**		23						
	Cx		27						
	Total	nd		nd	nd	nd	nd		Yes (Obese subjects)
Tuomilehto 2009 Finland 19011153	**Tx**		20						
	Cx		22						
	Total	nd		nd	nd	nd	nd		Yes (Obese subjects)
		Treatments used (prior to trial, including surgery)							
	Tx								
	Cx								
	Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

Author, Year Country PMID		N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Kemppainen 2008 Finland 18702908	**Treatment:**	26	11.0 ± 3.6						
	Control:	26	9 ± 2.7						
	Total:			nd	nd	nd	nd	nd	nd
Tuomilehto 2009 Finland 19011153	**Treatment:**	40	10.0 ± 3.0	10.1 ± 5.0		54.8 ± 11.9			
	Control:	41	9.3 ± 3.0	9.9 ± 4.8		51.2 ± 12.3			
	Total:				nd		nd	nd	

	Other Clinical symptoms, % (specify)	Airway characteristics, % (specify)	Other characteristics
Kemppainen 2008 Finland 18702908	nd	nd	nd
Tuomilehto 2009 Finland 19011153	nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Author, Year Country PMID	Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Kemppainen 2008 Finland 18702908	PSG	5-15	nd	nd	nd	nd		
Tuomilehto 2009 Finland 19011153	PSG by Embletta	OSA: ≥ 5 Mild OSA: 5-15	nd	Cessation (more than 90%) of airflow of more than 10 seconds with oxygen desaturation for more than 4%	Reduction (more than 30%) of airflow of more than 10 seconds with oxygen desaturation for more than 4%.	nd		

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

Author, Year Country PMID		Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
Kemppainen 2008 Finland 18702908	1	Weight Loss and Exercise Program	12 week group-based Very Low Calorie Diet (VLCD) with lifestyle, diet and exercise counseling		Supervised, individual lifestyle intervention by a clinical nutritionist. The intervention included weight reduction counseling and consuming a very low calorie diet for 3 months and an increase in daily physical activity.
	Control	No treatment	General Counseling		Single dietary and exercise counseling session by the study nurse and physician
Tuomilehto 2009 Finland 19011153	1	Weight Loss and Exercise Program	12 week group-based Very Low Calorie Diet with lifestyle, diet and exercise counseling	Weight Loss diets: Nutrilett [Nycomed Pharma, Oslo, Norway], Modifast [Novartis, Basel, Switzerland], Nutrifast [Leiras, Helsinki, Finland], or Naturdiet [Vitamex, Norrko¨ ping, Sweden])	12 week group-based Very Low Calorie Diet of 600–800 kcal/day 14 visits with the study nutritionist. Physiotherapist counseling in group sessions
	Control	No treatment	General Counseling		General oral and written information about diet and exercise at baseline, at the 3-month visit, and at the 1-year visit by the study nurse and physician
		For CPAP:	**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

Author, Year Country PMID		Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
Kemppainen 2008 Finland 18702908	1	Sleep study measures	AHI	Baseline, 3 months	
Tuomilehto 2009 Finland 19011153	1	Sleep study measures	AHI	Baseline, 1 year	
	2	Sleepiness measures	ESS	Baseline, 1 year	
	3	Sleepiness measures	Snores Outcome Survey (SOS) Score	Baseline, 1 year	nd (Data obtained from reference: The SOS contains 8 items that evaluate the duration, severity, frequency, and consequences of problems associated with SDB, snoring in particular. Scores on the SOS are normalized on a scale ranging from 0 (worst) to 100 (best).)
	4	Physical scale	Systolic Blood Pressure (SBP)	Baseline, 1 year	
	5	Physical scale	Diastolic Blood Pressure (DBP)	Baseline, 1 year	
	6	Other	Witnessed Apneas	Baseline, 1 year	In the sleep questionnaires, the respondents were also asked whether their bedfellows had noticed breathing pauses during their sleep and subsequently these were classified as ''witnessed apneas.'' This outcome measure is the proportion of people with witnessed apneas
	7	Other	Cured at 1 year	1 year	At 1 year, the OSA was considered objectively cured when the AHI was less than 5 events/hour

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Tuomilehto 2009 Finland 19011153	Witnessed Apneas	Tx	VLCD with lifestyle changes	1 year	23	35	nd	nd		0.011			<0.001	Age, sex, BMI,
		Cx	General counseling		33	37								
Tuomilehto 2009 Finland 19011153	Cured at 1 year	Tx	VLCD with lifestyle changes	1 year	22	35	OR	nd		0.033	0.24	0.018-0.72	0.011	Age, Sex, BMI, Baseline AHI
		Cx	General counseling		13	37								

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD	P	Value	SD/SE*	P
Kemppainen 2008 Finland 18702908	AHI		**Tx**	VLCD with lifestyle changes	3 months	26	11	3.6	7.8	nd	-3.2	9.2		-1.9		0.393
			Cx	General counseling		26	9	2.7	1.4	nd	-1.3	5.5				
Tuomilehto 2009 Finland 19011153	AHI		**Tx**	VLCD with lifestyle changes	1 year	40	10	3	6.0	nd	-4	5.6		-4.3		0.011
			Cx	General counseling		41	9.3	3	9.6	nd	0.3	8				
Tuomilehto 2009 Finland 19011153	ESS		**Tx**	VLCD with lifestyle changes	1 year	40	10.1	5	7.0	nd	-3.1	4		-1		0.25
			Cx	General counseling		41	9.9	4.8	7.8	nd	-2.1	2.9				
Tuomilehto 2009 Finland 19011153	SOS		**Tx**	VLCD with lifestyle changes	1 year	40	54.8	11.9	36.8	nd	19	14.2		7.2		0.025
			Cx	General counseling		41	51.2	12.3	38.6	nd	11.8	12.6				
Tuomilehto 2009 Finland 19011153	SBP		**Tx**	VLCD with lifestyle changes	1 year	40	131.2	10.2	129.5	nd	-1.7	14.7		-0.6		0.88
			Cx	General counseling		41	130.0	12.8	128.9	nd	-1.1	19.6				
Tuomilehto 2009 Finland 19011153	DBP		**Tx**	VLCD with lifestyle changes	1 year	40	81.8	8.9	79.9	nd	-1.9	10.6		-1.5		0.62
			Cx	General counseling		41	80.7	7.8	80.3	nd	-0.4	12.6				

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Author, Year Country PMID	Intervention	% Dropout	Reasons
Kemppainen 2008 Finland 18702908	Very Low Calorie Diet with counseling for lifestyle changes	0	No drop outs
Tuomilehto 2009 Finland 19011153	Very Low Calorie Diet with counseling for lifestyle changes, or control (information session)	11	Dislike of product, scheduling problems, unrelated death

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

Author, Year Country PMID	RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Kemppainen 2008 Finland 18702908	Yes	Yes	nd	Yes	No	nd	NA	Yes	NA	NA	Yes
Tuomilehto 2009 Finland 19011153	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	NA	Yes	Yes

	Author, Year Country PMID	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	Kemppainen 2008 Finland 18702908	Yes	No	Yes	Yes	NA	NA	NA	NA
	Tuomilehto 2009 Finland 19011153	Yes	Yes	Yes	Yes	NA	NA	NA	NA

Author, Year Country PMID		
Kemppainen 2008 Finland 18702908	**Reasons for drop-outs:**	No dropouts
	Other Issues:	Study assessed nasal volume and resistance, OSA improvement was not an aim so, AHI was a secondary outcome
	Overall Quality (A, B, C)	**B**

Tuomilehto 2009 Finland 19011153	**Reasons for drop-outs:**	Dislike of product
	Other Issues:	Raw scores at end point were not reported, but can be calculated form the change in scores reported, harder to assess compliance with dietary intervention
	Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Question 5 Training

A.

Author, Year	Guimaraes, 2009			**Intervention 1**	Oropharyngeal exercise
PMID*	19234106	**RefID**	3338	**Intervention 2**	
Key Question(s)				**Intervention 3**	
Design †	RCT(oropharyngeal exercise)			**Control**	Sham thearpy
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
25-65 yrs Moderate OSAS	BMI >40 Cranio facial malformations Regular hypnotic medications Hypothyroidism Previous stroke Neuromuscular diseases Heart failure Coronary disease Severe obstructive nasal disease Failed to comply to study	15-29.9	**NCT 00660777**	n	Brazil	FAPESP	N (authors state AHI was primary outcome)	nd	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx	**?(16)**	63	51.5(6.8)	60% caucasians	29.6(3.8)	18.8	nd	nd
Cx	**?(15)**	73	47.7(9.8)	71% caucasians	31.0(2.8)	33.3		
Total	**39(31)**							
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	6.3	6.3						
Cx	6.7	20	nd	nd	nd	nd	nd	n
Total								
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	16	22.4(4.8)	14(5)					
Control:	15	22.4(5.4)	14(7)	nd	nd	nd	nd	nd
Total:	31							
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	15- 29.9					na	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral exercise	Oropharyngeal exercsie		Exercise of the soft palate, tongue and facial muscles plus stomatognatic function exercises. Patient instructed by a speech pathologist [1]
2				
3				
Control	placebo	Sham therapy		Supervised weekly sessions (~30mins of deep breathing through the nose while sitting) Daily 30mins sessions of deep breathing through nose while sitting plus nasal lavage with 10ml normal saline in nostril 3 times a day. Bilateral chewing was recommended.
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here. [1]detailed descriptions of oral exercises available but not extracted.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measure	ESS	3 months	>10excessive daytime sleepiness
2	Sleep quality	Pittsburgh sleep quality questionnaire	3 months	>5poor sleep quality
3	Sleep study measure	AHI	3 months	
4	Sleep study measure	Min o2 sat	3 months	
5	Sleep study measure	Sleep efficiency	3 months	
6	Sleep study measure	arousals	3 months	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value	SD/SE*	P
Guimaraes, 2009 Brazil 19234106	ESS		**Tx**	Oropharyngeal exercise	3 months	16	14	5	8	6	-6			-4		0.0006
			Cx	Sham therapy	3 months	15	14	7	12	6	-2					
	Pittsburgh sleep quality questionnaire		**Tx**	Oropharyngeal exercise	3 months	16	10	4	6.9	2.5	-3.1			-2.9		0.001
			Cx	Sham therapy	3 months	15	11	4	10.8	4.1	-0.2					
	AHI	/hr	**Tx**	Oropharyngeal exercise	3 months	16	22.4	4.8	13.7	8.5	-8.7		<0.01	-12.2		<0.0001
			Cx	Sham therapy	3 months	15	22.4	5.4	25.9	8.5	3.5					
	Min o2 sat	%	**Tx**	Oropharyngeal exercise	3 months	16	83	6	85	7	2			4		
			Cx	Sham therapy	3 months	15	82	4	80	4	-2					
	Sleep efficiency		**Tx**	Oropharyngeal exercise	3 months	16	87	8	86	9	-1			-2		0.58
			Cx	Sham therapy	3 months	15	86	10	87	11	1					
	arousals		**Tx**	Oropharyngeal exercise	3 months	16	median 140	IQR(102-236)	nd	nd						
			Cx	Sham therapy	3 months	15	median 148	IQR(73-173)	nd	nd						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Oropharyngeal exercise	3/39	Low adherence defined as performing <85% of exercises, or who failed to return for 3 consecutive weeks
Sham therapy	5/39	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	Y?(baseline characteristics not comparable)	nd	y	nd	y	n	y	na	y	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	y	na	na			na
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)		**B**								

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments: concerned about randomization technique, discrepancies in results between tables

A.

Author, Year	Puhan, 2005			**Intervention 1**	Didgeridoo
PMID*	16377643	**RefID**	3715	**Intervention 2**	
Key Question(s)	KQ5 Miscellaneous			**Intervention 3**	
Design †	RCT			**Control**	No intervention
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
AHI 15-30 Snoring >18 yo	CPAP CNS-acting drugs Current/planned wt loss ≥14 EtOH/wk or ≥2/d BMI≥30 kg/m^2	15-30	2004-2005	No	Switzerland	Non-industry Pulmonary advocacy group Hospital	No	No	Yes (PSG)
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**14 (14)**	86%	50	nd	25.8	134/81	nd	nd
Cx	**11 (11)**	82%	47		25.9	133/77		
Total								
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	nd	nd	EtOH 2.2 drinks/wk	No
Cx							2.2 drinks/wk	
Total								
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	None							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	14	22.3	11.8	nd	100%	93%	8.7 y snoring	Pittsburgh quality of sleep index: 5.2
Control:	11	19.9	11.1		100%	100%	8.9 y	5.8
Total:								
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
(PSG implied)	15-30 (eligibility criteria)		>10 sec, ≥4% desat	>10 sec reduced airflow, ≥4% desatt or waking	Snoring (eligibility)	NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Other	Didgeridoo training		Training in lip technique, circular breathing, etc. 4 lessons over 8 weeks Home practice ≥20 min ≥5x/wk (on average, practiced 5.9±0.9 (range 4.6-6.9) times/wk for 25.3 minutes.
2				
3				
Control		Remain on waitlist for didgeridoo training		
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness	ESS	4 mo	
2	Sleep study measure	AHI		Sleep lab, SleepLab Pro
3	Sleep quality	Pittsburgh quality of sleep index		0-21 (21, worst) ≥5: impaired sleep quality
4	(QoL)	(SF-36)	final data not reported	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD	Value	SD/SE*	P	Value	CI	P
Puhan, 2005	AHI		Tx	Didgeridoo	4 mo	14	22.3	5.0	11.6	8.1	-10.7	7.7		Raw -6.2	-12.3, -0.1	0.05
Switzerland			Cx	No Tx		11	19.9	4.7	15.4	9.8	-4.5	6.9		Adj† -6.6	-13.3, -0.1	0.05
16377643																
	ESS		Tx	Didgeridoo	4 mo	14	11.8	3.5	7.4	2.3	-4.4	3.7		Raw -2.8	-5.7, -0.3	0.03
			Cx	No Tx		11	11.1	6.4	9.6	6.0	-1.4	2.6		Adj† -2.8	-5.4, -0.2	0.04
	Pittsburgh QoSI		Tx	Didgeridoo	4 mo	14	5.2	1.7	4.3	2.1	-0.9	1.6		Raw -0.7	-2.1, +0.6	NS
			Cx	No Tx		11	5.8	2.8	5.6	2.7	-0.2	1.7		Adj† -0.8	-2.3, +0.8	NS
	SF-36 PCS		Tx	Didgeridoo	4 mo	14	52.7	7.4								
			Cx	No Tx		11	52.7	7.0								
	SF-36 MCS		Tx	Didgeridoo	4 mo	14	41.1	12.1								
			Cx	No Tx		11	44.8	8.6								

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper
† ANCOVA: severity of disease (AHI and ESS)and weight change during study

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
	SF-36	Tx			"Didgeridoo playing did not have a significant effect on any domain of the SF-36."
		Cx			

Comments on Results	Individual components of SF-36 also reported.

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
	0	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	None					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	Yes	Yes	No	Yes (AHI)	Yes	Yes	NA	Yes	Yes

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	Yes	No	Yes	Yes	Yes	NA	NA	NA

Reasons for drop-outs:	NA
Other Issues:	
Overall Quality (A, B, C)	**A**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Randerath ,2004			**Intervention 1**	Tongue muscle training
PMID*	15124719	**RefID**	12732	**Intervention 2**	
Key Question(s)	5(Oral exercise)			**Intervention 3**	
Design †	RCT			**Control**	Sham training
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Newly diagnosed OSAS AHI 10-40	Acute heart failure Serious cardiac arrhythmias Acute illness that require CPAP use Neurologic or psychiatric disorders Pregnancy or lactation Drugs acting on neuromuscular systems Pacemakers, cardioverters, defribrillators IDDM Trauma, cutaneous lesions Prior surgery in submental region	10-40	2002-?	n	Germany	industry	nd	y	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx	**34(33)**	57	50.8(12.1)		29.1(4.4)			
Cx	**33(24)**	73	53.3(11.3)		28.9(4.9)			
Total	**67(57)**			nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**Attention (%) ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx				5.3(5)				
Cx				5.1(5.1)				
Total	nd	nd	nd		nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	33	24.7(8.6)	10.2(4.9)					
Control:	24	27.7(6.3)	9.4(4.7)					
Total:	57			nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	10-40		10secs	Reduction of effort 50% compared to baseline or o2 sat at least 4%		na	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral exercise	Tongue muscle training	Apone-Stim 400 Muscle Stimulator, BMR Neurotech Ltd., Derrybeg Industrial Estate, Co. Donegal, Ireland	Single channel output device place under the tongue and chin
2				
3				
Control	Placebo	Sham training		Same device as used in intervention group , but no electrical stimulation
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	8weeks	
2	Sleep study measure	Min o2 sat	8weeks	
3	Sleep study measure	Stage 3 and 4	8weeks	
4	Sleep study measure	REM	8weeks	
5	Sleep study measure	Arousals	8weeks	
6	QOL	FosQ	8weeks	
7	Sleepiness measure	ESS	8weeks	
8		attention	8weeks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/*	P	Value	SD/SE*	P
Randerath , 2004 15124719 Germany	AHI		**Tx**	Tongue training	8weeks	33	24.7	8.6	25.3	16.6	0.6	11.8	<0.05	0.4		NS
			Cx	Sham training	8weeks	24	27.7	6.3	27.9	9.9	0.2	10.1	NS			
	Min o2 sat	%	**Tx**	Tongue training	8weeks	33	81.7	6.8	81.4	8.3	-0.3	6.1	NS	1.1		NS
			Cx	Sham training	8weeks	24	82.3	5.8	80.9	5.8	-1.4	5.8	NS			
	Stage 3 and 4	% of TST	**Tx**	Tongue training	8weeks	33	19.1	13.6	25.0	35.7	6.8	38.7	NS	11		NS
			Cx	Sham training	8weeks	24	23.5	9.8	19.3	11.0	-4.2	8.3	<0.05			
	REM	% of TST	**Tx**	Tongue training	8weeks	33	11	4.7	12	5	1.1	6.6	NS	-0.3		NS
			Cx	Sham training	8weeks	24	12.9	5.2	14.3	4.7	1.4	6.5	NS			
	Arousals		**Tx**	Tongue training	8weeks	33	23.7	9.5	23.2	11	-0.7	12.1	NS	-1.9		NS
			Cx	Sham training	8weeks	24	23	9.8	24.2	9.6	1.2	9.5	NS			
	FosQ		**Tx**	Tongue training	8weeks	33	84.8	32.5	102.0	24.4	4.2	37.7	<0.05	1.6		NS
			Cx	Sham training	8weeks	24	74.2	36.9	94.8	30.7	2.6	36.2	<0.05			
	ESS		**Tx**	Tongue training	8weeks	33	10.2	4.9	9	4.3	-1.5	4.1	NS	-0.2		NS
			Cx	Sham training	8weeks	24	10.5	5.1	9.4	4.7	-1.3	3.5	<0.05			
	attention	%	**Tx**	Tongue training	8weeks	33	5.3	5	4.7	4.8	-0.2	5.6	NS	0.2		NS
-0.4			**Cx**	Sham training	8weeks	24	5.1	5.1	4.7	4.5	-0.4	3.6	NS			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
placebo	3/33	Professional reasons
placebo	2/33	Personal reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	y	y	y	y	n	y	na	y	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	y	na	na			na
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)	**A**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Friedman, 2008			**Intervention 1**	Palatal implants
PMID*	18241718	**RefID**	11239	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT (palatal implants)			**Control**	Placebo
Extractor	NO			**Comments**	Randomization performed by manufacturer

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Mild to moderate OSAS Snoring and excessive day time sleepiness Friedman stage 1,2,3	Some patients with Friedman stage 3 considered close to 4	AHI>=5 and <40	2005-2006	n	USA	Industry Restore medical inc	Y (AHI)	y	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**31(29)**	58	48.1(11.2)	nd	29.3(1.9)	nd	nd	nd
Cx	**31(26)**	48	39.0(9.9)	nd	28.7(2.3)	nd	nd	nd
Total	**62(55)**	53		nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	nd	nd	nd	n
Cx	nd	nd	nd	nd	nd	nd	nd	
Total	nd	nd	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	All patients had pre op mouth rinse with chlorhexidine plus post op prophylactic antibiotics for 5 days							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	29	23.8(5.5)	12.7(2.7)	nd	nd	nd	nd	nd
Control:	26	20.1(4.0)	11.7(2.7)	nd	nd	nd	nd	nd
Total:	55			nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						ndn		nd

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>=5 and <40		<10secs	Decrease in airflow <30% of baseline and 0_2 sat <4% in 10secs	Excessive day time sleepiness		

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Surgery	Palatal implants		
2				
3				
Control	Placebo			
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI		
2	QOL	SF 36 scores (average QOL)		Average of the 8 domains of SF-36 V2
3	Sleepiness measure	ESS		
4	Sleep study measure	REM sleep		
5	Sleep study measure	Min o_2 sat		

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD	Value	SD	P	Value	SD	P
Freidman, 2008 USA 18241718	AHI		Tx	implants	3months	29	23.8	5.5	15.9	7.6	-7.9	7.7	<0.0001	-8.8	6.3	<0.0001
			Cx	placebo	3months	26	20.1	4.0	21.0	4.8	+0.9	4.3				
	SF 36 scores (average QOL)		Tx	implants	3months	31	nd	nd	nd	nd	10.3	8.6		-11.9	7.0	<0.0001
			Cx	placebo	3months	31	nd	nd	nd	nd	-1.5	4.8				
	ESS		Tx	implants	3months	31	12.7	2.7	10.2	3.1	-2.4	2.2		-1.9	1.9	0.0002
			Cx	placebo	3months	31	11.7	2.7	11.1	2.7	-0.5	1.5				
	REM sleep	%	Tx	implants	3months	29	16.1	3.3	15.3	3.6	-0.8	3.4		-2	3.8	0.056
			Cx	placebo	3months	26	12.9	3.7	14.1	2.9	-1.2	4.2				
	Min o_2 sat		Tx	implants	3months	28	88.3	3.0	89.7	2.5	-1.3	3.7		-0.6	3.1	0.487
			Cx	placebo	3months	23	89.6	2.5	90.4	2.4	-0.7	2.1				

Study reported control-treatment*

Delete or correct the incorrect value/item. If change, highlight yellow.

** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
both	11	Patients refused post op PSG

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	?y (performed bymanufacturer)	y	y	y	y	y	y	NA	y	Y?

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	n	NA	NA	NA
Reasons for drop-outs:								
Other Issues:	Maybe due to rounding error but some of the numbers in table 4 do not add up.							
Overall Quality (A, B, C)	**A**							

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Question 5
Implants

A.

Author, Year	Steward, 2008			**Intervention 1**	Pillar palate implants
PMID*	18922335	**RefID**	11811	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	Sham placebo
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
-mild to moderate OSA -predominately retropalatal pharyngeal obstruction	-AHI <10 or >40 -BMI>32 kg/m2 -evidence of airway obstruction other than retropalatal (nasal polyps, severe nasal septal deviation, modified Mallampati class III/ Friedman tongue position III or IV, palatine tonsil hypertrophy, lingual tonsil hypertrophy, or hypopharyngeal obstruction obscuring laryngeal inlet on supine nasopharyngoscopy) 4) prior airway surgery other than nasal, adenoid, or tonsil 5) presence of another sleep disorder (restless legs, insomnia, narcolepsy, etc)	nd	nd	y	US	Restore Medical	Y Setting alpha at 0.05, 80 percent power (beta 0.80), a difference in mean change of 3, and standard deviation of 5 while considering a 10-percent dropout rate results in a sample size of 50 for each group	y	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?)	AFib/AFlutter, %	CVD †, % (specify)
Tx	**50**	78	47.2	Nd	<32	nd	nd	Nd
Cx	**50**	80	51.5	nd	<32	nd	nd	nd
Total								
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	nd	nd	nd	nd
Cx	nd	nd	nd	nd	nd	nd	nd	nd
Total								
	Treatments used (prior to trial, including surgery)							
Tx	Nd							
Cx	nd							
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	50	16.8	10.6	nd	nd	nd	nd	nd
Control:	50	16.7	10.7	nd	nd	nd	nd	nd
Total:	100							
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
FOSQ- 15.5 implant, 16.1 placebo								

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	10-40	Nd	Nd	Nd	Nd	Nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	3 soft palate implants	Restore Medical	nd
2				
3				
Control	Sham placebo	Identical devices devoid of implants	Nd	nd
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
none		
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep quality	AHI	3 mo.	Standard
2	Sleepiness	ESS	3 mo.	Standard
3	General symptom	FOSQ	3 mo.	Standard
4	Sleep quality	LSAT	3 mo.	Lowest oxyhemoglobin saturation

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
Steward, 2008 USA 18922335	AHI	index	Tx	Implant	3 mo.	50	16.8	nd	19.7	nd	2.9	Nd	nd	-6.0	nd	0.05
			Cx	Placebo		50	16.7	nd	25.6	nd	8.9	nd	nd			
	ESS	scale	Tx	Implant	3 mo.	50	10.6	nd	9.8	nd	-1.8	Nd	nd	-0.3	nd	0.62
			Cx	Placebo		50	10.7	nd	9.2	nd	-1.5	nd	nd			
	FOSQ	index	Tx	Implant	3 mo.	50	15.5	nd	14.1	nd	1.4	Nd	nd	0.83	nd	0.05
			Cx	Placebo		50	16.1	nd	15.5	nd	0.6	nd	nd			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
NA		

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
nd						

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	y	y	y	y	y	y	n	NA	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	n	y	NA	NA	NA	NA

Reasons for drop-outs:	NA
Other Issues:	
Overall Quality (A, B, C)	**B- Didn't account for multicenter in analysis**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Steward, 2008			**Intervention 1**	soft palate implants
PMID*	18922335	**RefID**	11811	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	sham implant
Extractor	SI			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
mild to moderate OSAS; predominantly retropalatal pharyngeal obstruction seeking tx	AHI <10 or >40 (home or lab); other airway obstructions; BMI >32; prior airway surgery; presence of other sleep disorders	>5	nd	yes (3 centers)	US	industry	yes (50 each arm)	yes	yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**50 (49)**	78	47.2	nd	27.4	nd	nd	nd
Cx	**50 (50)**	80	51.5	nd	27.8	nd	nd	nd
Total	**100 (99)**	79	49.4	nd	27.6	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	nd	nd	nd	no
Cx	nd	nd	nd	nd	nd	nd	nd	no
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx	nd							
Cx	nd							
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	50	16.8	10.6	nd	nd	nd	nd	
Control:	50	16.7	10.7	nd	nd	nd	nd	
Total:	100	16.8	10.6	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥5		nd	nd			

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Surgery	soft palate implants	Restore Medical, St. Paul, MN	standard placement of 3 implants
2				
3				
Control		sham		implant using identical devices devoid of the implants
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	change in AHI; O2 sat	3 mo	
2	Sleepiness measures	Epworth	3 mo	
3	QoL	FOSQ	3 mo	Functional Outcomes of Sleep Questionnaire
4	Sleep study measures	50% ↓ in AHI to ≤20	3 mo	50% ↓ in AHI to ≤20
5				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Steward, 2008 US 18922335	50% ↓ in AHI to ≤20	**Tx**	soft palate implants	3 mo		50 (?)	%	26		0.04				
		Cx	sham	3 mo		50 (?)	%	10						

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	CI*	P	Value	CI*	P
Steward, 2008 US 18922335	AHI		**Tx**	soft palate implants	3 mo	47	17.2		20.1		2.9	-2.1, 7.9	0.27	-6	0.9, -13	0.05
			Cx	sham	3 mo	50	16.7		25.7		8.9	4.1, 13.8	0.0005			
	Epworth		**Tx**	soft palate implants	3 mo	47					-1.8	-0.8, -2.9		-0.4	-1.8, 1.1	0.62
			Cx	sham	3 mo	49					-1.5	-0.4, -2.5				
	FOSQ		**Tx**	soft palate implants	3 mo	49					1.43	0.84, 2.03		0.83	0.00, 1.67	0.05
			Cx	sham	3 mo	49					0.6	0.01, 1.2				
	O2 sat nadir	%	**Tx**	soft palate implants	3 mo	46					0.1%	-1.4, 1.6		-2.9%	-0.8, -5	0.007
			Cx	sham	3 mo	48					3%	1.6, 4.5				

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			implants	sham		
Steward, 2008 US 18922335	sore throat	1 wk	16%	6%		
	foreign body sensation		18%	2%		
	infection		2%			
	extrusion		4%			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	y	y	y	y	n (?)	y	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**		**If a Crossover study, was the Washout period adequate?**
	y	n	n	y	n	NA			
Reasons for drop-outs:									
Other Issues:		details of randomization not reported; no adjustment for multiple centers							
Overall Quality (A, B, C)		**B**							

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Question 5
Surgery vs Control

A.

Author, Year	Back, 2009			**Intervention 1**	Radiofrequency ablation surgery
PMID*	19504550	**RefID**	3057	**Intervention 2**	
Key Question(s)	5(surgery)			**Intervention 3**	
Design †	RCT			**Control**	sham surgery
Extractor	NO			**Comments**	Study states that outcome assessors were blinded but no data on whether or not patients were blinded

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
30-65yrs Habitual snoring (≥ 4nights/week for one year) Excessive daytime sleepiness (subjective) BMI≤35kg/m2 AHI 5-15/hr Velopharyngeal obstruction	Retrolingual obstruction Skeletal deformities (micro or marcognathia) Nose breathing problems Obstructive tonsilar hypertrophy Previous Velopharyngeal or lingual surgery Exaggerated pharyngeal reflex Cardiac pacemaker	≥5	nd	n	Finland	University	Y(compound endpoint score based on AHI,ESS, SF36 scores)	Y(assumed)	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx					29.0(21.0-34.6)			
Cx					25.6(20.8-34.0)			
Total	**32(32)**	100	30-65yrs	nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Median and range
Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	17	11(5-15)	10(3-21)					
Control:	15	12(5-8)	8(3-16)					
Total:	32			nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % ()**		**Other characteristics**

* median(range)
Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Ambulatory sleep registration(SOMNO check)	5-15						

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Surgery	Radiofrequency ablation of the soft plate	Celon AG medical instruments, Teltow/Berlin, Germany	Under local anesthesia, surgical device used to stabilize soft palate
2				
3				
Control	Placebo	Sham surgery		Patients are anesthetized, surgical device inserted into soft palate but not turned on
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measure	ESS	4 months	
2	QOL	SF 36 PCS	4 months	
3	QOL	SF 36 MCS	4 months	
4	Sleep study measure	AHI	4 months	
5	Sleep study measure	ODI	4 months	
6	Sleep study measure	Min 02 sat	4 months	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	range*	Value	range*	Value	SD/SE*	P	Value	95%CI*	P
Back, 2009 Finland 19504550	ESS		**Tx**	RF surgery	4 months	17	10.0	3.0–21.0	7.0	0.0–20.0	-3			0	0,0	0.941
			Cx	Sham surgery	4 months	15	8.0	3.0–16.0	5.0	2.0–15.0	-3					
	SF 36 PCS		**Tx**	RF surgery	4 months	17	47.2	22.7–64.1	48.5	33.0–67.4	1.3			-4.6	-29.1,19.9	0.713
			Cx	Sham surgery	4 months	15	49.4	37.6–60.4	55.3	19.1–63.7	5.9					
	SF 36 MCS		**Tx**	RF surgery	4 months	17	53.7	20.9–68.2	55.3	19.1–63.7	1.6			8.2	-8.8,25.2	0.345
			Cx	Sham surgery	4 months	15	51.6	22.2–63.2	45.0	28.1–61.6	-6.6					
	AHI	/hr	**Tx**	RF surgery	4 months	17	11.0	5.0–15.0	13.0	2.0–26.0	2			3	-9.1,15.1	0.628
			Cx	Sham surgery	4 months	15	12.0	5.0–8.0	11.0	1.0–29.0	-1					
	ODI 4%	/hr	**Tx**	RF surgery	4 months	17	15.0	2.0–32.0	18.0	1.0–41.0	3			1	-0.9,2.9	0.313
			Cx	Sham surgery	4 months	15	7.0	4.0–37.0	9.0	2.0–45.0	2					
	Min O^2 sat	%	**Tx**	RF surgery	4 months	17	82.0	68.0–88.0	82.0	74.0–92.0	0			0	0,0	0.576
			Cx	Sham surgery	4 months	15	83.0	69.0–88.0	83.0	63.0–88.0	0					

All values median (range)
Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
0	0	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Comments: statistically in pain and speaking difficulties between 2 groups first day post op, more pain in RF surgery(P<0.05), significantly increased swelling sensation in Rf surgery day 1-7 post op(P<0.05). No change in breathing and mouth opening for both groups.

(Extracted From fig 2 page 1625)

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	y	y	Y (assumed)	y	y	y	na		y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y		na	na	na

Reasons for drop-outs:	
Other Issues:	
Overall Quality (A, B, C)	**A**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Ferguson, 2003			**Intervention 1**	Laser-assisted uvulopalatoplasty (LAUP)
PMID*	12502473	**RefID**	4252	**Intervention 2**	
Key Question(s)	KQ 5 Surgery v control			**Intervention 3**	
Design †	RCT			**Control**	No treatment
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
AHI 10.1-25, loud snoring	Nd	nd	nd	n	Canada	Ontario Thoracic Society; the Department of Medicine, University of Western Ontario; and the Department of Otolaryngology, University of Western Ontario, London, Canada.	90% power to detect a 25% reduction in AHI in the treatment group compared with no reduction in the control group with an alpha of 0.05	N	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**21(21)**							
Cx	**24(23)**							
Total	**45(44)**	78	44.6	nd	31.6	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	Mild OSA
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	21	18.6	10.7	nd	nd	nd	nd	
Control:	23	16.1	10.0	nd	nd	nd	nd	
Total:	44	nd	nd	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	Nd	Nd	cessation of airflow for at least 10 seconds accompanied by ongoing respiratory effort	reduction in airflow of at least 50% for at least 10 seconds accompanied by a reduction in respiratory effort	Nd	NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Surgery	LAUP	NA	A series of full-thickness vertical trenches were created with the CO2 laser on the free edge of the soft palate on either side of the uvula. The uvula was shortened and thinned to a fraction of its former size. The edge of the soft palate was also reduced. LAUP subjects had an average of 2.4±0.98 procedures
2				
3				
Control	No treatment	No treatment	NA	No treatment
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	ESS	Baseline; mean 8.2 mo in control, mean 15.4 mo in LAUP	
2	General symptom scales	SAQLI	Baseline; mean 8.2 mo in control, mean 15.4 mo in LAUP	Calgary Sleep Apnea Quality of Life Index
3	Sleep study measures	AHI	Baseline; mean 8.2 mo in control, mean 15.4 mo in LAUP	
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
Ferguson, 2003 Canada 12502473	ESS	number	Tx	LAUP	15.4 mo	21	10.7	3.7	9.3	3.8	1.4	nd		2.2	Nd	NS
			Cx	No Treatment	8.2 mo	23	10.0	5.2	10.8	9.3	-0.8	Nd				
	SAQLI	number	Tx	LAUP	15.4 mo	21	4.2	0.81	4.6	0.9	-0.4	Nd		0.2	Nd	0.548
			Cx	No Treatment	8.2 mo	23	4.1	1.0	4.3	1.5	-0.2	Nd				
	AHI	Events/hr	Tx	LAUP	15.4 mo	21	18.6	4.3	14.7	7.5	3.9	nd		10.5	Nd	0.03
			Cx	No Treatment	8.2 mo	23	16.1	4.0	22.7	15.2	-6.6	nd				

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
No treatment	1%	Severe illness

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			LAUP			
Ferguson, 2003 Canada 12502473	Moderate to severe pain immediately after procedure (despite analgesia)	Right after procedure	81%			
	Persistent difficulty swallowing	15.4 mo	19%			
	Mild bleeding	Nd	19%			
	Moderate to severe bleeding	Nd	24%			
	Change in vocal quality (temporary)	nd	5%			
	Nasal regurgitation	Brief period after surgery	24%			
	infection	Nd	19%			
	diarrhea	Nd	0.5%			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	Nd	Y	N	Nd	Nd	Y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Y	N	Y	Y	NA	NA	NA			NA
Reasons for drop-outs:	Severe illness									
Other Issues:										
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Guilleminault, 2008			**Intervention 1**	Cognitive behavioral therapy for insomnia (CBT-I)
PMID*	19014072	**RefID**	3330	**Intervention 2**	
Key Question(s)	5- Surgery v Cx			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	surgery
Extractor	KP			**Comments**	Extracted as a parallel trial. Paper was presented as a crossover study, but only first phase was extracted, as the crossover was between behavioral therapy and surgery (crossover may not be an appropriate study design in this case, if period effects are strong).

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
complaint of insomnia for ≥3 months, with sleep problems ≥ 3 times per week, and report of sleep disturbance for ≥30 minutes on the insomnia night; associated daytime consequences of daytime fatigue or sleepiness, presence of difficulty concentrating, and impairment of daytime social or professional activities; no hypnotic or psychiatric medications at the time of visit; willingness to undergo a complete sleep clinic evaluation including PSG testing.	presence of an associated psychiatric diagnosis and ongoing psychiatric treatment; obesity (BMI >28), untreated medical health problems; daytime sleepiness with impaired driving; oxygen desaturation below 80%; and discovery of another sleep disorder such as periodic limb movement syndrome not related to abnormal breathing during an overnight PSG.	nd	January 2002 – December 2003	n	USA	Palo-Alto Sleep Research Foundation	nd	n	n
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx- initial CT	**15**	33	30.9	Nd	24.1	nd	Nd	Nd
Cx- initial surgery	**15**	40	31.8	nd	23.9	Nd	nd	Nd
Total	**30**							
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	Nd	nd	Nd	nd	Nd	nd	Nd	no
Cx	nd	Nd	nd	Nd	nd	Nd	nd	No
Total								
	Treatments used (prior to trial, including surgery)							
Tx	Nd							
Cx	Nd							
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment- initial CT:	15	7.9	Nd	Nd	Nd	Nd	Nd	
Control- initial surgery:	15	9.7	Nd	Nd	Nd	Nd	Nd	
Total:								
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG			Drop of ≥30% of the amplitude of the signal ≥3 breaths	Drop of ≥80% of amplitude of the signal, oxygen desaturation ?=3% or the presence of a visible EEG arousal for ≥3 sec	Nd	NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Other	CBT-I	NA	CBT-I was administered in a group setting with an experienced psychologist with board certification in behavioral sleep medicine. Treatment consisted of seven 90-min sessions, over 9 weeks, including standard CBT-I components such as sleep hygiene, stimulus control, relaxation techniques, and sleep restriction.
2				
3				
Control	Surgery	Various surgeries, depending on patient	NA	Recommendations for the type of surgery were made based on the patient anatomy, disease severity, comorbid conditions, and patient preference. Surgeries included a combination of pharyngoplasty, tonsillectomy and adenoidectomy, genioglossal advancement, septoplasty, and radiofrequency reduction of inferior nasal turbinates.
For CPAP:		**How was the Pressure selected?**	NA	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description
Dental appliance	Recommendations for the use of a dental appliance with or without prior surgical treatment were made after evaluation by an otolaryngologist and an orthodontist specialized in the treatment of OSA. The dental device may have been part of the original treatment plan orwere added as an adjunctive treatment after demonstration of residual OSA post-surgery.
For CPAP:	**Describe the frequency of the initial education follow-up**

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	ESS	Baseline, 3 mo	
2	Sleepiness measures	FSS	Baseline, 3 mo	Fatigue severity scale
3	Sleep study measures	REM %	Baseline, 3 mo	
4	Sleep study measures	SWS	Baseline, 3 mo	Slow wave sleep
5	Sleep study measures	RDI	Baseline, 3 mo	
6	Sleep study measures	AHI	Baseline, 3 mo	
7	Sleep study measures	Min O2 sat	Baseline, 3 mo	
8	Sleep study measures	SL	Baseline, 3 mo	Sleep latency
9	Sleep study measures	WASO	Baseline, 3 mo	Wake time after sleep onset

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD	Value	SD/SE*	P	Value	(95%CI)*	P
Guilleminault, 2008 United States 19014072	ESS	number	**Tx**	CBT-I	3 mo	15	6.5	1.2	5.9	1.6	0.6	nd	nd	-1.3	-2.2,-0.3	0.005
			Cx	Surgery	3 mo	15	6.6	1.2	4.7	0.8	1.9	nd	nd			Nd
	REM %	%	**Tx**	CBT-I	3 mo	15	12.5	1.6	13.1	1.7	-0.6	nd	nd	2.2	1.0,3.3	<0.0001
			Cx	Surgery	3 mo	15	13.1	1.8	15.9	0.9	-2.8	nd	nd			Nd
	SWS %	%	**Tx**	CBT-I	3 mo	15	10.9	1.2	11.9	1.4	-1	nd	nd	2	-12.3,-10.4	<0.0001
			Cx	Surgery	3 mo	15	11.5	1.5	14.5	1.1	-3	nd	nd			Nd
	RDI	Events/hr	**Tx**	CBT-I	3 mo	15	21.7	7.3	21.3	8.6	0.4	nd	nd	-14.9	nd	nd
			Cx	Surgery	3 mo	15	21.7	9	6.4	1.7	15.3	nd	nd			Nd
	AHI	Events/hr	**Tx**	CBT-I	3 mo	15	7.9	4.8	8.9	5.7	-1	nd	nd	-7.6		<0.001
			Cx	Surgery	3 mo	15	9.7	5.7	3.1	1.3	6.6	nd	nd			Nd
	Min O2 saturation %	%	**Tx**	CBT-I	3 mo	15	91.6	1.6	91.9	1.8	-0.3	nd	nd	4.7	3.4,5.9	<0.0001
			Cx	Surgery	3 mo	15	91.3	1.9	96.3	1.4	-5	nd	nd			Nd
	Sleep Latency	Min	**Tx**	CBT-I	3 mo	15	27.3	8.7	11.5	2.1	15.8	nd	nd	11.6	-18.0,-5.1	<0.0001
			Cx	Surgery	3 mo	10	25.8	10.4	21.6	9.6	4.2	nd	nd			Nd
	WASO	min	**Tx**	CBT-I	3 mo	15	39.6	22.3	19.9	7.9	19.7	nd	nd	19.7-37		
			Cx	Surgery	3 mo	10	45.4	17.9	8.4	2.1	37	nd	nd		nd	Nd

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Guilleminault, 2008 United States 19014072	FSS	NA	3 mo	CBT-I	15	Surgery	10	Nd					

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Surgery	33%	Felt surgery improved symptoms, didn't proceed to CBT-I and weren't analyzed

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	Nd	N	N	Nd	N	Y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Y	y	y	n	n	NA	NA			NA
Reasons for drop-outs:	Felt surgery improved symptoms, didn't proceed to CBT-I and weren't analyzed									
Other Issues:	Designed/reported as crossover study, but crossover doesn't make sense given interventions, hence only first treatment considered here									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Koutsourelakis, 2008			**Intervention 1**	Surgery
PMID*	17898015	**RefID**	3478	**Intervention 2**	
Key Question(s)	5(Surgery)			**Intervention 3**	
Design †	RCT			**Control**	Sham surgery
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Nasal septum deviation AHI>5 OSAs	Upper or lower respiratory tract disease Nasal allergy Recent upper airway surgery Concurrent use of medication affecting nasal resistance (antihistamine, decongestants) History of neuromuscular or cardiovascular disease CPAP during study	≥5	nd	n	Greece		Y(AHI)	y	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx		63.1	39(7.5)		30.4(3.2)			
Cx		59.1	37.6(8.8)		29.9(3.5)			
Total	**49(49)**			nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	Y(deviated nasal septum patients)
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	27	31.5(16.7)	13.4(2.9)					
Control:	22	30.6(13.8)	13.7(4.4)					
Total:	49	30.6(13.8)		nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥5				snoring		

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Surgery	Surgery		Patients had submucous resection of the deviated septum and bilateral resection of inferior turbinates
2				
3				
Control	Placebo	Sham surgery		Simulated submucosal resection o f the nasal septum. Patients anesthetized and sham surgery performed, doctors asked for instruments like they would in surgery and patients followed every other protocol as if they has surgery. They also had nasal packing, nasal irrigation
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	4months	
2	Sleepiness measure	ESS	4 months	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD *	Value	SD *	P	Value	SD *	P
Koutsourelakis, 2008 Greece 17898015	AHI		Tx	surgery	4months	27	31.5	16.7	31.5	18.2	0		NS	-1.5		0.732
			Cx	Sham surgery	4 months	22	30.6	13.8	32.1	14.3	1.5		NS			
	ESS		Tx	surgery	4months	27	13.4	2.9	11.7	3.4	-1.7		0.01	-0.5		0.639
			Cx	Sham surgery	4 months	22	13.7	4.4	12.5	3.7	-1.2		NS			

Data for subgroup analysis between responders/treatment success and non responders/treatment failure not extracted (only treatment data available, no control data)
Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
both	3	Willingness to begin CPAP

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	n	y	y	y	y	y	na	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	n	na	na	na

Reasons for drop-outs:	
Other Issues:	
Overall Quality (A, B, C)	**A**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Lojander, 1996, 1999			**Intervention 1**	UPPP
PMID*	8681614, 10188139	**RefID**		**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	2 RCTs			**Control**	conservative treatment
Extractor	SI			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
mental or physical effects of OSAS and ODI findings; previously untreated; experts decided that UPPP is the preferred treatment	asthma, COPD, periodic leg movement syndrome, hypothyroidism, serious concomitant disease, unable to work because of somnolence, BMI >40;	nd	1987-1992	no	Finland	Ahokas and Ida Montin Foundation	yes, 12 pts per arm	no	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**18**	94	47		30 (range 24-39)	nd	nd	nd
Cx	**14**	100	48		32 (range 26-39)	nd	nd	nd
Total	**32**	97	47		31	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	121 (109-141, Wechsler Verbal)	nd	nd	no
Cx	nd	nd	nd	nd	124 (97-140)	nd	nd	no
Total	nd	nd	nd	nd	122	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx	none							
Cx	none							
Total	none							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	ODI4*	Epworth*	MSLT* †	Heavy Snorers#	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	18	45 (21-72)	nd	nd	14/18	nd	nd	nd
Control:	14	34 (20-68)	nd	nd	11/14	nd	nd	nd
Total:	32	40	nd	nd	78%	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

not defined; * Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	nd					

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Surgery	UPPP ± mandibular osteotomy		uvulopalatopharyngoplasty per Fujita
2				
3				
Control		Conservative treatment		
For CPAP:		**How was the Pressure selected?**	adjusted individually	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	daytime somnolence	3 mo and 12 mo	VAS (not extracted as this is not an externally validated instrument)
2	Sleep study measures	ODI4	3 mo and 12 mo	no. of desat of ≥4% per h in bed
3	Cognitive scale	Wechsler	3 mo and 12 mo	
4	Sleep study measures	ODI10	3 mo and 12 mo	no. of desat of ≥10% per h in bed

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
Lojander, 1996 Finland 8681614	ODI4		Tx	UPPP	12 mo	16	45 (n=18)		14 (n=16)		-31		<0.01	-20		NS
			Cx	conservative	12 mo	10	34 (n=14)		23 (n=10)		-11					
	ODI10		Tx	UPPP	12 mo	16	17 (n=18)		3 (n=16)		-14			-6		NS
			Cx	conservative	12 mo	10	14 (n=9)		6 (n=10)		-8					
Lojander, 1999 Finland 10188139	Wechsler Verbal		Tx	UPPP	12 mo	10	121 (n=12)				-1 (n=10)					NS
			Cx	conservative	12 mo	10	111 (n=11)				-2 (n=10)					
	Wechsler Performance		Tx	UPPP	12 mo	10	115 (n=12)				-13 (n=10)					NS
			Cx	conservative	12 mo	10	114 (n=11)				-3 (n=10)					
	Wechsler Memory		Tx	UPPP	12 mo	10	128 (n=12)				-1 (n=10)					NS
			Cx	conservative	12 mo	10	118 (n=11)				-10 (n=10)					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention	Intervention
			UPPP	UPPP	UPPP alone	UPPP + osteotomy	UPPP + osteotomy
Lojander, 1996 Finland 8681614	MI		1/18				
	TIA			1/18			
	velopharyngeal insufficiency				2/13		
	tracheotomy					1/5	
	infection needing reoperation						2/5

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	n		nd	y	y	n	NA	n

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	n	y	y	y	y	nd		
Reasons for drop-outs:								
Other Issues:	expert panel decided patients would be more suitable for UPPP							
Overall Quality (A, B, C)	**C**							

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Sahlman, 2009			**Intervention 1**	Surgery
PMID*	19863323	**RefID**	56	**Intervention 2**	
Key Question(s)	5 (Surgery			**Intervention 3**	
Design †	Cohort Retrospective			**Control**	Counseling
Extractor	NO			**Comments**	Questionnaire used : validated Finnish questionnaires including the Basic Nordic Sleep Questionnaire (BNSQ)

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Patients who visited otorhinolaryngology Dept Excessive daytime sleepiness Snoring Witnessed apneas Mild OSA AHI 5-15	Current use of CPAP	5-15	1998-2004	n	Finland	university		na	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**40(40**	87	46.0(8.4)		27.6(3.7)			
Cx	**41(41)**	92	52.2(8.9)		29.1(4.7)			
Total	**81(81)**	88		nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	nd
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	All patients were counseled at baseline. Weight loss reduction advice, avoidance of smoking and alcohol consumption advice							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	40	9.2(3.3)						
Control:	41	9.3(3.0)						
Total:	81							
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Ambulatory cardiorespiratory recording	5-15 AASM		≥10secs	>30% reduction in airflow with >4% o_2 desaturation			

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Surgery	UPPP, Radiofrequency ablation of soft palate, Uvulectomy, Tonsillectomy or Septoplasty		
2				
3				
Control	Positional therapy	Counseling plus positional device		Weight loss reduction advice, avoidance of smoking and alcohol consumption advice. Plus positional device to avoid sleeping supine
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measure	Daytime sleepiness	~3years follow up	
2	Physical scale	Tired at work	~3years follow up	
3	Sleep quality	Poor quality of sleep	~3years follow up	
4		Insomnia	~3years follow up	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Sahlman, 2009 Finland **19863323**	Daytime sleepiness	**Tx**	Surgery	2.8years		40	Adj OR				0.05	(0.01,0.25)	<0.001	Sex, age, BMI, AHI, baseline status of symptom and follow up time
		Cx	control	2.9 years		41								
	Tiredness at work	**Tx**	Surgery	2.8years		40	Adj OR				0.19	(0.05,0.70)	0.005	
		Cx	control	2.9 years		41								

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value	SD/SE*	P
Sahlman, 2009 Finland 19863323	Poor quality sleep	%	**Tx**	Surgery	2.8years	40	54.8		36.1		-18.7			-37.4		
			Cx	control	2.9 years	41	41.9		60.6		18.7					
	Insomnia	%	**Tx**	Surgery	2.8years	40	35.0		22.5		-12.5			-19		
			Cx	control	2.9 years	41	35.0		41.5		6.5					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
n	na	na	y	n	nd	y	y	na	n	Y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	Y(only patients who had surgery in one hospital, not clear how patients were selected into 2 groups)	y	y	n	na	na			na
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Woodson, 2003			**Intervention 1**	CPAP
PMID*	12825037	**RefID**	4977	**Intervention 2**	RFA (tongue & palate)
Key Question(s)	KQ 5 CPAP/RFA/Placebo			**Intervention 3**	
Design †	RCT			**Control**	Sham RFA
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA AHI 10-30 18-65 y Daytime somnolence	BMI >34 Prior surgery or CPAP Other sleep disorder Tonsillar hypertrophy Nasal or supraglottic obstruction ASA class IV/V Claustrophobia Latex allergy Pregnancy Major depression or nonstablized psychiatric disorder Drug or EtOH abuse Accident due to sleepiness	10-30 (or 5-40) [two parts of methods section disagree with each other]	nd	Yes	US	Industry	Yes 30/arm (1/SRT)	Yes (to RFA) CPAP patients not blinded	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx: CPAP	**30 (28)**	75	52	nd	29.1	nd	nd	nd
Tx: RFA	**30 (29)**	90	49		27.7			
Sham RF	**30 (30)**	70	46		28.5			
Total			P=0.04					
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	0 (eligibility)	nd	0 (eligibility)	nd	Restricted eligibility
Cx								
Total								
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	No CPAP or surgery							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Tx: CPAP	27	19.8±9.9	12.6±5.0	nd	nd	nd	nd	
Tx: RFA	29	21.3±11.1	11.9±4.6					
Sham RF	30	15.4±7.8	11.6±3.5					
Total		P=0.06						

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify)	Other characteristics
No	Neck circumference normal (~41 cm) Upper airway volume 73.6 cm^3	

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Home Autoset PDS or PSG	>5		Cessation of inspiratory airflow ≥10 sec	Reduction of airflow ≥10 sec with 4% desat or EEG arousal		Separate (auto-titrate)	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	nCPAP	Autoset T	
2	RFA	Temperature controlled RF tissue ablation		5 tongue and 2 palate sessions planned, at 4 week intervals Nonoverlapping lesions in 2 (1000 J) or 3 (750 J) sites. Target 85º C, Max 10 W. 1 midline (650 J) and 2 lateral (325 J) soft palate lesions per session
3				
Control		Sham RFA		Similar process for tongue only (3 "lesions"). No energy delivered. 3 sessions. Same anesthesia, medications, and probe insertion
For CPAP:		**How was the Pressure selected?**	Titrated unattended over ≥3 nights with AutoSet T device	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	nd. Seen at 1, 2 & 4 wk to troubleshoot & increase compliance

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Physical/Psychomotor	Slowest reaction time (SRT)	8 wk	Mean of slowest 10% of reaction times on the Psychomotor Vigilance Task (PVT-192). Analyzed as 1/SRT (larger values better).
2	QoL	Functional Outcomes of Sleep Questionnaire (FOSQ)		
3	QoL	Symptoms of Nocturnal Obstruction and Related Events (SNORE25) [Same as OSA Patient Oriented Severity Index]		
4	Sleepiness	Epworth Sleepiness Scale		
	QoL	SF-36 MCS & PCS		
	Sleep measure	AHI		
	Sleep measure	Minimum O2 saturation		
	Sleep measure	Total arousal index		
	Adverse events	Pain, swallowing problems	1 & 3 wk post-surgery	10 cm VAS (0=no pain, normal swallow)
	Adverse events	self-reported	8 wk	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed Base/Final	Baseline		Effect Size (F mean - Base mean)/ (Base SD) + improve ≥0.5 = ≥"moderate"		Change (Final – Baseline)			Net Δ (Δ test – Δ control)		
							Value	SD	Value		Value	SD	P	Value	95% CI	P
Woodson, 2003	AHI	/hr	Tx	CPAP	8 wk	27/	19.8	9.9			nd					
US			Tx	RFA		29/24	21.3	11.1	0.38		-4.5	13.8	NS	-2.7	(-9.9, 4.5)	NS
12825037			Cx	Sham RF		30/28	15.4	7.8	0.24		-1.8	11.5	NS			
	Min SaO2	%	Tx	CPAP	8 wk	27/	86.0	6.4			nd					
			Tx	RFA		29/24	86.3	7.6	-0.08		-0.6	4.6	NS	-1.2	(-3.8, 1.4)	NS
			Cx	Sham RF		30/28	88.3	3.9	0.15		0.6	4.7	NS			
nl <10	ESS		Tx	CPAP	8 wk	27/25	12.6	5.0	0.44		-2.3	5.2	0.02	-1.4	(-3.8, 1.1)	NS
			Tx	RFA		29/26	11.9	4.6	0.50		-2.1	3.9	0.005	-1.2	(-3.1, 0.8)	NS
			Cx	Sham RF		30/28	11.6	3.5	0.27		-1.0	3.1	NS	0.20	(-2.39,2.80)	NS
nl>17.8	FOSQ		Tx	CPAP	8 wk	27/25	16.0	2.6	0.61		1.5	2.1	0.02	1.2	(0.1, 2.3)	0.02
			Tx	RFA		29/26	16.5	2.0	0.66		1.2	1.6	0.005	0.9	(-0.1, 1.9)	0.04
			Cx	Sham RF		30/28	16.8	2.1	0.18		0.4	2.0	NS	-0.29	(-1.35, 0.77)	NS
	SNORE25		Tx	CPAP	8 wk	27/	1.5	0.6	0.46		-0.30	0.52	0.005	-0.09	(-0.39, 0.21)	NS
			Tx	RFA		28/	1.6	0.7	0.65		-0.43	0.56	<0.001	-0.22	(-0.53, 0.09	0.08
			Cx	Sham RF		30/	1.6	0.7	0.31		-0.21	0.56	0.06	-0.13	(-0.44, 0.18)	NS
Norm 50	SF36 MCS		Tx	CPAP	8 wk	27/24	47.2	10.5	0.22		2.0	6.1	NS	1.7	(-1.8, 5.2)	NS
			Tx	RFA		28/24	46.4	9.4	0.32		2.9	7.3	0.08	2.5	(-1.4, 6.4)	NS
			Cx	Sham RF		30/27	46.7	9.8	0.04		0.4	6.4	NS	0.83	(-3.07, 4.74)	ns
Norm 50	SF36 PCS		Tx	CPAP	8 wk	27/24	50.7	6.7	0.02		0.1	7.7	0.08	-1.4	(-5.8, 3.0)	NS
			Tx	RFA		28/24	50.1	8.3	0.06		0.5	6.8	NS	-1.0	(-5.1, 3.1)	NS
			Cx	Sham RF		30/27	19.9	8.0	0.18		1.5	7.8	NS	0.38	(-3.86, 4.62)	NS
nl≥2.88	1/SRT	1/msec	Tx	CPAP	8 wk	28/19	2.77	0.66	0.30		0.18	0.60	NS	0.12	(-0.26, 0.51)	NS
			Tx	RFA		29/23	2.71	0.69	0.42		0.32	0.57	0.006	0.27	(-0.09, 0.62)	0.07
			Cx	Sham RF		29/25	2.88	0.55	0.09		0.05	0.66	NS	-0.15	(-0.22, 0.52)	NS

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper
RFA versus (minus) CPAP

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Tx: CPAP	4/30 (13%)	1 withdrew prior to intervention, 2 found to have AHI>40, 1 lost to follow-up
Tx: RFA	4/30 (13%)	1 withdrew prior to intervention, 1 found to have AHI<5, 2 lost to follow-up
Sham RF	2/30 (7%)	1 withdrew prior to intervention, 1 lost to follow-up

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			CPAP	RFA	Sham RFA	
Woodson, 2003	Hematomas (% sessions)	1, 3 wk	NA	2.3% (3/26)	3.5% (3/28)	
US	Ulcerations (% of sessions)	same	NA	0.8% (1/26)	0	
12825037	Infections (% of sessions)	same	NA	0	0	
	(Pain & swallowing VAS reported but not extracted; hard to interpret)					
	Nasal dryness, congestion, bleeding or sinusitis	8 wk	38% (8/21)			
	Delayed sleep or subjective sleep fragmentation		43% (9/21)			
	Noise inconvenience and/or spouse objection		33% (7/21)			
	Aerophagia, Chest wall discomformt, or mouth breathing		33% (7/21)			
	Skin or eyes complaint		38% (8/21)			
	Total subjects affected by CPAP		95% (20/21)			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	Yes	Yes	Yes, but not CPAP	Yes	Yes	Yes (but not for baseline imbalances)	Yes	Not baseline imbalances	Except for AHI eligibility
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	No. AHI	No	Yes	No. Not scales	No (for CPAP)	Yes	NA			NA
Reasons for drop-outs:	See above									
Other Issues:	Extensive statistical methods section raises confidence that important issues were considered and dealt with appropriately									
Overall Quality (A, B, C)	**A (with caveat about AHI eligibility criteria)**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Question 5
Surgery vs PAP

A.

Author, Year	Anand, 1991			**Intervention 1**	UPPP
PMID*	1945423	**RefID**	6014	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Retrospective cohort			**Control**	CPAP
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
nd	nd	nd	1983-1990	n	USA	nd	nd	n	n
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**66(45)**	82	51.2					
Cx	**?(50)**	68	52.9					
Total				nd	nd	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx	28 received adjunctive tonsillectomy, 24 adjunctive, nasal surgery, 3 received Epiglottopexy and 14 received adjunctive tonsillectomy							
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	43			7.2				
Control:	29			6.9				
Total:		nd	nd		nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	nd	nd	nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Surgery	UPPP		
2				
3				
Control	PAP	CPAP ()	Respironics	
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measure	MSLT		% of patients who increased MSLT score by at least 3 minutes
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Anad 1991 1945423 USA	MSLT	**Tx**	UPPP	16 days to 87 months	13	43	%	30						
		Cx	CPAP	21 days to 38 months	12	29	%	41						

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
			Tx													
			Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
Anad 1991 1945423 USA		**Tx**			
		Cx			

Comments on Results	Data on apnea index, no of <85% desaturation and maximum o2 desaturation not extracted

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			UPPP			
Anand 1991 1945423 USA	Velopharyngeal incompetence > 1 month		8			
	Voice change, long term		1			
	Unilateral choanal stenosis		1			
	Post operative bleeding with return to operating room		1			
	Reintubation		1			
	Death		1			
	Nasal synechiae		2			
	Tracheal stenosis		1			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
n	n	na	na	n	n	n	y	n	n	n

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	n		y		n	nd	na	na
Reasons for drop-outs:								
Other Issues:	Inadequate reporting with many discrepancies in results							
Overall Quality (A, B, C)	**C**							

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Ceylan, 2009			**Intervention 1**	temperature controlled RF tissue volume reduction
PMID*	19770425	**RefID**		**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	NRCS, retrospective			**Control**	nasal CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
persistent Sx of OSA; AHI 5-40; nasal, oropharynx, and hypopharynx obstruction; Friedman tongue II, III; tonsil sizes 0-2 and nasal obstruction	needed intervention to reduce palatine tonsils; >70 yrs; BMI >40; cardiopulmonary failure; coag disorders; pacemaker, uncontrolled HTN	≥5	2003-2006	no	Turkey	nd	no	no	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):					not adjusted				

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**26**	88%	46	nd	28.6±3.8	nd	nd	nd
Cx	**21**	90	47		29.1±3.6	nd	nd	nd
Total	**47**	89	46		28.8	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	nd	nd	nd	no
Cx	nd	nd	nd	nd	nd	nd	nd	no
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx	nd							
Cx	nd							
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	lowest O2 sat (%)
Treatment:	26	29.6±7.8	10.8±3.2	nd	nd	nd	nd	86.8±8.9
Control:	21	28.5±6.9	11.1±3.1	nd	nd	nd	nd	88.4±8.5
Total:	47	29.1	10.9	nd	nd	nd	nd	87.5
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd								

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥5						

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Surgery	temperature controlled RF tissue volume reduction and septoplasty ± nasal valve suspension	Gyrus-ENT, Tennessee	350 J to 3 sites in inf turbinate; 650 J to mid palate; 325 J to each side; 3000 J to 10 sites in tongue
2				
3				
Control	nasal CPAP	nd	nd	nd
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	nd

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Epworth	12 mo	
2	Sleep study measures	AHI; O2 nadir	12 mo	
3		Treatment Success	12 mo	change in AHI ≥50% and post tx AHI ≤20 and ESS <10
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Ceylan, 2009 Turkey 19770425	tx success	**Tx**	RF ablation	12 mo	14	26	%	53.8		0.92				
		Cx	n-CPAP	12 mo	11	21	%	52.4						

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD/SE*	P	Value	95CI*	P
Ceylan, 2009 Turkey 19770425	AHI	events/h	**Tx**	RF ablation	12 mo	26	29.6	7.8	16.1	3.9	-13.5		<0.001	-0.7	-4.8,3.4	0.74
			Cx	n-CPAP	12 mo	21	28.5	6.9	15.7	4.2	-12.8		<0.001			
	Epworth		**Tx**	RF ablation	12 mo	26	10.8	3.2	8.2	2.7	-2.6		0.003	+0.1	-0.7,0.9	0.81
			Cx	n-CPAP	12 mo	21	11.1	3.1	8.4	2.9	-2.7		0.006			
Ceylan, 2009 Turkey 19770425	O2 sat nadir	%	**Tx**	RF ablation	12 mo	26	86.8	8.9	94.6	4.9	7.8		<0.001	2.7	-4.7,10.2	0.48
			Cx	n-CPAP	12 mo	21	88.4	8.5	93.5	5.8	5.1		0.03			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			RF ablation			
Ceylan, 2009 Turkey 19770425	postop bleeding	perioperative	0/26			
	need for tracheostomy	perioperative	0/26			
	uncontrollable pain	perioperative	0/26			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
n	NA	NA	NA	n	nd	n	n	NA	n	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	y	y	y	NA	nd				
Reasons for drop-outs:										
Other Issues:	pts who preferred n-CPAP and rejected RF tx were treated with n-CPAP; small sample sizes									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Condrat, 1998			**Intervention 1**	Surgery (Maxillomandibular advancement osteotomy (MMO)
PMID*	9785277	**RefID**	5162	**Intervention 2**	CPAP
Key Question(s)	5(surgery)			**Intervention 3**	
Design †	Prospective cohort			**Control**	
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Patients with craniofacial abnormalities	nd	nd	1993-1996	n	Germany	Deutsche Forschungsgemeinschaft (DFG) Foundation	n	n	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**24(24)**	100	42.7(10.7)	nd	26.7(2.9)	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	Y(craniofacial abnormalities
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	All except 2 patients had 3 months of CPAP therapy prior to surgery							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	24	nd	nd	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	nd	10secs	3% decline in O_2 saturation		separate	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP		
2	Surgery	MMO		Maxillomandibular advancement osteotomy
3				
Control				
For CPAP:		**How was the Pressure selected?**	manual	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	RDI	3 months	Respiratory disturbance index(Number of apneas and hypopneas and other obstructive events per hour of sleep)
2	Sleep study measure	NREM 3/4	3 months	
3	Sleep study measure	REM	3 months	
4	Sleep study measure	Sleep efficiency	3 months	
5	Sleep study measure	Number of arousals	3 months	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value		P
Conradt, 1998 Germany 9785277	RDI		Tx	CPAP	3 months	24	59.4	24.1	5.33	6.0	-54.07		<0.05	-0.27		NS
			Tx2	MMA	3 months	24	59.4	24.1	5.6	9.6	-53.8		<0.05			
	NREM 3/4	%	Tx	CPAP	3 months	24	8.0	6.08	18.2	12.8	10.2		<0.05	3.8		NS
			Tx2	MMA	3 months	24	8.0	6.08	14.4	7.26	6.4		<0.05			
	REM		Tx	CPAP	3 months	24	19.6	7.38	21.2	6.27	1.6		NS	-0.1		NS
			Tx2	MMA	3 months	24	19.6	7.38	21.3	5.61	1.7		NS			
	Sleep efficiency		Tx	CPAP	3 months	24	80.2	9.91	85.2	6.52	5		<0.05	1		NS
			Tx2	MMA	3 months	24	80.2	9.91	84.2	9.25	4		NS			
	Number of arousals		Tx	CPAP	3 months	24	54.3	20.0	19.3	20.0	-35		<0.05	-0.4		NS
			Tx2	MMA	3 months	24	54.3	20.0	19.7	13.6	-34.6		<0.05			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
	0	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
n	n	n	y	n	nd	n	y	n	n	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	n	Y(no clear eligibility criteria)	y	y	n	y	na			na
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)		**C**								

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Katsantonis 1988			**Intervention 1**	UPP
PMID*	327 8184	**RefID**	6336	**Intervention 2**	Orthognathic device
Key Question(s)	5			**Intervention 3**	Tracheostomy
				Intervention 4	Medication(TCA)
				Intervention 5	Tongue retaining device
Design †	NRCS			**Control**	nCPAP
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	Exclusion	AHI Criteria to Dx OSA	Enrollment Years	Multicenter?	Country	Funding source	Power calculation? (specify outcome)	Blinding, patient	Blinding, outcome assessor
Patients treated for moderate to severe OSA with pre and post PSG data	nd	nd	1982-1986	y	USA	nd	n	n	n
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	(analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx	**98**	92	Mean 49.5(range 20-72)	nd				
Tx2	**2**	nd	nd	nd	nd	nd	nd	nd
Tx3	**51(24)**	nd	nd	nd	nd	nd	nd	nd
Tx4	**35**	nd	nd	nd	nd	nd	nd	nd
Tx5	**6**	nd	nd	nd	nd	nd	nd	nd
Cx	**138**	81	Mean 49.1(range 19-78)					
Total								
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Tx	**98**							
Tx2	**2**							
Tx3	**51**							
Tx4	**35**							
Tx5	**6**							
Control:	**138**							
Total:	330	nd	nd	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	nd	nd	nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Surgery	UPP		Follow up on average 8.1 weeks after surgery range(1-122weeks)
2		Orthodontic device		Follow up
3		Tracheostomy		Follow up 4 to 62 months , average of 32 months
4		Medication(TCA)		Follow up 3 to 14 months, average of 6months
5		Tongue retaining device		
Control		nCPAP	Respironics	Follow up on average 7 months , range(2- 12 months)
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1		AHI		Number of abnormal breathing events per hour of sleep
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
			Tx													
			Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	Patients were categorized into good, poor and moderate responders based on AHI. Good responders had >50% improvement in AHI from baseline, poor responders had <50% improvement in AHI, moderate responders were does in between. I UPP group, 37.7 were good responders, 33.6%, moderate and 28.5% were poor responders. nCPAP group, 100% good responders. Mean(SD) AHI during CPAP 14.4(10.8) Tracheostomy group :all patients upper airway obstruction were eliminated Medication group compliance rate and success rates were poor Tongue retaining device: 2/3 patients showed significant improvement in obstructive sleep apnea Orthognatic device:1/2 patients showed significant improvement in obstructive sleep apnea

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
ncPAP	6.5%	Claustrophobia
ncPAP	3.6%	Mask discomfort

ncPAP	2.1%	Mental retardation
Trachoestomy	4 patients	Decanulated following formation of granulation tissue on tracheostomy site
Trachoestomy	1 patient	Refused after accidental decannulation
Medication	14 patients	Anticholinergic side effects
TRD	50%	Discomfort and no perceived benefit

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
n	n	n		n	n	n	nd	y	n	n
	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?			If a Crossover study, was the Washout period adequate?
	n		y	n	n	y				
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)	C									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Keenan 1994			**Intervention 1**	UPPP
PMID*	8275724	**RefID**	5458	**Intervention 2**	nCPAP
Key Question(s)	5			**Intervention 3**	
Design †	Retrospective Cohort			**Control**	
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Patients with OSA treated with UPPP or nCPAP	nd	≥5	1984-1990	n	Canada		n	n	n
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
UPPP	**154(149)**	89	50(11)		30(5)			
nCPAP	**208(126)**	79	52(12)		36(9)			
Total	**362(275)**			nd		nd	**nd**	**nd**
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	**nd**	**nd**	**nd**	**nd**	**nd**	**nd**	**nd**	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
UPPP	149							
nCPAP	126							
Total:	275	nd	nd	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥5	nd	nd	nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Surgery	UPPP		
2	PAP	nCPAP		
3				
Control				
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Mortality	Death	43 +/- 13 (mean +/-SD) months	
2	Mortality	5 year survival	28 +/- 13 (mean +/-SD) months	
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Keenan 1994 8275724	Survival		UPP	43(13) months	6	149	%		NS	NS				
			CPAP	28(13) months	3	126	%		NS	NS				

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SD/SE*	P	Value	SD/SE*	P
Keenan 1994 8275724	Probability of 5 year survival			UPP	43(13) months	149			0.94	0.02						
				CPAP	28(13) months	126			0.95	0.03						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
AI>20	Keenan 1994 8275724	deaths		UPP	51(21) months	4	73	%	5		NS				
				CPAP	29(12) months	1	48	%	2		NS				

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SE*	Value	SE*	Value	SD/SE*	P	Value	SD/SE*	P
AI>20	Keenan 1994 8275724	5 year survival			UPP	51(21) months	73			0.92	0.02						NS
					CPAP	29(12) months	48			0.30	0.02						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
n	n	n	na	n	n	n	y	n	n	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	n		n	y	n	nd	na			na
Reasons for drop-outs:										
Other Issues:	Results were not consistently reported , significant difference between follow up periods in both arms									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Lin, 2006			**Intervention 1**	Extended UVPP
PMID*	16735919	**RefID**		**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	NRCS, retrospective			**Control**	CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA with RDI >5; attended sleep center	nd	RDI >5	2000-2001	no	Taiwan	nd	no	no	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**55 (55)**	nd	45		26.4±4.1	nd	nd	nd
Cx	**84 (54?)**	nd	51		28.1±3.6	nd	nd	nd
Total	**139 (109)**	nd	48		27.2	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	nd	nd	nd	no
Cx	nd	nd	nd	nd	nd	nd	nd	no
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx	nd							
Cx	nd							
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	RDI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	55	43.6±29.7	11.8±5.47	nd	nd	nd	nd	nd
Control:	54	65.3±24.7	14.1±4.43	nd	nd	nd	nd	nd
Total:	109	54.3	12.9	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	RDI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>5	nd	nd	nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Surgery	Extended UVPP		see Fig. 1 in paper
2				
3				
Control	CPAP		nd	
For CPAP:		**How was the Pressure selected?**	nd	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	QoL	SF-36	6 mo; 3 yr	
2	Sleep study measures	RDI	6 mo; 3 yr	
3	Sleepiness measures	Epworth	6 mo; 3 yr	
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value	95%CI*	P
Lin, 2006 Taiwan 16735919	RDI	events/h	**Tx**	surgery	6 mo	55	43.6	29.7	12.1	19.1	-31.5	29	<0.05	31.1	12.5,49.6	<0.001
			Cx	CPAP	6 mo	54	65.3	24.7	2.9	5.96	-62.6	24.5	<0.05			
	RDI	events/h	**Tx**	surgery	3 yr	7	nd		26.7	32.3	-16.9	27.2	<0.05	44.3		nd
			Cx	CPAP	3 yr	11	nd		4.3	6.87	-61.2	20.3	<0.05			
	Epworth		**Tx**	surgery	6 mo	55	11.1	3.72	7.32	4.29	-3.78		0.017	+1.09		NS
			Cx	CPAP	6 mo	54	14.1	4.43	9.23	6.11	-4.87		0.036			
	Epworth		**Tx**	surgery	3 yr	55 (?)	nd				23.4%	70.5%	<0.05			NS
			Cx	CPAP	3 yr	54 (?)	nd				13.1%	43.8%	<0.05			
	SF-36 RP		**Tx**	surgery	6 mo	55					40	36				NS
			Cx	CPAP	6 mo	54					46.9	104				
	SF-36 RP		**Tx**	surgery	3 yr	55 (?)					43.2	83.6				NS
			Cx	CPAP	3 yr	54 (?)					47.5	95.1				
	SF-36 VT		**Tx**	surgery	6 mo	55					37.6	55.4				NS
			Cx	CPAP	6 mo	54					53.7	86.5				
	SF-36 VT		**Tx**	surgery	3 yr	55 (?)					47.8	73.8				NS
			Cx	CPAP	3 yr	54 (?)					74.6	113				
	SF-36 MH		**Tx**	surgery	6 mo	55					19.6	44.4				NS
			Cx	CPAP	6 mo	54					6.03	21.6				
	SF-36 MH		**Tx**	surgery	3 yr	55 (?)					22.9	61.9				NS
			Cx	CPAP	3 yr	54 (?)					10.4	25				

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
Lin, 2006 Taiwan 16735919	SF-36 PF, BP, GH, SF, RE	**Tx**			NS
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	@ 6 mo 35.7%	uncomfortable (19%); inconvenience (13%); forgot (6%); hesitate (4%)
	@ 3 yr 75%	uncomfortable (11%); inconvenience (12%)

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
n	NA	NA	NA	n	nd	nd	n	NA	n	n

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	n	y	n	y	n	y		
Reasons for drop-outs:	Significant differences in baseline characteristics (age, BMI, RDI) between groups; unclear reporting of total number analyzed at 3 yrs							
Other Issues:								
Overall Quality (A, B, C)	**C**							

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Robinson, 2009			**Intervention 1**	surgery, stepwise approach
PMID*	19643262	**RefID**		**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	NRCS, retrospective			**Control**	CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
consecutive adults with OSAS (RDI >15) with surgery or CPAP; only pts with a patent nasal airway who had rejected or found the devices ineffective were offered surgery	CPAP treated pts with subsequent pharyngeal or bariatric surgery	RDI >15	2003-2004	n	Australia	none	70 pts in each arm	n	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):					ranked ANCOVA				

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	77	86	52.3	nd	30.9±0.62	nd	nd	nd
Cx	89	88	60	nd	32.2±0.6	nd	nd	nd
Total	166	88	56.4	nd	31.6	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	nd	nd	nd	nd
Cx	nd	nd	nd	nd	nd	nd	nd	nd
Total	nd	nd	nd	nd	nd	nd	nd	nd
	Treatments used (prior to trial, including surgery)							
Tx	nd							
Cx	nd							
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	RDI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	77	44±2.3	40.7% >10	nd	nd	nd	nd	nd
Control:	89	46.5±2.8	44.4% >10	nd	nd	nd	nd	nd
Total:	166	45.3	43% >10	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd								

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	RDI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>15						

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Surgery	stepwise as needed	Coblation reflex 55 wand (Arthrocare, CA)	UVPP; geniotubercle advancement (if needed); palatal advancement (if needed); hypoid suspension (if needed); RF ablation (if needed); submucosal glossectomy (if needed)
2				
3				
Control				
For CPAP:		**How was the Pressure selected?**	manual after review of diagnostic PSG results; repeat titration needed in 6/73	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	QoL	Glasgow Benefit Inventory	42 mo (surgery); 46 mo (CPAP)	
2	Sleepiness measures	Epworth		
3	Sleep study measures	RDI		
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Robinson, 2009 Australia 19643262		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	*	Value	*	Value	SD/SE*	P	Value	SD/SE*	P
Robinson, 2009 Australia 19643262	Glasgow Benefit Inventory		Tx	Surgery	42 mo	77			19.44 (median)	25 (IQR)						0.308 (unadjusted) 0.793 (adjusted for age, RDI, length of f/u)
			Cx	CPAP	46 mo	89			16.67 (median)	22.22 (IQR)						
	Epworth		Tx	Surgery	42 mo	77	9 (median)	7 (IQR)	4 (median)	4 (IQR)	-5			1.5	- 8.7,11.7	0.732 (unadjusted) 0.775 (adjusted for age, RDI, Epworth, length of f/u
			Cx	CPAP	46 mo	89	10.5 (median)	8.75 (IQR)	4 (median)	6.00 (IQR)	-6.5					
	RDI		Tx	Surgery	20 mo	69	44 (mean)	2.26 (SE)	22 (mean)	2.62 (SE)	-22		<0.001			
			Cx	CPAP	nd	nd	nd	nd	nd	nd	nd	nd	nd			
	lowest O2 sat	%	Tx	Surgery	20 mo	69	81.35	0.92	86.53	0.77	5.18		<0.001			
			Cx	CPAP	nd	nd	nd	nd	nd	nd	nd	nd	nd			
	Arousal index		Tx	Surgery	20 mo	69	39.2	2.71	24.12	1.9	-15		<0.001			
			Cx	CPAP	nd	nd										

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
Robinson, 2009 Australia 19643262	subjective compliance with CPAP				69.8%

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			surgery			
Robinson, 2009 Australia 19643262	aspiration		3/77			
	numbness/paresthesia		11/77			
	dysphagia		7/77			
	voice change		2/77			
	taste alteration		1774			
	wound dehiscence		1/77			
	infection		2/77			
	palatal fistula (transient)		1/77			
	claustrophobic from CPAP		1/89			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
n	NA	NA	NA	n	nd	nd	y	n	y	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	y	not for CPAP	y	y	y				
Reasons for drop-outs:										
Other Issues:	only pts with a patent nasal airway who had rejected or found the devices ineffective were offered surgery; results from CPAP incompletely reported									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Weaver, 2004			**Intervention 1**	UPPP
PMID*	15195049	**RefID**	4943	**Intervention 2**	
Key Question(s)	5			**Intervention 3**	
Design †	Cohort, retrospective			**Control**	CPAP
Extractor	si			**Comments**	Data obtained from VA Outpatient Care File (CPT codes, ICD-9); Patient Treatment File; Beneficiary Identification and Records Locator System Death File database

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
sleep apnea pts treated with CPAP or UPPP at VA facilities from 1997-2001; complete inpatient and outpatient admin records	nd	nd	1997-2001	y	US	govt	n	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	2072	97	51	82% white	nd	nd	nd	nd
Cx	18754	98	57	82% white	nd	nd	nd	nd
Total	20826	98	57	82% white	nd	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Comorbidity index**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	nd	nd	1.1	
Cx	nd	nd	nd	nd	nd	nd	2	
Total	nd	nd	nd	nd	nd	nd	2	
	Treatments used (prior to trial, including surgery)							
Tx	some had CPAP							
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	2072	nd	nd	nd	nd	nd	nd	
Control:	18754	nd	nd	nd	nd	nd	nd	
Total:	20826	nd	nd	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
nd	nd	nd	nd	nd	nd	nd	nd

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Surgery	UPPP		
2				
3				
Control	PAP	CPAP		
For CPAP:		**How was the Pressure selected?**	nd	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Death	Mortality		
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Weaver, 2004 US 15195049	Mortality Hazard CPAP vs. UPPP	**Tx**	UPPP	6 year										
		Cx	CPAP	6 year			HR	2.11	1.66-2.68		1.31	1.03-1.67	0.03	age at tx; sex, race, date tx initiated; and comorbidity
Weaver, 2004 US 15195049	Mortality Hazard age at tx vs. 1 yr prior	**Tx**	UPPP											

		Cx	CPAP				HR	1.07	1.07-1.08		1.06	1.06-1.07	<0.001	age at tx; sex, race, date tx initiated; and comorbidity
Weaver, 2004 US 15195049	Mortality Hazard male vs. female	**Tx**	UPPP											
		Cx	CPAP				HR	2.76	1.52-4.99		1.82	1.01-3.30	0.048	age at tx; sex, race, date tx initiated; and comorbidity
Weaver, 2004 US 15195049	Mortality Hazard white vs. non white	**Tx**	UPPP											
		Cx	CPAP				HR	1.16	1.00-1.35		0.98	0.84-1.13	0.77	age at tx; sex, race, date tx initiated; and comorbidity
Weaver, 2004 US 15195049	Mortality Hazard date of tx vs. 1 yr prior	**Tx**	UPPP											
		Cx	CPAP				HR	0.93	0.88-0.98		0.92	0.87-0.97	0.001	age at tx; sex, race, date tx initiated; and comorbidity
Weaver, 2004 US 15195049	Mortality Hazard comorbidity index vs. one less index score	**Tx**	UPPP											
		Cx	CPAP				HR	1.11	1.10-1.12		1.09	1.08-1.10	<0.001	age at tx; sex, race, date tx initiated; and comorbidity

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD*	Value	SD/SE*	P	Value	95%cl*	P
Weaver, 2004 US 15195049	survival	yr	**Tx**	UPPP	4 yr	2072			2.81	1.17				0.06	0.005,0.762	0.03
			Cx	CPAP	4 yr	20826			2.75	1.21						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
n	NA	NA	NA	nd	nd	nd	y	n	y	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y		n	y	n	nd				

Reasons for drop-outs:	
Other Issues:	VA databases analyses based on CPT and ICD-9 codes; no details on OSA severity; relatively short follow up
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Woodson, 2001			**Intervention 1**	temperature- controlled radiofrequency volumetric tissue reduction (RFVTR) of the tongue base
PMID*	11593163	**RefID**	4979	**Intervention 2**	
Key Question(s)	5 (surgery)			**Intervention 3**	
Design †	NRCS(prop)			**Control**	Nasal CPAP
Extractor	NO			**Comments**	

* or Cochrane number

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSAS AHI >15 to <60 BMI<35kg/m^2 18-60yrs Anesthesia risk group ASA class I, II, or III	Preexisting swallowing or speech disorder Sever unstable CVD Prior respiratory tract cancer Prior radiotherapy of respiratory tract Active upper respiratory tract infection Bleeding abnormalities Neurologic disorders Drug or alcohol abuse pregnancy	>15	nd	y	USA	Industry (Somnus Inc)	n	n	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):					No adjustment				

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx	**73(69)**	92	47.1(9.5)		30.6(4.1)			
Cx	**100(77)**	77	48.7(9.1)		31.2(4.8)			
Total	**173(146)**			nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify) prior pharyngeal surgery**	**Is this a Special Population? (which?)**
Tx							92.9	
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	Y(ASA class I,II, III)
	Treatments used (prior to trial, including surgery)							
Tx	UPP,Tonsillectomy, Turbinate reduction, septoplasty, lasser assisted uvulopalatoplasty, tongue suspension suture, hyoid suspension, palatoplasty, genioglossus advancement, tracheostomy, midline glossectomy							
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	50	40.5(21.5)	11.1					
Control:	74	nd	11.8					
Total:				nd	nd	nd	nd	nd

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify)	Other characteristics
nd	nd	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG			>10secs	Defined using subjects sleep lab [1]		nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation) [1]Authors disclose that there was a revision in definition of hypopnea during the study
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Surgery	temperature- controlled radiofrequency volumetric tissue reduction (RFVTR) of the tongue base	Somnoplasty system, (Sunnyvale, CA)	
2				
3				
Control	PAP	Nasal CPAP		
For CPAP:		**How was the Pressure selected?**	nd	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description
For CPAP:	**Describe the frequency of the initial education follow-up**

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1		Successful response	8-12 weeks	50% reduction in AHI and AHI<20/hr
2	QOl	SF36 vitality	8-12 weeks	
3	QOL	SF36 physical role functioning	8-12 weeks	
4	QOL	SF 36 mental health	8-12 weeks	
5	Sleepiness measure	FOS Q	8-12 weeks	
6	Sleepiness measure	ESS	8-12 weeks	
7	Sleep study measure	AHI	8-12 weeks	
8	Sleep study measure	Min o2 sat	8-12 weeks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
	Successful response	**Tx**	RFVTR		11		%	20						
		Cx	nCPAP											

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD*	Value	SD*	P	Value	SD/SE*	P
Woodson, 2001 11593163 USA	SF36 vitality		**Tx**	RFVTR	8-12 weeks	50	40.5	23.52	52.2	22.43	11.7	20.34		-8.7		0.0205
			Cx	nCPAP	8-12 weeks	74	31	21.96	52.4	24.02	20.4	20.18				
	SF36 physical role functioning		**Tx**	RFVTR	8-12 weeks	50	80.6	20.6	85.1	19.23	4.4	12.71		0.3		0.9124
			Cx	nCPAP	8-12 weeks	74	76.4	22.33	80.5	21.81	4.1	17.56				
	SF 36 mental health		**Tx**	RFVTR	8-12 weeks	50	71.7	16.83	74.9	16.32	3.2	16.67		-6.7		0.023
			Cx	nCPAP	8-12 weeks	74	64.7	19.13	74.5	17.56	9.9	15.36				
	Fos Q		**Tx**	RFVTR	8-12 weeks	18	72.3	13.8	80.1	13.7	7.8	9.1		-4.4	-10.2,1.4	0.14
			Cx	nCPAP	8-12 weeks	74	69.9	19.7	82.1	17.9	12.2	17.3				
	ESS		**Tx**	RFVTR	8-12 weeks	50	11.1		7.4		-3.7			0.7		nd
			Cx	nCPAP	8-12 weeks	74	11.8		7.4		-4.4					
	AHI	/ hr	**Tx**	RFVTR	8-12 weeks	50	40.5	21.5	32.8	22.6			0.01			
			Cx	nCPAP	8-12 weeks	74										
	Min o2 sat	%	**Tx**	RFVTR	8-12 weeks	50	80.6	8.8	82.2	7.1			NS			
			Cx	nCPAP	8-12 weeks	74										

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
surgery	15	Lost to follow up, withdrew from therapy, failed to receive post treatment PSG. One had interval UPPP during study

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	Subgroup analysis showed no difference between groups when patients were stratified by apnea severity (AHI<20,20-40 and >40), total energy delivered (<15000 J or >15000 J) and changes in BMI.

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			RFVTR			
Woodson, 2001 11593163 USA	Tongue abscess	6weeks	1 (1.1%)			
	Infection/cellulitis	6weeks	7 (2.0%)			
	Edema/ecchymosis	6weeks	3 (0.8%)			
	Thrush	6weeks	1 (0.3%)			
	Vasovagal reaction	6weeks	1 (0.3%)			
	Blindness (nontreatment related)	6weeks	1 (0.3%)			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
n	n	n	y	n		n	y	n	No	n

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	n	nd	na	na
Reasons for drop-outs:								
Other Issues:								
Overall Quality (A, B, C)		**C**						

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Woodson, 2003			**Intervention 1**	CPAP
PMID*	12825037	**RefID**	4977	**Intervention 2**	RFA (tongue & palate)
Key Question(s)	KQ 5 CPAP/RFA/Placebo			**Intervention 3**	
Design †	RCT			**Control**	Sham RFA
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA AHI 10-30 18-65 y Daytime somnolence	BMI >34 Prior surgery or CPAP Other sleep disorder Tonsillar hypertrophy Nasal or supraglottic obstruction ASA class IV/V Claustrophobia Latex allergy Pregnancy Major depression or nonstablized psychiatric disorder Drug or EtOH abuse Accident due to sleepiness	10-30 (or 5-40) [two parts of methods section disagree with each other]	nd	Yes	US	Industry	Yes 30/arm (1/SRT)	Yes (to RFA) CPAP patients not blinded	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx: CPAP	**30 (28)**	75	52	nd	29.1	nd	nd	nd
Tx: RFA	**30 (29)**	90	49		27.7			
Sham RF	**30 (30)**	70	46		28.5			
Total			P=0.04					
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	0 (eligibility)	nd	0 (eligibility)	nd	Restricted eligibility
Cx								
Total								
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	No CPAP or surgery							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Tx: CPAP	27	19.8±9.9	12.6±5.0	nd	nd	nd	nd	
Tx: RFA	29	21.3±11.1	11.9±4.6					
Sham RF	30	15.4±7.8	11.6±3.5					
Total		P=0.06						

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify)	Other characteristics
No	Neck circumference normal (~41 cm) Upper airway volume 73.6 cm^3	

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Home Autoset PDS or PSG	>5		Cessation of inspiratory airflow ≥10 sec	Reduction of airflow ≥10 sec with 4% desat or EEG arousal		Separate (auto-titrate)	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	nCPAP	Autoset T	
2	RFA	Temperature controlled RF tissue ablation		5 tongue and 2 palate sessions planned, at 4 week intervals Nonoverlapping lesions in 2 (1000 J) or 3 (750 J) sites. Target 85º C, Max 10 W. 1 midline (650 J) and 2 lateral (325 J) soft palate lesions per session
3				
Control		Sham RFA		Similar process for tongue only (3 "lesions"). No energy delivered. 3 sessions. Same anesthesia, medications, and probe insertion
For CPAP:		**How was the Pressure selected?**	Titrated unattended over ≥3 nights with AutoSet T device	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	nd. Seen at 1, 2 & 4 wk to troubleshoot & increase compliance

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Physical/Psychomotor	Slowest reaction time (SRT)	8 wk	Mean of slowest 10% of reaction times on the Psychomotor Vigilance Task (PVT-192). Analyzed as 1/SRT (larger values better).
2	QoL	Functional Outcomes of Sleep Questionnaire (FOSQ)		
3	QoL	Symptoms of Nocturnal Obstruction and Related Events (SNORE25) [Same as OSA Patient Oriented Severity Index]		
4	Sleepiness	Epworth Sleepiness Scale		
	QoL	SF-36 MCS & PCS		
	Sleep measure	AHI		
	Sleep measure	Minimum O2 saturation		
	Sleep measure	Total arousal index		
	Adverse events	Pain, swallowing problems	1 & 3 wk post-surgery	10 cm VAS (0=no pain, normal swallow)
	Adverse events	self-reported	8 wk	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed Base/Final	Baseline		Effect Size (F mean - Base mean)/ (Base SD) + improve ≥0.5 = ≥"moderate"		Change (Final – Baseline)			Net Δ (Δ test – Δ control)		
							Value	SD	Value		Value	SD	P	Value	95% CI	P
Woodson, 2003	AHI	/hr	Tx	CPAP	8 wk	27/	19.8	9.9			nd					
US			Tx	RFA		29/24	21.3	11.1	0.38		-4.5	13.8	NS	-2.7	(-9.9, 4.5)	NS
12825037			Cx	Sham RF		30/28	15.4	7.8	0.24		-1.8	11.5	NS			
	Min SaO2	%	Tx	CPAP	8 wk	27/	86.0	6.4			nd					
			Tx	RFA		29/24	86.3	7.6	-0.08		-0.6	4.6	NS	-1.2	(-3.8, 1.4)	NS
			Cx	Sham RF		30/28	88.3	3.9	0.15		0.6	4.7	NS			
nl <10	ESS		Tx	CPAP	8 wk	27/25	12.6	5.0	0.44		-2.3	5.2	0.02	-1.4	(-3.8, 1.1)	NS
			Tx	RFA		29/26	11.9	4.6	0.50		-2.1	3.9	0.005	-1.2	(-3.1, 0.8)	NS
			Cx	Sham RF		30/28	11.6	3.5	0.27		-1.0	3.1	NS	0.20	(-2.39,2.80)	NS
nl>17.8	FOSQ		Tx	CPAP	8 wk	27/25	16.0	2.6	0.61		1.5	2.1	0.02	1.2	(0.1, 2.3)	0.02
			Tx	RFA		29/26	16.5	2.0	0.66		1.2	1.6	0.005	0.9	(-0.1, 1.9)	0.04
			Cx	Sham RF		30/28	16.8	2.1	0.18		0.4	2.0	NS	-0.29	(-1.35, 0.77)	NS
	SNORE25		Tx	CPAP	8 wk	27/	1.5	0.6	0.46		-0.30	0.52	0.005	-0.09	(-0.39, 0.21)	NS
			Tx	RFA		28/	1.6	0.7	0.65		-0.43	0.56	<0.001	-0.22	(-0.53, 0.09	0.08
			Cx	Sham RF		30/	1.6	0.7	0.31		-0.21	0.56	0.06	-0.13	(-0.44, 0.18)	NS
Norm 50	SF36 MCS		Tx	CPAP	8 wk	27/24	47.2	10.5	0.22		2.0	6.1	NS	1.7	(-1.8, 5.2)	NS
			Tx	RFA		28/24	46.4	9.4	0.32		2.9	7.3	0.08	2.5	(-1.4, 6.4)	NS
			Cx	Sham RF		30/27	46.7	9.8	0.04		0.4	6.4	NS	0.83	(-3.07, 4.74)	ns
Norm 50	SF36 PCS		Tx	CPAP	8 wk	27/24	50.7	6.7	0.02		0.1	7.7	0.08	-1.4	(-5.8, 3.0)	NS
			Tx	RFA		28/24	50.1	8.3	0.06		0.5	6.8	NS	-1.0	(-5.1, 3.1)	NS
			Cx	Sham RF		30/27	19.9	8.0	0.18		1.5	7.8	NS	0.38	(-3.86, 4.62)	NS
nl≥2.88	1/SRT	1/msec	Tx	CPAP	8 wk	28/19	2.77	0.66	0.30		0.18	0.60	NS	0.12	(-0.26, 0.51)	NS
			Tx	RFA		29/23	2.71	0.69	0.42		0.32	0.57	0.006	0.27	(-0.09, 0.62)	0.07
			Cx	Sham RF		29/25	2.88	0.55	0.09		0.05	0.66	NS	-0.15	(-0.22, 0.52)	NS

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper
RFA versus (minus) CPAP

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Tx: CPAP	4/30 (13%)	1 withdrew prior to intervention, 2 found to have AHI>40, 1 lost to follow-up
Tx: RFA	4/30 (13%)	1 withdrew prior to intervention, 1 found to have AHI<5, 2 lost to follow-up
Sham RF	2/30 (7%)	1 withdrew prior to intervention, 1 lost to follow-up

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			CPAP	RFA	Sham RFA	
Woodson, 2003	Hematomas (% sessions)	1, 3 wk	NA	2.3% (3/26)	3.5% (3/28)	
US	Ulcerations (% of sessions)	same	NA	0.8% (1/26)	0	
12825037	Infections (% of sessions)	same	NA	0	0	
	(Pain & swallowing VAS reported but not extracted; hard to interpret)					
	Nasal dryness, congestion, bleeding or sinusitis	8 wk	38% (8/21)			
	Delayed sleep or subjective sleep fragmentation		43% (9/21)			
	Noise inconvenience and/or spouse objection		33% (7/21)			
	Aerophagia, Chest wall discomformt, or mouth breathing		33% (7/21)			
	Skin or eyes complaint		38% (8/21)			
	Total subjects affected by CPAP		95% (20/21)			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	Yes	Yes	Yes, but not CPAP	Yes	Yes	Yes (but not for baseline imbalances)	Yes	Not baseline imbalances	Except for AHI eligibility
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	No. AHI	No	Yes	No. Not scales	No (for CPAP)	Yes	NA			NA
Reasons for drop-outs:	See above									
Other Issues:	Extensive statistical methods section raises confidence that important issues were considered and dealt with appropriately									
Overall Quality (A, B, C)	**A (with caveat about AHI eligibility criteria)**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Zorick, 1990			**Intervention 1**	CPAP
PMID*	2086548	**RefID**	9998	**Intervention 2**	
Key Question(s)	5- CPAP vs Surgery			**Intervention 3**	
Design †	NRCS, prospective			**Control**	UPPP
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Excessive daytime sleepiness, loud snoring	nd	nd	Nd	N	USA	nd	n	No	no
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**46**	80%	51.7	Nd	38.3	Nd	Nd	Nd
Cx	**46**		47.2	nd	35.5	nd	nd	Nd
Total	**92**							
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	Nd	nd	Nd	nd	Nd	nd	Nd	No
Cx	nd	Nd	nd	Nd	nd	Nd	nd	no
Total								
	Treatments used (prior to trial, including surgery)							
Tx	Nd							
Cx	nd							
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	46	nd	nd	4.4 (average LAT)	nd	nd	nd	
Control:	46	nd	nd	4.1 (average LAT)	nd	nd	nd	
Total:								
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
Apnea index: 49.0 CPAP, 42.0 UPPP						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	nd	cessation of airflow and/or effort for 10 sec or more	50% reduction in airflow and/or effort for 10 sec or more	nd	split	classified as central apneas (cessation of both oronasal airflow and respiratory effort), obstructive apneas (cessasation of oronasal airflow with continued respiratory effort), or mixed apneas (episodes with central and obstructive components)

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Respironics Sleep Easy	nd
2				
3				
Control	surgery	UPPP	nd	nd
For CPAP:		**How was the Pressure selected?**	set at the lowest effective pressure to prevent airway obstruction during the 8-hour adjustment night	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	Respiratory index	6 wks	Nd
2	Sleep study measures	Apnea index	6 wks	Nd
3	Sleep study measures	% Stage 3/4 sleep	6 wks	
4	Sleep study measures	% Stage REM sleep	6 wks	
	Sleepiness measures	MSLT average LAT	6 wks	nd

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD*	Value	SD/SE*	Value	SD/SE*	P	Value	95% CI*	P
Zorick, 1990 USA 2086548	Respiratory index	Nd	**Tx**	CPAP	6 wk	46	76.0	23	7.0	9	-69	Nd		-41	-81.8,-0.2	<0.05
			Cx	UPPP	6 wk	46	71.0	30	43.0	30	-28	Nd				
	Apnea index	Nd	**Tx**	CPAP	6 wk	46	49.0	26	4.0	9	-45	Nd		-26	-51.8,-0.1	<0.05
			Cx	UPPP	6 wk	46	42.0	28	23.0	23	-19	Nd				
	% Stage 3/4 sleep	Nd	**Tx**	CPAP	6 wk	46	1.0	3	9.0	8	8	Nd		7	0.03,13.9	<0.05
			Cx	UPPP	6 wk	46	4.0	6	5.0	7	1	Nd				
	% Stage REM sleep	Nd	**Tx**	CPAP	6 wk	46	10.0	6	21.0	7	11	Nd		8	0.03,15.9	<0.05
			Cx	UPPP	6 wk	46	10.0	5	13.0	6	3	Nd				
	MSLT average LAT	nd	**Tx**	CPAP	6 wk	46	4.4	0.9	10.3	1.1	5.9	Nd		4.5	0.02,8.9	<0.05
			Cx	UPPP	6 wk	46	4.1	1.0	5.5	0.9	1.4	nd				

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
	nd	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
UPPP responders	Zorick, 1990 USA 2086548	Respiratory index	Nd	**Cx**	UPPP	6 wk	Nd	71.0	30	17.0	13	-54	Nd	nd			
		Apnea index	Nd	**Cx**	UPPP	6 wk	Nd	42.0	28	9.0	10	-33	Nd	nd			
		% Stage 3/4 sleep	Nd	**Cx**	UPPP	6 wk	Nd	4.0	6	8.0	9	4	Nd	nd			
		% Stage REM sleep	Nd	**Cx**	UPPP	6 wk	Nd	10.0	5	15.0	6	5	Nd	nd			
		MSLT average LAT	nd	**Cx**	UPPP	6 wk	Nd	4.1	1.0	8.5	1.1	4.4	Nd	nd			
UPPP nonresponders	Zorick, 1990 USA 2086548	Respiratory index	Nd	**Cx**	UPPP	6 wk	Nd	71.0	30	67.0	19	-4	Nd	nd			
		Apnea index	Nd	**Cx**	UPPP	6 wk	Nd	42.0	28	37.0	23	-5	Nd	nd			
		% Stage 3/4 sleep	Nd	**Cx**	UPPP	6 wk	Nd	4.0	6	2.0	4	-2	Nd	nd			
		% Stage REM sleep	Nd	**Cx**	UPPP	6 wk	Nd	10.0	5	12.0	6	2	Nd	nd			
		MSLT average LAT	nd	**Cx**	UPPP	6 wk	nd	4.1	1.0	3.0	0.8	-1.1	Nd	nd			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
n	NA	NA	Nd	N	N	Nd	Y	NA	nd	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	n	y	n	n	n	n	NA	NA

Reasons for drop-outs:	Nd
Other Issues:	Non-randomized study missing much information (exclusion criteria, definitions of outcomes, adverse events, etc)
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Question 5
Drugs

A.

Author, Year	Carley, 2007			**Intervention 1**	Mirtazapine 4.5 mg
PMID*	17310863	**3137**		**Intervention 2**	Mirtazapine 15 mg
Key Question(s)	KQ% Drugs			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	Placebo
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA, newly confirmed No previous treatment	CV, endocrine hematologic, metabolic, neurologic, psychiatric, pulmonary, renal, non-OSA sleep disorders HTN medication (other than diuretics) Pregnancy, EtOH or drug abuse, night shift work w/in 6 mo, CNS-active drug, Serotonergic drug	AASM 1999	nd	No	US	Pharmaceutical		Yes	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**12 (12)**	58%	41 (18-67)	nd	37.8	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								(Most hypertensives excluded)
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	None							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	12	Men: 22.0±11.2 Wom: 24.1±22.8	nd	nd	nd	nd	New diagnosis	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	AASM 1999	>3%	Oronasal airflow decreased by >90%	Airflow decreased 50-90% >3% desat, or arousal	No	NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Drug	Mirtazapine4.5 mg	Remeron	30 min pre-bedtime
2	Drug	Mirtazapine15 mg	Remeron	
3				
Control		Placebo		
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep measure	Sleep efficiency	7 d	% total sleep time
2	Sleep measure	Stage 3-4		% total sleep time
3	Sleep measure	REM		%
4	Sleep measure	Arousal index		
	Sleep measure	AHI		
	Sleep measure	Minimum SaO2		
	Sleep measure	ODI		
	Sleepiness	Stanford Sleepiness Scale		q2 hr while awake 1 (alert, wide awake, energetic) 7 (cannot stay awake, sleep onset soon)

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference Final (F test – Fcontrol)		
							Value		Value	SEM	Value	SD/SE*	P	Value	SD/SE*	P
Carley, 2007	Sleep efficiency	%	**Tx**	Mirtazapine 4.5 mg	7 days	12	nd		87.7	4.9						NS
US			**Tx**	Mirtazapine 15 mg		12			90.1	3.4						0.05
17310863			**Cx**	Placebo		12			82.9	6.4						
	Stage 3-4	%	**Tx**	Mirtazapine 4.5 mg	7 days	12	nd		7.5	1.8						NS
			Tx	Mirtazapine 15 mg		12			7.2	2.2						NS
			Cx	Placebo		12			5.1	1.9						
	REM	%	**Tx**	Mirtazapine 4.5 mg	7 days	12	nd		15.6	1.3						NS
			Tx	Mirtazapine 15 mg		12			22.2	1.6						0.04
			Cx	Placebo		12			16.6	2.2						
	Arousal index	/hr	**Tx**	Mirtazapine 4.5 mg	7 days	12	nd		41.9	9.4						NS
			Tx	Mirtazapine 15 mg		12			28.1	6.7						0.02
			Cx	Placebo		12			41.1	7.2						
	AHI	/hr	**Tx**	Mirtazapine 4.5 mg	7 days	12	nd		13.5	3.7						0.004
			Tx	Mirtazapine 15 mg		12			11.4	3.6						0.004
			Cx	Placebo		12			22.3	4.8						
	Min SaO2	%	**Tx**	Mirtazapine 4.5 mg	7 days	12	nd		81.1	2.7						NS
			Tx	Mirtazapine 15 mg		12			80.8	2.5						NS
			Cx	Placebo		12			81.7	2.3						
	ODI	/hr	**Tx**	Mirtazapine 4.5 mg	7 days	12	nd		10.6	3.7						NS
			Tx	Mirtazapine 15 mg		12			8.1	3.1						0.04
			Cx	Placebo		12			19.1	4.8						
	Stanford SS		**Tx**	Mirtazapine 4.5 mg	7 days	12	nd		2.18	0.30						NS
			Tx	Mirtazapine 15 mg		12			2.24	0.33						NS
			Cx	Placebo		12			2.62	0.34						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	None					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	Yes	Yes	Yes	Yes	Yes (all)	Yes	NA	nd	Yes
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Yes	No	Yes	Yes	No (measured but not reported)	NA	No			Probably (no washout)
Reasons for drop-outs:	NA									
Other Issues:										
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments
The reader needs to be aware of the following information. On June 27, 2006, Cypress Bioscience Inc. announced "that the results of recently completed Phase IIa trials do not support continuing a development program evaluating combinations of mirtazapine with another approved drug as potential pharmaceutical treatments for obstructive sleep apnea (OSA). Cypress and Organon, the human healthcare business unit of Akzo Nobel, had each independently conducted Phase IIa trials that served as the basis for today's announcement. A previous independently conducted small preliminary investigator sponsored pilot trial found that mirtazapine was able to reduce the number of abnormal respiratory events over the course of the night by roughly fifty percent. However, those data were not replicated in the recently completed phase IIa trials." (source: http://cypressbio.com/news/20060627.pdf)

A.

Author, Year	Clarenbach, 2008			**Intervention 1**	Xylometazoline
PMID*	18710420	**RefID**	11153	**Intervention 2**	
Key Question(s)	KQ 5 Medication			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	Placebo
Extractor	EMB			**Comments**	ClinicalTrials.gov identifier is NTC00630474.

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA Chronic nasal congestion (impaired nasal breathing that interfered with subjective sleep quality ≥3 noc/wk x 3 mo Age 20-75 (CT.gov)	Nasal surgery w/in 6 mo Current nasal decongestant or steroid Other sleep disorders Medical or psych disorders that interfered with sleep	>10	2004-2005 (From clinicaltrials.gov)	No	Switzerland	Gov't Lung advocacy group Non-industry	Yes (AHI, sleep efficiency, ESS)	Yes	Yes ("Double blind")
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**12 (12)**	87%	49	nd	30.7	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	No
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	12	32.6	11.8	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
Nasal congestion 100%								

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG (implied)	>10	no	>50%, >10 s	nd	ESS>8 Excessive daytime sleepiness	NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Medication	Xylometzoline 0.1% 3gtt (0.15 mg) each nostril at bedtime		1 week
2				
3				
Control	Placebo			
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	1 week	
2	Sleep quality	ESS		
3	Sleep study measure	Sleep efficiency		% sleep of time in bed
4	Sleep study measure	Stage 3 / 4		
	Sleep study measure	REM sleep		
	Sleep study measure	Arousal index		events/hr Sleep Disorders Atlas Task Force of the American Sleep Disorders Association EEG Arousals., 1992
	Sleep measure	Vigilance	4 x during day after PSG	Oxford Sleep Resistance Test (OSLER)

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference (Final test – Final control)*		
							Value	SD	Value	SD	Value	SD/SE*	P	Value	SD	P
Clarenbach, 2008	AHI		**Tx**	Xylometazoline	1 wk	12	32.6	24.5	29.3	32.5				-2.9		NS
Switzerland			**Cx**	Placebo		12			32.2	32.8						
18710420																
	Sleep efficiency	%	**Tx**	Xylometazoline	1 wk	12	nd		86	12				-2		NS
			Cx	Placebo		12			88	6						
	Sleep stage 3/4	%	**Tx**	Xylometazoline	1 wk	12	nd		9	8				-2		NS
			Cx	Placebo		12			7	6						
	Sleep stage REM	%	**Tx**	Xylometazoline	1 wk	12	nd		10	5				-1		NS
			Cx	Placebo		12			11	5						
	Arousal index	/hr	**Tx**	Xylometazoline	1 wk	12	nd		54	12				-2		NS
			Cx	Placebo		12			56	12						
	ESS		**Tx**	Xylometazoline	1 wk	12	11.8	4.5	10.5	3.8				-1.3		NS
			Cx	Placebo		12			11.8	4.4						
	Sleep resistance	min	**Tx**	Xylometazoline	1 wk	12	nd		33.6	8.8				+0.2		NS
			Cx	Placebo		12			33.4	10.1						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
	None	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd (cross-over)	nd	Yes	Yes	Yes	all analyzed	For final values, yes. But no baseline data for most outcomes	NA	Yes
	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?		If a Crossover study, was the Washout period adequate?
	Yes	No	Yes	Yes	No	NA	Yes		Yes (short acting drug)
Reasons for drop-outs:	NA								
Other Issues:									
Overall Quality (A, B, C)	**A**								

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Kiely, 2004			**Intervention 1**	Fluticasone
PMID*	14694248	**RefID**	4438	**Intervention 2**	
Key Question(s)	KQ5 Drug			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	Placebo
Extractor	EMB			**Comments**	Subgroup of non-apneic snorers not extracted here

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Apneic snorers	Fixed nasal obstruction Other medication that could influence nasal patency (eg, antihistamines, decongestantts)	≥10 (subgroup analysis ≥5)	nd	No	Ireland	Pharmaceutical	No	Yes	Yes (PSG)
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**13 (13)**	nd	47	nd	29.8	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	Snorers
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	None (implied)							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	13	median 26.5	mean 12	nd	100%	nd	New	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
						FEV1 103% (of predicted) FVC 103% FEV1/FVC 103% Nasal airflow resistance 3.64 cm H20/L/sec		

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥10 (subgroup analysis ≥5)		nd	nd		NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Drug	Fluticasone 100 µg 2x daily		
2				
3				
Control		Matching placebo		
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	4 wk	
2	Sleep study measure	Sleep efficiency		Total sleep time / total sleep period time
3	Sleep study measure	Stage 3		
4	Sleep study measure	Stage 4		
	Sleep study measure	REM		
	Sleep study measure	Minimum SaO2		
	Sleepiness	Daytime alertness		4-point scale (1: best positive/least severe; 4: most negative/most severe), measured daily wk 2-4
	Sleep quality	Subjective sleep quality		ditto

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference Final (F test – F control)*		
							Median	Quartile range	Median	Quartile range	Value	SD/SE*	P	Value	95% CI	P †
Kiely, 2004	AHI (base AHI≥10)		**Tx**	Fluticasone 100 µg 2x daily	4 wk	13	26.5	26.9	23.3	21.3				-6.5 (median)	-29.5, +1.8	<0.05
Ireland			**Cx**	Placebo		13			30.3	31.9						
14694248																
	AHI (base AHI≥5)		**Tx**	Fluticasone 100 µg 2x daily	4 wk	18	nd		17	23.6				-5.6 (median)	-22.6, -0.7	0.01
			Cx	Placebo		18			24.3	28.4						
	TST/TOT	%	**Tx**	Fluticasone 100 µg 2x daily	4 wk	13	nd		91.7	10.2				0		NS
			Cx	Placebo		13			91.7	6.1						
	Stage 3	%	**Tx**	Fluticasone 100 µg 2x daily	4 wk	13	nd		7.4	11.0				+1.7		NS
			Cx	Placebo		13			5.1	8.7						
	Stage 4	%	**Tx**	Fluticasone 100 µg 2x daily	4 wk	13	nd		0	5.9				-5.5		NS
			Cx	Placebo		13			5.5	12.2						
	REM	%	**Tx**	Fluticasone 100 µg 2x daily	4 wk	13	nd		10.9	8.0				+0.4		NS
			Cx	Placebo		13			10.5	4.2						
	Min SaO2	%	**Tx**	Fluticasone 100 µg 2x daily	4 wk	13	nd		78	11.5				0		NS
			Cx	Placebo		13			78	14						
	Daytime alertness	scale	**Tx**	Fluticasone 100 µg 2x daily	4 wk	13	nd		2.1	0.7				-0.1		NS
			Cx	Placebo		13			2.2	0.7						

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference Final (F test – F control)*		
							Median	Quartile range	Median	Quartile range	Value	SD/SE*	P	Value	95% CI	P †
	Subjective Sleep Quality	scale	**Tx**	Fluticasone 100 µg 2x daily	4 wk	13	nd		1.7	1.0				-0.1		NS
			Cx	Placebo		13			1.8	1.1						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper
† By Wilcoxon matched pairs test

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
	None	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	NA	Yes	Yes	Yes	No	Maybe (nonparametric on final values)	NA	NA	Yes (except medians analyzed)

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	Yes	No	Yes	Not scales (what were the questions?	No	NA	No	Yes (essentially 1 week)

Reasons for drop-outs:	One subject (nd whether apeneic) excluded because violated protocol.
Other Issues:	Subgroup analysis of study including non-apneic snorers
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Kraiczi, 1999			**Intervention 1**	paroxetine
PMID*	9989366	**RefID**	11437	**Intervention 2**	
Key Question(s)	5- Rx v Cx			**Intervention 3**	
Design †	Randomized cross-over			**Control**	placebo
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Age 25-65; ODI≥10	Known psychiatric disease, regular intake of CNS-active drugs, symptomatic coronary heart disease, intolerance to paroxetine, alcohol or drug abuse, as well as general reasons for ineligibility as judged by the investigators	nd	nd	N	Sweden	Swedish Medical Research Council, the Medical Faculty of Goteborg University, the Swedish Heart and Lung Foundation and Novo Nordisk	Based on the treatment variability observed and the number of 17 patients completing both treatment periods, power of the corresponding tests was 80%.	y	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**20 (20)**							
Cx	**20 (20)**							
Total	**20 (20)**	100	52.7	nd	28.7	nd	nd	Nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	20							
Control:	20							
Total:	20	nd	nd	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
ODI = 25.4						nd		nd

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd	≥10/hr	episodes lasting 10 seconds or longer with airflow cessation associated with a desaturation of hemoglobin oxygen of at least 4%.	Reductions of the thermistor signal amplitude by at least 50%	nd	NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Other	Paroxetine	Seroxat, Novo Nordisk	Serotonin uptake inhibitor
2				
3				
Control	other	placebo		
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1		Sleep efficiency	6 wk	
2		Stage 3+4 sleep	6 wk	
3		REM sleep	6 wk	
4		AHI	6 wk	
5		CPRS symptom score	6 wk	Comprehensive Psychopathological Rating Scale- assesses psychotic, mood and neurotic disorders

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Final test - control		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	95%CI	P
Kraiczi, 1999 Sweden 9989366	Sleep efficiency	%	Tx	Paroxetine	6 wk	17	Nd	Nd	77.2	13.3	nd	nd	Nd	Nd	(-10.6,4.3)	0.411
			Cx	Placebo	6 wk	17	Nd	nd	80.3	17.1	Nd	nd	nd			
	Stage 3+4 sleep	%	Tx	Paroxetine	6 wk	17	Nd	Nd	12.2	9.2	nd	nd	Nd	Nd	(-6.4,4.7)	0.778
			Cx	Placebo	6 wk	17	Nd	nd	12.8	11.5	Nd	nd	nd			
	REM sleep	%	Tx	Paroxetine	6 wk	17	Nd	Nd	9.7	6.7	nd	nd	Nd	Nd	(-7.4,1.4)	0.191
			Cx	Placebo	6 wk	17	Nd	nd	12.9	6.8	Nd	nd	nd			
	AHI	Events/hr	Tx	Paroxetine	6 wk	17	Nd	Nd	30.2	18.5	nd	nd	Nd	Nd	(-17.9,0.6)	0.021
			Cx	Placebo	6 wk	17	Nd	nd	36.3	24.7	Nd	nd	nd			
	CPRS Symptom Score	#	Tx	Paroxetine	6 wk	17	Nd	Nd	5.3	4.8	nd	nd	Nd	Nd	(-8.3,1.1)	0.138
			Cx	Placebo	6 wk	17	Nd	nd	9.3	9.5	Nd	nd	nd			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
paroxetine	15%	Fatigue, patient feeling better on treatment

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			Paroxetine	placebo		
Kraiczi, 1999 Sweden 9989366	Dizziness	6 wk	5.9%	5.9%		
	Fatigue	6 wk	11.8%	5.9%		
	Dryness of the mouth	6 wk	0%	5.9%		
	Somnolence	6 wk	5.9%	5.9%		
	Ejaculation disturbances	6 wk	17.6%	0%		
	Decreased libido	6 wk	11.8%	0%		
	nervousness	6 wk	5.9%	0%		
	Constipation	6 wk	5.9%	0%		
	Headache	6 wk	5.9%	0%		
	Infectious pneumonia	6 wk	5.9%	0%		
	Lyme disease	6 wk	5.9%	0%		
	sweating	6 wk	5.9%	0%		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	y	y	y	y	Y	y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	NA	Y			y

Reasons for drop-outs:	Fatigue, feeling better on treatment
Other Issues:	Good quality but relatively small crossover study
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Ryan, 2009			**Intervention 1**	humidified CPAP
PMID*	19961025	**RefID**	125	**Intervention 2**	steroid CPAP
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA with AHI ≥10; successful CPAP titration study; adequate nasal breathing	prior CPAP; required bilevel CPAP; supplemental O2; malignancy; psychiatric illness; regular narcotics, sedatives, or psychoactive meds	≥10	nd	no	Ireland	industry supplied CPAP devices and steroid	yes; 38 per group	no	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx1	**42**	95	50		35.3±6.1			
Tx2	**42**	95	48		33±5.3			
Cx	**39**	92	48		35.1±6.4			
Total	**123 (112)**	94	49	nd	34.4	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx1		31						
Tx2		31						
Cx		21						
Total	nd	28 (current)	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx1								
Tx2								
Cx								
Total	no prior CPAP							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	42	36±20	13±6					
Tx2	42	35±21	13±6					
Control:	39	36±22	12±5					
Total:	123	35.7	12.7	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
nd	nd	nd	nd	nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP + heated humidfication	humidifier HA 50 (Breas Medical, Sweden) + PV10 (Breas Medical)	
2	PAP	CPAP + nasal steroid	fluticsasone 50 mcg 2x daily (Glaxo Wellcome, spain) + PV10	
3				
Control	PAP	dry CPAP only	PV10	
For CPAP:		**How was the Pressure selected?**	nd	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	QoL	SF-36; Mini Rhinoconjunctivitis QoL	baseline, 4 wk	MiniRQLQ (14 items in 5 domains; 0 (no impairment) to 6 (severely impaired))
2	Sleepiness measures	Epworth	baseline, 4 wk	
3	Compliance	mean h per night use	4 wk	
4				

* QoL; ; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Ryan, 2009 Ireland 19961025	Epworth		**Tx1**	humidified CPAP	4 wk	42 (?)	13	6	8	6				-2	1.22	ANOVA P=0.694
			Tx2	steroid + CPAP	4 wk	42 (?)	13	6	9	5						
			Cx	dry CPAP	4 wk	39 (?)	12	5	9	5						
Ryan, 2009 Ireland 19961025	Compliance	h per night	**Tx1**	humidified CPAP	4 wk	42 (?)	NA		5.21	1.84				0	0.275	NS
			Tx2	steroid + CPAP	4 wk	42 (?)	NA		5.66	1.68						
			Cx	dry CPAP	4 wk	39 (?)	NA		5.21	1.66						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Intervention 3		Favors**		If Significant Difference		
				Name	N	Name	N	Name	N	Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Ryan, 2009 Ireland 19961025	SF-36		4 wk	humidified CPAP	42 (?)	steroid + CPAP	42 (?)	dry CPAP	39 (?)	0				
Ryan, 2009 Ireland 19961025	MiniRQLQ	activity limitations	4 wk	humidified CPAP	42 (?)	steroid + CPAP	42 (?)	dry CPAP	39 (?)	0				
		practical problems								0				
		eye limitations								0				
		nose symptoms								humidifier vs. steroid (P=0.008)	1.27±1.15 vs. 2.16±1.48 vs. 1.56±1.22 (ANOVA, P=0.009)	6	0	
		other symptoms								0				

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
nasal CPAP	10/123	5 intolerant to treatment; 5 unknown reasons
	1/123	myocardial infarction 10 d after enrollment
dry CPAP or humidity CPAP	8/81	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
u	nd	nd	y	n	nd	y	y/n	n	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	y				
Reasons for drop-outs:										
Other Issues:	no details on randomization; no adjustment for multiple comparisons									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Suurna, 2008			**Intervention 1**	pantoprazole
PMID*	18656731	**RefID**	3856	**Intervention 2**	
Key Question(s)	5- Rx v Cx			**Intervention 3**	
Design †	Randomized cross-over			**Control**	placebo
Extractor	KP			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
-history of GERD and mild to moderate obstructive sleep disordered breathing -ESS ≥8 -mild to moderate obstructive sleep disordered breathing (AHI ≤30) -typical symptoms and findings of GERD (acid regurgitation or heartburn)	-sleep disorders other than obstructive sleep disordered breathing -AHI>30 -absence of typical GERD findings and symptoms -acid reflux therapy within 1 month (proton pump inhibitors or histamine receptor type 2 blocker) -allergy to proton pump inhibitor; other treatment of obstructive sleep apnea (surgery or device)	Nd	Feb 2004 – Aug 2006	N	US	Wyeth Pharmaceuticals	effect size of 0.5 for ESS change. Based on the assumption that alpha is 0.05, beta is 0.2 (80% power), and effect size difference of 0.5 for ESS, the sample size was estimated at 68 subjects after accounting for an expected 10 percent dropout rate	Y	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx	**57**							
Cx	**57**							
Total	**57**	42	51	Nd	31	Nd	Nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	Nd	Nd	100%	Nd	Nd	Nd	Nd	All patients have GERD
	Treatments used (prior to trial, including surgery)							
Tx	nd							
Cx	nd							
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	57							
Control:	57							
Total:	57	10	14	Nd	Nd	Nd	Nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
Nd						Nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	Mild to moderate – AHI≤30	Nd	Nd	Nd	Nd	NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	other	Pantoprazole	Wyeth	40 mg once daily
2				
3				
Control	Other	placebo		
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	ESS	Baseline, 2 wks	
2	General symptom scales	FOSQ	Baseline, 2 wks	
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD	Value	95%CI	P	Value	SD	P
Suurna, 2008 USA	ESS	Numbers on a scale	Tx	pantoprazole	2 wk	57	14	3.5	12.2	Nd	-1.8	(-3.0,-0.5)	0.04	-0.5	nd	0.04
			Cx	placebo	2 wk	57	14	3.5	12.7	Nd	-1.3	(-2.1,-0.4)	0.0066			
	FOSQ	Numbers on a scale	Tx	pantoprazole	2 wk	57	nd	Nd	48.9	Nd	-8.1	(-11.1,-4.9)	<0.0001	-2.6	nd	0.06
			Cx	placebo	2 wk	57	nd	nd	51.5	nd	-5.5	(-9.1,-1.8)	0.0045			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
All	16.2%	nd

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	y	y	Y	y	y	y	NA	nd	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a over study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	n	y	N	NA	y			Y
Reasons for drop-outs:	nd									
Other Issues:	No adverse event data, no reasons given for drop out									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Whyte, 1988			**Intervention 1**	Acetazolamide
PMID*	3067313	**RefID**	16941	**Intervention 2**	Protriptyline
Key Question(s)				**Intervention 3**	
Design †	Cross over(Medication)			**Control**	Placebo
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Patients who failed to respond to weight reduction and alcohol avoidance OSAHS AHI>15 At least two supporting sleep apnea symptoms(daytime somnolence, recurrent nocturnal awakening, unsatisfying nocturnal sleep)	nd	>15	nd	n	UK	nd	n	y	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**10(10)**	80	34-67 years	nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	10	>15	nd	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>15		10secs	≥ 50% reduction in thoraco abdominal movement	Excessive daytime sleepiness Recurrent nocturnal awakenings	na	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Medication	Acetazolamide 250mg twice daily for one week then 250 mg 4 times daily for 1 week		
2	Medication	Protryptyline 20mg at night for 2 weeks		
3				
Control	Placebo	Placebo		nd
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1		Arousals	2weeks	
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Whyte, 1988 UK 3067313	Arousals		Tx	Acetazolamide	2weeks				26	26						
			Tx	Protriptyline	2weeks				21	11						
			Cx	placebo	2weeks				16	10						
	AHI		Tx	Acetazolamide	2weeks				26	20						
			Tx	Protriptyline	2weeks				46	23						
			Cx	placebo	2weeks				50	26						
	Sleep efficiency		Tx	Acetazolamide	2weeks				~80							
			Tx	Protriptyline	2weeks				~82							
			Cx	placebo	2weeks				~70							
	REM		Tx	Acetazolamide	2weeks				23	8						
			Tx	Protriptyline	2weeks				18	12						
			Cx	placebo	2weeks				19	8						
	Stage 3 and 4		Tx	Acetazolamide	2weeks				~15							
			Tx	Protriptyline	2weeks				~14							
			Cx	placebo	2weeks				~15							

* some figures were approximated from tables
Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			Protriptyline	Acetazolamide		
Whyte, 1988 UK **3067313**	Dose dependent dry mouth		2/10	Present(no data on number affected)		
	Visual upset		1/10			
	Urinary symptoms		1/10			
	Paraesthesia			8/10		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	n	y	y	y	n	y	na	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	n	Y(no information on exclusion criteria, not sure how 10 patients were selected)	y	y	?	na	n	nd

Reasons for drop-outs:	
Other Issues:	
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Question 5
Complementary & Alternative Medicine

A.

Author, Year	Freire, 2006			**Intervention 1**	Acupuncture
PMID*	17023212	**RefID**	3288	**Intervention 2**	Sham acupuncture
Key Question(s)	KQ 5 CAM			**Intervention 3**	
Design †	RCT			**Control**	No treatment
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA Acupuncture-naïve	High EtOH intake Morbid obesity Lung, neurological disease Intellectual deficits Facial skeletal abnormalities Central SA Hypnotic drugs Orofacial surgery h/o CPAP or oral devices	15-30 (moderate)	2002-2004	No	Brazil	Government	Yes (N~24); specific outcome not reported	Yes (acupuncture vs sham acupuncture)	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?)	AFib/AFlutter, %	CVD †, % (specify)
Tx Ac	**12 (12)**	nd	54, median	nd	26.9, median	nd	nd	nd
Tx Sh	**12 (12)**		53		25.7			
Cx	**12 (12)**		57		28.6			
Total		44%						
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	No
	Treatments used (prior to trial, including surgery)							
Tx								
Tx								
Cx								
Total	None							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Acup:	12	18.0, median	11.1					
Sham:	12	19.0	12.7					
Control:	12	19.1	11.0					
Total:				nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	Moderate: 15-30		>10 sec	≥3% desaturation or microarousal ≥10 sec	No	NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	CAM	Acupuncture		Preset acupuncture sites, needle manipulation, 10 sessions (1/wk)
2	Control	Sham acupuncture		Same number of needles, near but not at sites, no needle manipulation, 10 sessions (1/wk)
3				
Control	No treatment			Weight loss and/or sleep hygiene counselling
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	QoL	SF-36	12 wk	
2	Sleep quality	ESS		
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD	Value	SD	P	Value	SD	P
Freire, 2006	ESS		**Tx**	Acupuncture	12 wk	10	11.1	3.3	7.5	3.0	-3.6		.03			<.05 v Cx NS v Sh
Brazil			**Tx**	Sham Acup		7	12.7	4.3	13.1	5.0	0.4		NS	-4		
17023212			**Cx**	No Tx		9	11.0	5.7	13.3	7.0	2.3		.047	-5.9		
	SF36 PF		**Tx**	Acupuncture	12 wk	10	65.4	26.0	69.5	22.0	4.1		NS			NS
			Tx	Sham Acup		7	70.7	22.0	71.4	24.0	0.7		NS	3.4		
			Cx	No Tx		9	52.8	25.0	57.8	23.0	5		NS	-0.9		
	SF36 RP		**Tx**	Acupuncture	12 wk	10	52.5	44.8	72.5	40.0	20		.03			<.05 v Cx NS v Sh
			Tx	Sham Acup		7	71.4	41.9	75.0	25.0	3.6		NS	16.4		
			Cx	No Tx		9	38.9	46.9	33.3	41.0	-5.6		NS	25.6		
	SF36 GH		**Tx**	Acupuncture	12 wk	10	50.6	16.7	69.9	21.0	19.3		.03			<.05 v Cx NS v Sh
			Tx	Sham Acup		7	69.9	11.1	70.0	20.0	0.1		NS	19.2		
			Cx	No Tx		9	41.4	22.3	46.9	19.0	5.5		NS	13.8		
	SF36 Pain		**Tx**	Acupuncture	12 wk	10	62.1	19.7	71.8	24.3	9.7		NS			NS
			Tx	Sham Acup		7	73.4	14.9	72.4	16.3	-1		NS	10.7		
			Cx	No Tx		9	60.6	18.5	57.2	16.0	-3.4		NS	13.1		
	SF36 Vital		**Tx**	Acupuncture	12 wk	10	36.5	25.0	56.5	25.0	20		.03			<.05 v Cx NS v Sh
			Tx	Sham Acup		7	58.6	26.0	65.0	18.0	6.4		NS	13.6		
			Cx	No Tx		9	45.0	17.0	43.3	14.0	-1.7		NS	21.7		
	SF36 SF		**Tx**	Acupuncture	12 wk	10	60.0	29.3	67.5	24.0	7.5		NS			NS
			Tx	Sham Acup		7	73.2	24.4	75.0	26.0	1.8		NS	5.7		
			Cx	No Tx		9	62.5	27.2	68.1	23.0	5.6		NS	1.9		
	SF36 RE		**Tx**	Acupuncture	12 wk	10	53.3	44.9	73.3	34.0	20		NS			NS
			Tx	Sham Acup		7	61.9	40.5	66.7	43.0	4.8		NS	15.2		
			Cx	No Tx		9	37.0	48.4	44.4	44.0	7.4		NS	12.6		
	SF36 MH		**Tx**	Acupuncture	12 wk	10	50.4	23.1	68.4	21.0	18		.005			<.05 v Cx NS v Sh
			Tx	Sham Acup		7	70.3	15.5	81.7	15.0	11.4		.04	6.6		<.05 v Cx
			Cx	No Tx		9	55.6	17.9	52.0	16.0	-3.6		.03	21.6		

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD	Value	SD	P	Value	SD	P
	Sleep efficiency	%	**Tx**	Acupuncture	12 wk	10	79.4	9.2	85.7	11.0	6.3		.03			NS
			Tx	Sham Acup		7	75.9	5.6	86.6	9.0	10.7		.02	-4.4		
			Cx	No Tx		9	80.3	12.6	89.9	6.2	9.6		.04	-3.3		
	REM stage	%	**Tx**	Acupuncture	12 wk	10	16.5	6.6	20.1	6.8	3.6		NS			NS
			Tx	Sham Acup		7	16.6	5.3	13.8	4.8	-2.8		NS	6.4		
			Cx	No Tx		9	14.9	4.2	15.4	5.0	0.5		NS	3.1		
	AHI		**Tx**	Acupuncture	12 wk	10	19.9	4.1	10.1	5.6	-9.8		.005			.002 v Cx <.05 v Sh
			Tx	Sham Acup		7	21.6	5.3	24.6	11.0	3		NS	-12.8		
			Cx	No Tx		9	20.4	4.4	28.2	18.0	7.8		NS	-17.6		
	Microarousal	#	**Tx**	Acupuncture	12 wk	10	102.1	44.6	85.3	20.0	-16.8		NS			NS
			Tx	Sham Acup		7	140.7	52.3	164.7	89.0	24		NS	-40.8		
			Cx	No Tx		9	141.7	76.1	160.7	102.0	19		NS	-35.8		

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Total	28%	7: long travel distance or length of study; 1: started acupuncture for pain; 2: stopped sham acupuncture (nd)
Acupuncture	17%	2/12
Sham	42%	5/12
No treatment	25%	3/12

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	None					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	Yes	No	Yes (v Sham)	Yes	No	Yes	No, given unequal, large dropout	Yes
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**			
	Yes	Yes, due to dropouts	Yes	Yes	No				

Reasons for drop-outs:	See above
Other Issues:	Unequal dropouts. Controls had lower baseline QoL and other features. N<10 per arm final
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention for quality to be A
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Wang, 2009			**Intervention 1**	CAM: Auricular plaster therapy
PMID*	19514178	**RefID**	3942	**Intervention 2**	
Key Question(s)	KQ 5 CAM			**Intervention 3**	
Design †	RCT			**Control**	Control
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Obstructive sleep apnea	Previous treatment. No severe obstruction of pharyngeal cavit	≥5	nd	No	China	nd	nd	No	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**30 (30)**	100	48 (range, 27-72)	(Chinese)				
Cx	**15 (15)**	93%	45 (32-69)					
Total					nd	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	No
	Treatments used (prior to trial, including surgery)							
Tx	20% tonsillectomy. No other							
Cx	20% tonsillectomy. No other							
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	30	72.4	nd	nd	nd	nd	16.5 (range 2-35) y	
Control:	15	73.5					14 (2-25) y	
Total:								
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥5	NA	≥10 s	≥4% decrease in SO2	No	NA	or apnea and hypoventilation ≥30 times in 7 hr

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	CAM	Auricular plaster therapy		Applied to various auricular points pressed 3-5 times a day, 10-20 pressings each time
2				
3				
Control		Vitamin C 100 mg 3x/d		
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	10 days	
2	(Symptoms)	Snoring, dizziness, lethargy, "oppressed feeling in the chest", pharyngeal obstruction, nocturnal urination		Not extracted because nd for control group ("unchanged")
3	(Sleep study measure)	(Sleep stage 3 or 4)		Not extracted because nd for control group
4	(Sleep study measure)	(Waking frequency)		Times per night. Not extracted because nd for control group

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD (implied)	Value	SD	Value	SD/SE*	P	Value	SD/SE*	P
Wang, 2009	AHI		Tx	Auricular plaster	10 d	30	72.40	7.92	59.22	10.55	-13.18		<0.01	-12.66		
China			Cx	Vit C		15	73.50	7.20	72.98	6.90	-0.52		NS			
19514178																
			Tx	Auricular plaster	10 d	30										
			Cx	Vit C		15										

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	None reported					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	nd	No	No	nd	NA	Yes	NA	No. Incomplete reporting
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**			
	Yes	No	Probably	Yes	No				
Reasons for drop-outs:	0 dropouts (or not described)								
Other Issues:	Only partial reporting of outcomes for control group (these outcomes not extracted)								
Overall Quality (A, B, C)	**B**								

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention for quality to be A
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Question 5
Atrial Overdrive Pacing

A.

Author, Year	Melzer, 2006			**Intervention 1**	Atrial overdrive pacing 75 bpm
PMID*	17040007	**RefID**	3593	**Intervention 2**	
Key Question(s)	KQ5 AOD vs Cx			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	(Sham/minimal) atrial overdrive pacing 45 bpm
Extractor	EMB			**Comments**	Not all were diagnosed with a sleep test.

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Medtronic pacemaker Able to tolerate set rate of 45 bpm Age ≥18 y Sx'ic SA* or AHI>15 * ESS score >10 and Sleep apnea subscale of Sleep Disorders Questionnaire score >32 (women), >36 (men)	Arrhythmia requiring pacer mode other than DDD(R) or AAI(R) SA intervention (eg, CPAP or oral appliance) CHF exacerbation Severe nasal congestion	>15 (unclear if applied to everyone)	nd	Yes	Germany, Switzerland	nd	Yes 18 patients required for 95% confidence and 90% power to detect a 50% reduction in AHI	No	Yes (PSG)

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**20 (19)**	84%	69±11	nd	29.5±6.0	134/84	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	NYHA class: 1.3±0.8 EF: 53.4% AV block 47% Sinus arrest 37% AVB & SArr 5% Bradycardia 11%	
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	None							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	19		9.0±3.9	nd	nd	nd	~0	SA-SDQ (12-60) 32.7±9.5
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		Require pacemaker

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	Mild 5-15 Mod 15-30 Severe >30		≥10 sec	(editing problem in article) REF: Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The Report of an American Academy of Sleep Medicine Task Force. Sleep 1999;22:667-9.	no	NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Atrial Overdrive Pacing	Overnight 75 bpm	Medtronic pacemaker with sleep function (Thera, Kappa 400, Kappa 700 or Kappa 900),	DDD(R) or AAI (R). Also daytime rate of 60 bpm
2				
3				
Control	Sham AOP	Overnight 45 bpm		DDD(R) or AAI (R). Also daytime rate of 60 bpm
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study	AHI	7-10 d	
2	Sleep study	Sleep stage 3-4	7-10 d	% of total sleep time in stages 3-4
3	Sleep study	REM sleep	7-10 d	% of total sleep time in REM
4	Sleep study	AHI Response	7-10 d	AHI improvement of at least 1 AASM severity level

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)			Adjusted (reported)			
							Metric*	Result		Result	95% CI	P btw	Adjusted for:
Melzer, 2006	AHI response	Tx	AOP 75 bpm	1 wk	7	19	%	37%	See M Subgroup				
Germany, Switzerland		Cx	AOP 45 bpm		0 (implied)	19							
17040007													

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference Final (test – control)*		
							Value	SD/SE*	Value	SD	Value	SD/SE*	P	Value	SD/SE*	P
Melzer, 2006	AHI		Tx	AOP 75 bpm	1 wk	19	nd		23.0	16.7	nd			-3.8		0.49
Germany, Switzerland			Cx	AOP 45 bpm		19			26.8	17.1						
17040007																
	Stage 3-4	%	Tx	AOP 75 bpm	1 wk	19	nd		14	12	nd			1		0.86
			Cx	AOP 45 bpm		19			13	10						
	REM	%	Tx	AOP 75 bpm	1 wk	19	nd		10	6	nd			0		0.93
			Cx	AOP 45 bpm		19			10	6						

* Delete the incorrect value/item
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	Important to point out that ~1/3 had an AHI response, so “effective” in subset of patients.

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	Reasons
Total	1: PSG = primary insomnia with total sleep time <3 hours

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Difference Final (test – control)*		
										Value	SD			P	Value	SD/SE*	P
AHI Responders	Melzer, 2006	AHI		Tx	AOP 75 bpm	1 wk	7	nd		12.3	4.0	nd			-17.0		0.004
	Germany, Switzerland			Cx	AOP 45 bpm		7			29.3	12.1						
	17040007																
Non-Responders				Tx			12			29.1	18.5				+3.7		0.64
				Cx			12			25.4	19.8						
AHI Responders		Stage 3-4	%	Tx	AOP 75 bpm		7	nd		12	13				+5		0.41
				Cx	AOP 45 bpm		7			7	8						
Non-Responders				Tx	AOP 75 bpm		12			14	11				-2		0.65
				Cx	AOP 45 bpm		12			16	10						
AHI Responders		REM	%	Tx	AOP 75 bpm		7	nd		12	7				+2		0.45
				Cx	AOP 45 bpm		7			10	4						
Non-Responders				Tx	AOP 75 bpm		12			8	5				-2		0.48
				Cx	AOP 45 bpm		12			10	7						

* Delete the incorrect value/item

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	None reported					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	nd	Yes	No	Yes	Yes (all)	Yes	NA	Yes
	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?		If a Crossover study, was the Washout period adequate?
	Yes	No	Yes	Yes	NA	NA	Yes		Yes
Reasons for drop-outs:		1 not randomized due to inadequate time in sleep							
Other Issues:									
Overall Quality (A, B, C)		**A**							

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments
Important to point out that ~1/3 had an AHI response, so "effective" in subset of patients.

A.

Author, Year	Simantirakis 2005			**Intervention 1**	AOD
PMID*	16354893	**RefID**	3811	**Intervention 2**	CPAP
Key Question(s)	5 AOD v CPAP			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
"Moderate or severe" OSA Sleep-related bradyarrhythmias (Sinus pauses >6 s or transient AVB ≥2 episodes syncope in past year	LV dysfunction (EF<50%) Heart failure Central SA	nd	nd	No	Greece	nd	No	no	nd

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**16 (16)**	75%	60±11	nd	nd	nd	nd	Sinus pause 75% Complete heart block 25%
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	LVEF 59±4 HR 55±6	Bradyarrhythmia (pacer)
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	None							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total	16	49±49	15.7	nd	nd	nd	nd	Arousal index 41±17 SaO2 (mean) 88±4 SaO2 (lowest) 77±6
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	nd (but all >20)		nd	nd	Separate nights	Manual scoring

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	AOD	Dual chamber pacemaker implanted (for syncope and bradyarrhythmia) AOP pacing 15 bpm greater than spontaneous mean nocturnal HR		
2	CPAP	No AOP n-CPAP	Auto-CPAP Respironics	
3				
Control				
For CPAP:		**How was the Pressure selected?**	nd	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	2 noc in sleep lab, daily by phone x 7, f/up at 2 & 4 wk

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study	AHI	1 mo	
2	Sleep study	Arousal index	1 mo	# arousals/hr
3	Sleep study	Desaturation index	1 mo	# desats/hr (SaO2<90%)
4	Sleep quality	Epworth SS	1 mo	0-24 (24 worst)

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	95% CI	P	Value	SD/SE*	P
Simantirakis 2005	AHI		Tx	AOP	1 mo	16	49.0	nd	49.2	nd	+0.2	-2.7, +2.3	0.87	+46.5		nd
Greece			Cx	CPAP		16	49.0		2.7		-46.3	-56.2, -36.5	<.001			
16354893																
	Arousal		Tx	AOP	1 mo	16	40.75		41.3		+0.55	-2.0, +3.1	0.65	+36.7		nd
			Cx	CPAP		16	40.75		4.6		-36.15	-44.9, -27.4	<.001			
	Desat		Tx	AOP	1 mo	16	56.4		56.4		+0.3	-2.6, +3.2	0.82	+52.9		nd
			Cx	CPAP		16	56.4		3.5		-52.6	-64.8, -4.04	<.001			
	ESS		Tx	AOP	1 mo	16	15.7		15.8		+0.1	-0.24, +0.36	0.67	+10.3		nd
			Cx	CPAP		16	15.7		5.5		-10.2	-11.7, -8.8	<.001			

* Delete the incorrect value/item
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	No difference in outcomes of interest by order of intervention.

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE *	Value	SD/SE *	Value	SD/SE *	P	Value	SD/SE *	P
				Tx													
				Cx													

* Delete the incorrect value/item

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			None reported			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	nd	No	No	nd	Yes (all included)	Yes	NA	Yes (mostly)
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**		**If a Crossover study, was the Washout period adequate?**
	Yes	No	Yes (mostly)	Yes	No/NA	nd	No		Yes
Reasons for drop-outs:	NA								
Other Issues:	No description of how pressure was titrated. (Small n, but crossover and screened 2329 to get 16 eligible)								
Overall Quality (A, B, C)	**B**								

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Sinha, 2009			**Intervention 1**	AFx™ algorithm: AOD 5-10 bpm above intrinsic rhythm for 15 cycles of overdrive pacing
PMID	19250100	**RefID**	3816	**Intervention 2**	
Key Question(s)	5: AOD vs Cx			**Intervention 3**	
Design*	Randomized cross-over			**Control**	AFx™ algorithm turned off
Extractor	EMB			**Comments**	

* RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Dual chamber pacemaker or ICD. PSQI>5 AHI>5/hour	Ventilatory sleep apnea therapy Permanent AFib Hx acute cardiopulmonary decompensation	>5	nd	No	Germany	nd No conflicts of interest	nd	nd	nd

* or Cochrane number

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?)**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**23 (12)**	83%	61±10	nd	28.9±6.5	nd	(High degree AV block: 17%)	CAD 67% Dilated cardiomyopathy 25% VT 25%
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	Pacemaker 83% Implantable cardoverter defibrillator 17%	Required dual chamber pacemaker or ICD for cardiac condition
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	None							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	12	38.0±29.7	nd	nd	nd	nd	nd	PSQI 9.6±4.4
Control:								

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify)	Other characteristics
OSA 9/12 (75%) Mixed SA 3/12 (25%)	nd	

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Somnocheck® portable recorder	>5		nd	NA	NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	AOD	AOD 5-10 bpm above intrinsic rhythm	AFx™ algorithm	AFx™ algorithm, which provides dynamic atrial overdrive pacing above the intrinsic atrial rate for prevention of atrial fibrillation. The algorithm ensured a high percentage of atrial pacing at a rate 5–10 bpm above the patient's intrinsic rhythm, limited by the maximum sensor rate. After 15 cycles of overdrive pacing, the algorithm slowly steps down to the programmed base rate of 50 bpm, or until the intrinsic atrial rhythm emerges.
2				
3				
Control	Control	No AOD		Algorithm turned off
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
none		
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	3 mo ± 14 d (in each phase of cross-over	
2	Sleep quality	Pittsburgh Sleep Quality Index (PSQI)	same	Validated self-rating questionnaire for analysis of sleep quality and QoL 19 items, 7 component scores. Global score 0-21. Higher = worse sleep quality. Threshold >5.
3	Physical function	6 minute walk test N=8 (not extracted)	same	Distance (in meters) walked in 6 minutes.
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Intervention		Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD	Value	SD/SE*	P	Value	SD/SE*	P
Sinha, 2009	PSQI	score	Tx	AOD	3 mo ± 14 d	Gp A 6	8.2	3.5	13.0	5.7	+4.8		<.05	+5.0		<.05
Germany						Gp B 6	10.6	4.9	9.8	4.1	-0.8		NS	+1.9		NS
19250100			Cx	No AOD		Gp A 6	8.2	3.5	8.0	3.8	-0.2		NS			
						Gp B 6	10.6	4.9	7.9	4.6	-2.7		NS			
	AHI	#/hr	Tx	AOD	3 mo ± 14 d	Gp A 6	26.5	28.9	30.5	23.8	+4.0		NS	+9.0		NS
						Gp B 6	43.8	32.5	43.5	17.4	-0.3		NS	+14.8		<.05
			Cx	No AOD		Gp A 6	26.5	28.9	21.5	23.3	-5.0		NS			
						Gp B 6	43.8	32.5	28.7	15.4	-15.1		NS			

* Delete the incorrect value/item
** If data is presented graphically, please reference the appropriate figure in the primary paper

Group A had pacing turned on in the first period, and then turned off in the second period, while Group B had the pacing turned off in the first period and then turned on in the second period.

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	Data provided for Groups A and B separately, but not for all on AOD vs all off AOD. Study terminated early because of "trend toward a negative effect conferred by AOD on PSQI and AHI".

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	Reasons
	nd provided for 11 enrolled who were not analyzed, unless this was due to early termination of study.

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE *	Value	SD/SE *	Value	SD/SE *	P	Value	SD/SE *	P
				Tx													
				Cx													

* Delete the incorrect value/item

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	None					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	nd	Unclear	nd	nd	No	No. Not analyzed as AOD v no AOD	NA	Yes
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**		**If a Crossover study, was the Washout period adequate?**
	Yes	No	Yes	Yes	NA	NA	No		Yes
Reasons for drop-outs:		Unclear (probably due to early termination)							
Other Issues:		N=12							
Overall Quality (A, B, C)		**C**							

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments
Study terminated early because of “trend toward a negative effect conferred by AOD on PSQI and AHI”.

Key Question 5
Miscellaneous

A.

Author, Year	Cartwright, 1991			**Intervention 1**	
PMID*	1798889	**RefID**	4126	**Intervention 2**	
Key Question(s)	KQ5 Positional			**Intervention 3**	
Design †	RCT			**Control**	
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Sleep apnea Male Positionality of SA	nd	≥12.5	nd	No	US	Gov't	nd	No	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**% Ideal Body Weight**	**SBP>104**	**DBP>100**	**AFib/AFlutter, %**	**CVD †, % (specify)**
TRD	**15 (15)**		50		1.20	27%	13%		
PA	**15 (15)**		49		1.35	40%	47%		
TRD+PA	**15 (15)**		46		1.31	20%	13%		
Cx	**15 (15)**		50		1.28	20%	27%		
Total	**60 (60)**	100		nd				nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**		**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx									
Cx									
Total	nd	nd	nd	nd	nd	nd		nd	No
	Treatments used (prior to trial, including surgery)								
Tx									
Cx									
Total	nd								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Side AHI	Back AHI	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
TRD	15	27.36±17.64	7.95±9.70	50.79±19.33						
PA	15	33.25±21.30	9.73±9.74	62.53±30.05						
TRD+PA	15	30.70±14.54	13.95±13.04	63.90±25.59						
Cx	15	26.69±13.31	7.72±8.86	87.29±59.72						
Total:					nd	nd	nd	nd	nd	

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify) "Nasal pathology scale (0-8)" ‡		Other characteristics
	TRD	4.40	
	PA	3.40	
	TRD+PA	3.73	
	Cx	4.47	

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

‡ Right and left nasal airway were rated as normal, mildly, moderately, or severely obstructed. This was converted to a scale of 0-8.

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	12.5		nd	nd	nd	NA	Positionalality (not defined)

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	Tongue retaining device (TRD)		nd
2	Positional therapy	Posture alarm (PA)		Auditory beep if supine >15 seconds
3	Combination	TRD + PA		
Control	No additional intervention			
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.

If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description
Good health habits for sleep apnea	Weight loss, exercise, no evening alcohol, sleep on side
Weekly phone call	
For CPAP:	**Describe the frequency of the initial education follow-up**

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study	AHI	8 wk	
2	Sleep study	AHI (categorical)		<5.5
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Cartwright, 1991	AHI <5.5	Tx	TRD	8 wk	9	15								
US		Tx	PA		8	15								
1798889		Tx	TRD+PA		11	15								
		Cx	Cx		9	15								

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ (Δ test – Δ control)*		
							Value	SD	Value	SD	Value		P Final v Final	Value	SD/SE*	P
Cartwright, 1991	AHI (total)		Tx	TRD	8 wk	15	27.36	17.64	11.38	15.05	-15.98		0.01 (t=2.85, df=14)	+0.80		
US			Tx	PA		15	33.25	21.30	20.83	29.25	-12.42		0.08 (t=1.88, df=14)	+4.36		
1798889			Tx	TRD+PA		15	30.70	14.54	7.87	12.27	-22.83		<0.001 (t=5.24, df=14)	-6.05		
			Cx	Cx		15	26.69	13.31	7.72 †	9.91	-16.78		<0.01 (t="524"†, df=14)			
										ANOVA NS						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper
† 6.28, P<0.001 based on reported raw data. But mean = 7.66 (not 7.72

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	Also data for "Side AHI" and "Back" AHI

Pearson (r) correlations of 5 variables with total AHI. (see D for definition of nasal patency)

TABLE 8. *The relation of five factors to posttreatment total A + HI*

	All cases	TRD	PA	Both	HH
A + HI pre (severity)	0.378**	0.095	0.527*	0.172	0.524*
A + HI lateral	0.369**	0.555*	0.464	0.172	0.777**
Initial weight	0.289*	0.098	0.270	0.491*	0.246
Weight change	0.107	0.045	0.010	−0.584*	0.010
Nasal patency	0.021	0.573*	−0.145	−0.210	0.303

* $p < 0.05$.
** $p < 0.01$.

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	No	Yes	No	nd	Yes (all)	No Comparison of final values, but pt-level data reported	NA	Yes	No (some results numbers are wrong)

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	No ("Positionality" not clear)	No	No (TRD?)	Yes	No	NA	NA	NA

Reasons for drop-outs:	NA
Other Issues:	
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Krakow 2006			**Intervention 1**	Nasal Dilator Strip therapy
PMID*	16496118	**RefID**	11439	**Intervention 2**	
Key Question(s)	5 (Miscellaneous)			**Intervention 3**	
Design †	RCT			**Control**	No treatment
Extractor	DM			**Comments**	It is not clear if the authors supplied the Nasal Strips to the subjects. If not, the intervention was only the instruction on use, not the nasal strip itself

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
primary sleep complaint of chronic sleep-maintenance insomnia and sleep disordered breathing symptoms	obesity; signs, symptoms, or previous PSG diagnosis of severe OSA; Comorbid sleep disturbances; Previously diagnosed severe or unstable breathing disorders; current psychiatric disorder or psychotropic medication use; Untreated or uncontrolled allergic rhinitis; severe or unstable medical conditions	nd	Jun 2002 – Dec 2003	No	USA	Industry (CNS, Inc, MN, USA - manufacturer of Breathe Right strips)	No	No	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race White, non Hispanic (%)	BMI*	HTN, % (how defined?)	AFib/AFlutter, %	CVD †, % (specify)
Tx	51 (42)	52	53.1 ± 12.3	81	25.1 ± 3			
Cx	40 (38)	61	54.2 ± 13.5	87	25.5 ± 2.7			
Total	91 (80)					nd	nd	nd
	NIDDM, %	Smokers, % (define)	GERD, %	MVA ‡ etc, %	Cognitive Function **	Depression, %	Other Comorbidities, % (Reported classic sleep disordered breathing symptoms)	Is this a Special Population? (which?)
Tx							52	
Cx							60	
Total	nd	nd	nd	nd	nd	nd		No
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	42							
Control:	38							
Total:	80	nd	nd	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
Symptoms of sleep disordered breathing were recorded but baseline values were not reported						Features of airway crowding were omnipresent, with 100% showing at least one site of nasal or oral airway obstruction		nd

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Questionnaire as per American Academy of Sleep Medicine self-report research criteria (1999)					snoring, gasping or choking during sleep, dry mouth upon awakening, nocturia and morning headache	NA	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Other	Nasal Dilator Strips Therapy Instructions with Sleep Disordered breathing information	Breathe Right Nasal Strips	
2				
3				
Control	No Treatment			
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
Nonspecific educational reviews of current sleep complaints	Nonspecific educational reviews of sleep logs and intake questionnaires	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measures	Insomnia Severity Index (ISI)	Baseline & 4 weeks	Seven items on 5-point scales (0–4) with a total range of 0–28. Scores greater than or equal to 11 reflect clinically meaningful insomnia.
2	Sleepiness measures	Pittsburgh Sleep Quality Index (PSQI)	Baseline & 4 weeks	Validated self-rating questionnaire for analysis of sleep quality and QoL 19 items, 7 component scores. Global score 0-21. Higher = worse sleep quality. Threshold >5.
3	QoL	Functional Outcomes of Sleep Questionnaire (FOSQ)	Baseline & 4 weeks	Reported as a mean score and changes from baseline to endline are reported as Cohen d score (the standardized mean difference, based on mean group change scores divided by the pooled standard deviation) for net treatment effect differences
4	QoL	Quality of Life Enjoyment and Satisfaction Questionnaire summary sheet (QLSESQ)	Baseline & 4 weeks	Assesses the degree of enjoyment and overall satisfaction levels in various areas of daily functioning using 16 questions scored on a 5-point scale (1–5) to provide an average item score. A Q-LES-Q score of 3 equals "fair," and a score of 4 equals "good."

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Difference* (test – control)*		
							Value	SD/SE*	Value	SD/SE*	Change	SD/SE*	P	Value	SD/SE*	P
Krakow 2006 USA 16496118	Insomnia Severity Index (ISI)	Units on a scale	**Tx**	Nasal Dilator Strips Therapy Instructions with Sleep Disordered breathing information	4 weeks	42	15.6	nd	10.2	Nd	-5.4			-3.9	Nd	<0.001
			Cx	No treatment		38	15.5	Nd	14	nd	-1.5					
Krakow 2006 USA 16496118	Pittsburgh Sleep Quality Index (PSQI)	Units on a scale	**Tx**	Nasal Dilator Strips Therapy Instructions with Sleep Disordered breathing information	4 weeks	42	9.0	nd	8.2	nd	-0.8			2.7	Nd	<0.001
			Cx	No treatment		38	10.0	Nd	6.5	Nd	-3.5					
Krakow 2006 USA 16496118	Functional Outcomes of Sleep Questionnaire (FOSQ)	Units on a scale	**Tx**	Nasal Dilator Strips Therapy Instructions with Sleep Disordered breathing information	4 weeks	42	15.2	nd	16.7	nd	1.5			1.3	Nd	<0.02
			Cx	No treatment		38	14.8	Nd	15.0	Nd	0.2					
Krakow 2006 USA 16496118	Quality of Life Enjoyment and Satisfaction Questionnaire summary sheet (QLSESQ)	Units on a scale	**Tx**	Nasal Dilator Strips Therapy Instructions with Sleep Disordered breathing information	4 weeks	42	3.6	nd	4.0	nd	0.4			0.3	Nd	0.01
			Cx	No treatment		38	3.5	Nd	3.6	Nd	0.1					

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Breather right Nasal Strips	18%	Withdrew (3), Adverse Effect (2), Intercurrent Health Condition (4)
Control group	5%	Withdrew (2)

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
Krakow 2006 USA 16496118	Itchiness around the nose and increased nasal congestion	4 weeks	Breathe Right Nasal Strip			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	Yes	Yes	No	Yes	No	Yes	MA	NA	No
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Yes	No	No	Yes	NA	NA	NA			NA
Reasons for drop-outs:	Withdrew due to time constraints (3), Adverse Effect (2), Intercurrent Health Condition (4)									
Other Issues:	There was no objective measurement of sleep apnea (PSG)									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments
Sleep apnea diagnosis was made with subjective tools

Key Question 5
Surgical Cohorts

A.

Author, Year	Benazzo, 2008			**Intervention 1**	Hyoid, nose, and palate surgery (combined)
PMID*	18568505	**RefID**	14075	**Intervention 2**	
Key Question(s)	KQ 5 cohort AE			**Intervention 3**	
Design †	Retrospective cohort			**Control**	
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	Exclusion	AHI Criteria to Dx OSA	Enrollment Years	Multicenter?	Country	Funding source
OSAS Underwent hyoidthyroidpexia and nose and palate surgery	nd	>5 (implied)	1998-2005	No	Italy	nd

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	Other, % (specify)	Is this a Special Population? (which?)
Tx	**109 (109)**	92%	51					
	Treatments used (prior to trial, including surgery)							
Tx	CPAP ≥6 months							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	109	median 35 (IQR 22-49)	median 10 (IQR 8-12) ≥10: 67%	nd	nd	nd	nd	

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify)	Other characteristics
	Reduction in the posterior airway space: 0% Changes in skeletal measurements (SNA, SNB) at the lateral cephalometric radiograph: 0% Muller maneuver hypopharynx region transversal collapse: 75-100% in all	

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

F. INTERVENTIONS

	Intervention Category	Specific Intervention	Description
1	Surgery	Hyoid surgery combined with nose (septoplasty and turbinate reduction) and palate surgery	Hyoid surgery: Riley et al. (Riley RW, Powell NB, Guilleminault C. Obstructive sleep apnea and the hyoid: a revised surgical procedure. Otolaryngol Head Neck Surg 1994;111:717-21.) No other description
2			
3			

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness	ESS	6 mo	
2	Sleep measure	AHI		
3	Surgical	Responder		Reduction in AHI to <20
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI		Result	95% CI		Adjusted for:
Benazzo, 2008	Responder (AHI ↓ <20)	Tx	Hyoid, Nose, Palate surgery	6 mo	67	109	%	61%			Non-responders had a much higher average BMI (29.1 v 27.7, P=0.02) Non-responders had a much higher median AHI (44 v 30, P=0.004)			
Italy														
18568505	Responder (AHI<10)				44	109	%	40%						

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)		
							Value	IQR/SD	Value	IQR/SD	Value	SD/SE*	P
Benazzo, 2008	ESS≥10		Tx	Hyoid, Nose, Palate surgery	6 mo	109	73 (67%)		17 (16%)				0.01
Italy													
18568505	ESS, median						10	8-12	7	6-8			<0.0001
	ESS, mean						10.5	3.1	7.2	2.3	-3.3	2.9	
	AHI, median						35	22-49	14	7-26	-17	-31, -7	<0.0001
	AHI, mean						37.0	19.1	18.7	16.0	-18.2	18.6	

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			Hyoid, Nose, Palate surgery			
	"Major complication"	Post-operative period	0/109			
	Neck seroma	Post-operative period	1/109			
	Transient dysphagia (2-3 days)	Post-operative period	minority			

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Esclamado 1989			**Intervention 1**	UPPP ± other procedures
PMID*	2530406	**RefID**	16212	**Intervention 2**	
Key Question(s)	KQ 5 cohort			**Intervention 3**	
Design †	Retrospective cohort			**Control**	
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	Exclusion	AHI Criteria to Dx OSA	Enrollment Years	Multicenter?	Country	Funding source
Surgery for OSAS	nd	nd	1983-1987	No	US	nd

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	Other, % (specify)	Is this a Special Population? (which?)
Tx	**135 (135)**	~94%	50	nd	146% IBW	nd	nd	No
	Treatments used (prior to trial, including surgery)							
Tx								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:		AI 59	nd	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
Documented arrhythmias 14%								

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

F. INTERVENTIONS

	Intervention Category	Specific Intervention	Description
1	Surgery	UPPP	n=135
2		+ tonsillectomy	n=36
3		+ septoplasty	n=20
		+ septoplasty + tonsillectomy	n=15
		+ tracheostomy	n=12

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Complication	Perioperative complications	During anesthesia, surgery, or within 24 h after surgery	Required active intervention by the surgeon or anesthesiologist
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	%	
			UPPP ± other procedures		
	Overall complications	24 h	18/135	13%	
	Airway obstruction requiring reintubation	24 h	7/135	5%	
	Long-term sequelae due to airway obstruction	nd	0/135		
	Death	24 h	1/135	0.7%	Failed initial intubation, attempted oral intubation, died from hypoxic cardiopulmonary arrest despite emergency tracheostomy
	Acute post-obstructive pulmonary edema requiring diuresis and ventilation x 3 d	24 h	1/135	0.7%	
	Postoperative hemorrhage requiring return to OR	24 h	3/135	2%	
	Postoperative nocturnal bradycardia (no intervention required)	24 h	1/135	0.7%	
	(Failed intubation)	(preop)	(7/135)	(5%)	

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments
Also did analysis of predictors of complications: Univariate associations with complications (including failure to intubate) include: Minimum O2 sat was lower in those with complications (66% vs 79%; P<0.001) Apnea index was higher in those with complications (75 vs 57; P<0.02) % ideal body weight (IBW) was higher in those with complications (155% vs 145%; P=0.06) Age, sex, arrhythmia on PSG, coexisting medical problems (COPD, HTN, cardiac disease, CVA, dementia) were not significantly different between those with and without complications. No significant difference in rates of complications related to addition of simultaneous surgical procedures to UPPP. Higher doses of narcotic (fentanyl or sufentanil) were used those with complications. Only for extubation complications.

A.

Author, Year	Friedman, 2003			**Intervention 1**	UPPP
PMID*	14663425	**RefID**	4288	**Intervention 2**	UPPP + Tongue base RF
Key Question(s)	KQ 5 surgical cohort			**Intervention 3**	
Design †	Retrospective cohort			**Control**	
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**
Selected for specific surgical procedure. Significant symptoms of snoring, excessive daytime somnolence, AHI≥15 CPAP trial and failure.	Stage I disease (high palate, large tonsils) [For UPPP+TBRF group only] BMI >40 Previous UPPP Candidates for TBRF only “Obvious palatal obstruction” "Obvious micrognathia" Post-operative PSG <6 hours in duration or incomplete follow-up	≥15 (for treatment)	2000 and earlier	No	US	nd

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**Other, % (specify)**	**Is this a Special Population? (which?)**
UPPP	**134**	73%	40	nd	30.0	nd	nd	Restrictive population by anatomy
UPPP + TBRF	**143**	73%	47		31.5			
	Treatments used (prior to trial, including surgery)							
Tx	CPAP (implied)							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
UPPP	**134**	35±25	nd					Min O2 sat 84±12%
UPPP + TBRF	**143**	44±24	15.2		7.6 out of 10 point scale	nd	nd	81±10%
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
						Data on Friedman palate position and tonsil size available		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

F. INTERVENTIONS

	Intervention Category	Specific Intervention	Description
1	Surgery	UPPP + Tongue base reduction by RF	Prospective analysis UPPP modified per Friedman M, Landsberg R, Tanyeri H. Submucosal uvulopalatopharyngoplasty. Otolaryngol Head Neck Surg 2000; 11:26–29. TBRF: 2-3 sites, 750 J per site (rarely 1000 J). Subsequent treatments at at least 1 month. Repeated until Sx eliminated and PSG normalized or patient refused further treatment. (Post-op antibiotics and steroids)
2		UPPP alone	Retrospective analysis
3			

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep measure	AHI	≥6 mo	AHI ↓50% to <20
2	Sleep measure	Min O2 sat		
3	Sleepiness	ESS		
4	Complications			

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI		Result	95% CI		Adjusted for:
Friedman, 2004	AHI ↓50% to <20	Tx	UPPP (Stage I, see pdf)	≥6 mo			%	80.6%						
US			UPPP (Stage II)					37.9%						
15091218			UPPP (Stage III)					8.1%						
			UPPP+TBRF (Stage II)			51		74.0%						
			UPPP+TBRF (Stage III)			89		43.8%						

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)		
							Value	SD	Value	SD	Value	SD/SE*	P
Friedman, 2004	AHI		Tx	UPPP (Stage I)	≥6 mo	nd	24.0	12.8	6.7	4.7			<0.05
US				Stage II		nd	47.2	31.3	34.2	29.9			<0.05
15091218				Stage III		nd	34.9	22.4	39.1	22.7			NS
				UPPP+TBRF (Stage II)	≥6 mo	51	47.9	26.6	19.5	16.4			<0.05
				Stage III		89	41.7	21.8	28.5	21.9			<0.05
	O2 sat min			UPPP (Stage I)	≥6 mo	nd	85.9	12.5	93.1	1.9			<0.05
				Stage II		nd	80.0	15.0	85.3	8.2			<0.05
				Stage III		nd	85.7	8.8	82.8	12.9			NS
				UPPP+TBRF (Stage II)	≥6 mo	51	82.1	9.7	87.5	6.7			<0.05
				Stage III		89	79.9	14.3	83.8	14.8			<0.05

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			UPPP	UPPP+TBRF		
Friedman, 2004	Airway complications	Peri-operative	0/134	0/143		
US	Return to OR for abscess drainage	Peri-operative	0/134	0/143		
15091218	Re-hospitalization	Peri-operative	0/134	0/143		
	Hypoglossal nerve paralysis	Peri-operative	NA	1/143		
	Transient nerve paralysis (resolved within 1 wk)	Peri-operative	NA	2/143		
	Increased pain (resolved with antibiotics)	>3 d post-operative	4/277			

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Friedman 2007			**Intervention 1**	3-level treatment, single phase
PMID*	17713449	**RefID**	11240	**Intervention 2**	
Key Question(s)	KQ 5 cohort			**Intervention 3**	
Design †	Retrospective cohort			**Control**	
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**
3-level treatment of nose, palate, and tongue base Friedman tongue position II or III and tonsil size 0,1, or 2	AHI>40 BMI>40 Inadequate data in medical records	nd	2005-2006	No	US	nd

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**Other, % (specify)**	**Is this a Special Population? (which?)**
Tx	**145 (122)**	66%	42		28.3			
	Treatments used (prior to trial, including surgery)							
Tx								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

F. INTERVENTIONS

	Intervention Category	Specific Intervention	Description
1	Surgery	3-level treatment, single phase	Nose: Nasal septoplasty, when appropriate; Turbinate reduction either by RF or submucous resection, when appropriate; Nasal valve suspension, when indicated
			Oropharynx: 3 Pillar implants in midline and just off midline; parital uvulectomy to 1 cm (if ≥1.5 cm)
			Tongue base reduction: RF 3000 J to 10 locations equally dispersed to sides of midlein between the circumvallate papillae and the vallecula

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1				
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			3-level			
	Major complication	nd	0/122			
	Nasal septum perforation, tongue mucosal ulceration, & hypoglossal nerve weakness <1 month		1/122			
	Exposure of bone of the turbinate requiring debridement		2/122			
	Foreign body reaction to nasal valve implant requiring suture removal		3/122			
	Tongue base ulceration due to RF, healed w/in 2 wk		3/122			
	Pillar extrusion requiring removal and replacement		5/122			

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Haavisto 1994			**Intervention 1**	UPPP
PMID*	7923849	**RefID**	1400	**Intervention 2**	
Key Question(s)	KQ 5 cohort			**Intervention 3**	
Design †	Retrospective cohort			**Control**	
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**
UPPP for OSAS	nd	nd	1989-1990	No	Finland	nd

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**Other, % (specify)**	**Is this a Special Population? (which?)**
Tx	**101 (101)**	88%	47 (24-73)	nd	93 kg (55-155)			
	Treatments used (prior to trial, including surgery)							
Tx								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

F. INTERVENTIONS

	Intervention Category	Specific Intervention	Description
1	Surgery	UPPP	Fujita 1981, under GA with local anesthesia
2			
3			

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1				
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention		
			UPPP			
	Hemorrhage	postoperative	14/101	14%	5 required return to OR	
	Airway problems	postoperative	11/101	11%		
	Tracheostomy		4			
	Ventilation required		3			
	Asystole after extuabation		1		Died 3 d after resuscitation	
	Infections	postoperative	0/101			
	Arrhythmia	postoperative	0/101			
	Nasopharyngeal regurgitation	6 wk	51/91	56%		
		1 y	22/91	24%		
	Pharyngeal dryness	6 wk	32/91	35%		
		1 y	28/91	31%		
	Difficulty swallowing	6 wk	30/91	33%		
		1 y	9/91	10%		
	Difficulty with speech or change in voice quality	6 wk	14	15%		
		1 y	6	7%		
	Loss of taste	6 wk	8	9%		
		1 y	2	2%		
	Breathing difficulty	6 wk	5	5%		
		1 y	5	5%		
	Hemorrhage	6 wk	6	6%		
		1 y	1	1%		
	Others	increased mucus secretion, pain, gagging, difficulty sleeping, cough, burning sensation, anosmia, difficulty singing and playing saxophone etc.				

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments
Those with breathing difficulties were heavier (≥93 Kg), more likely to have previous heart disease, had more frequent obstructive apnea periods, and lower minimum O2 saturation (<80%)

A.

Author, Year	Harmon 1989			**Intervention 1**	Various surgical (mostly UPPP)
PMID*	2916139	**RefID**	18043	**Intervention 2**	
Key Question(s)	KQ 5 cohort			**Intervention 3**	
Design †	Retrospective cohort			**Control**	
Extractor	EMB			**Comments**	6/132 operated on for snoring only

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	Exclusion	AHI Criteria to Dx OSA	Enrollment Years	Multicenter?	Country	Funding source
Surgical treatment for OSA			1981-1987			

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	Other, % (specify)	Is this a Special Population? (which?)
Tx	**132 (132)**	80%	19-70					
	Treatments used (prior to trial, including surgery)							
Tx								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

F. INTERVENTIONS

	Intervention Category	Specific Intervention	Description
1	Surgery	UPPP	n=63
2		UPPP + septoplasty	n=25
3		UPPP + tracheostomy	n=36
		UPPP + adenoidectomy	n=2
		Tracheostomy	n=4
		Tracheostomy + tonsillectomy	n=1
		Septoplasty	n=1

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1				
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention		
			UPPP	All surgeries		
	Oropharyngeal hemorrhage		7/126 (6%)			
	Rhinolalia		2/126 (2%)			
	Nasopharyngeal reflux		0/126			
	Pharyngeal infection		0/126			
	Pneumonia			2/132 (2%)		
	Death			2/132 (2%)	1: presumed PE, 21 days post-op 1: cerebral infarction after external carotid embolization to control lingual artery bleeding	
	Emergency tracheostomy			2/132 (2%)		
	Prolonged intubation, pulmonary edema, reintubation, difficult intubation, respiratory arrest			6/132 (5%)		
	Total complications			34/132 (26%)		

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Kezirian, 2004			**Intervention 1**	UPPP
PMID*	15091217	**RefID**	12447	**Intervention 2**	
Key Question(s)	KQ 5 cohort			**Intervention 3**	
Design †	Prospective cohort			**Control**	
Extractor	EMB			**Comments**	Analysis of prospective VA National Surgical Quality Improvement Program. Multiple combined surgeries, but very large N, so included.

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	Exclusion	AHI Criteria to Dx OSA	Enrollment Years	Multicenter?	Country	Funding source
Undergoing UPPP at any VAMC	Concomitant neck dissection or ablative surgery	nd	1991-2001	Yes	US	Government

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	Other, % (specify)	Is this a Special Population? (which?)
Tx	**3130**	97%	50	nd	nd	nd	Current smokers 31%	VA population
	Treatments used (prior to trial, including surgery)							
Tx								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:		nd	nd	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

F. INTERVENTIONS

	Intervention Category	Specific Intervention	Description
1	Surgery	UPPP	Current Procedural Terminology (CPT) code 42145 or 42299
2			
3			

G. CO-INTERVENTIONS

Co-intervention	Description	
Tonsillectomy	36%	
Septoplasty	38%	
Turbinate procedure	22%	
Mandible/genioglossus advancement, or rhinoplasty, or hyoid suspenstion	<2% each	
For CPAP:	**Describe the frequency of the initial education follow-up**	NA

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Complication	Death	30 days post-op	
2		Respiratory complication		reintubation, pneumonia, prolonged ventilation (>48 h), emergent tracheotomy, pulmonary edema
3		Cardiovascular complication		Cardiac arrest, MI, CVA, pulmonary embolism
4		Hemorrhage		>4 units pRBC
		Deep vein thrombosis		
		Kidney failure		

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	%	95% CI	
			UPPP			
Kezirian, 2004	Death	30 days	7/3130	0.2%	0.1, 0.4%	
US	Respiratory complication		33/3130	1.1%	0.7, 1.4%	
15091217	Reintubation		17/3130	0.5%		
	Emergent tracheotomy		7/3130	0.2%		
	Ventilation >48 h		6	0.2%		
	Pneumonia		11	0.4%		
	Cardiovascular complication		8	0.3%	0.1, 0.4%	
	Hemorrhage		9	0.3%	0.1, 0.5%	
	Deep vein thrombosis		0	0		
	Kidney failure		0	0		
	Total serious complications (including death)		51/3130	1.6%		

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Labra 2008			**Intervention 1**	Tongue base somnoplasty
PMID*	19128623	**RefID**	7501	**Intervention 2**	
Key Question(s)	KQ 5 cohort			**Intervention 3**	
Design †	Retrospective cohort			**Control**	
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	Exclusion	AHI Criteria to Dx OSA	Enrollment Years	Multicenter?	Country	Funding source
Tongue base somnoplasty either as part of a multilevel somnoplasty approach for OSA (base of the tongue, palate, turbinates) or as a unique procedure	nd	nd	2002-2005	No	Mexico	nd

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	Other, % (specify)	Is this a Special Population? (which?)
Tx	**237 (237)**	83%	42 (27-64)					
	Treatments used (prior to trial, including surgery)							
Tx								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:		RDI 41 (3-63)						
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

F. INTERVENTIONS

	Intervention Category	Specific Intervention	Description
1	Surgery	Tongue base somnoplasty	n=36
2		Tongue base somnoplasty + palate + turbinates	n=201
3			RF at 85º C. First 143 cases 800 J to midline, posterior to the vertex of the circumvalate papillae, 400 J in the midline anterior tot the vertex, and 400 J on both sides of the tongue. Second 95 cases, 300 J to the same four areas

G. CO-INTERVENTIONS

Co-intervention	Description	
Local anesthesia	first 127 patients. Topical 10% lidocaine and infiltration with 2% lidocaine	
Local anesthesia + sedation	second 110 patients. Intravenous fentanyl and midazolam	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Complications	Complication		nd
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention			
			Tongue base RF			
	Dysphagia x 4-5 days due to mucosal lesions	Postoperative	2/237 (0.8%)	(Both had "important" gagging reflex; both had local anesthesia only)		
	Hospital admission	Postoperative	0/237			
	Intraoperative complications	Intraoperative	0/237			

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Lundkvist 2009			**Intervention 1**	UPPP
PMID*	19863325	**RefID**	55	**Intervention 2**	
Key Question(s)	KQ 5 cohort			**Intervention 3**	
Design †				**Control**	
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**
OSAS, failed or refused CPAP and mandibular retaining device ODI>5 and/or AHI>9, daytime symptoms of OSAS Underwent UPPP	Negative attitude to surgical treatment, severe heart, pulmonary, psychiatric or neurological diseases, ASA class >3, coagulopathy	ODI>5 and/or AHI>9	2002-2006	No	Sweden	nd

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**Other, % (specify)**	**Is this a Special Population? (which?)**
Tx	**158 (158)**	88%	45 (20-75)	nd	median 29 (20-48)			
	Treatments used (prior to trial, including surgery)							
Tx								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:		median ODI 23 (6-100)	median 12 (0-21)					
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

F. INTERVENTIONS

	Intervention Category	Specific Intervention	Description
1	Surgery	UPPP alone	Conservative UPPP with tonsillectomy. Modified method of Fujita (Otolaryngol Head Neck Surg 1981) Mucosa from the anterior soft palate and anterior tonsil pillar was reduced ~2-3 mm, in the upper lateral corner by 3-4 mm. Mucosa between anterior and posterior pillar removed. Posterior tonsil pillar preserved. Uvula cut to a width and length of ~1 cm. Extracapsular tonsillectomy. Posterior pillar lifted up laterally and sewn up to the anterior pillar. Under general anesthesia. Also local anesthesia. Penicillin prophylaxis.
2			
3			

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1				
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			UPPP			
	Serious complications requiring reintubation	Postoperative care unit	4/158	2.5%		
	Profuse bleeding from tonsillectomy		2/158	1.3%		
	Substantial largyngeal edema		2/158	1.3%		
	Long-term sequelae from complications		0/158			
	Death		0/158			

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Riley, 1993			**Intervention 1**	UPPP±GAHM±MMO
PMID*	8441535	**RefID**	9758	**Intervention 2**	
Key Question(s)	KQ 5 cohort			**Intervention 3**	
Design †	Prospective cohort			**Control**	
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**
Documented OSA (by PSG) Implied: met criteria for UPPP and/or GAHM	Postoperative PSG (mostly for financial reasons) or loss to followup Previous UPPP Young patients with facial skeletal deformities.	nd	nd	No	US	nd

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**Other, % (specify)**	**Is this a Special Population? (which?)**
Tx	**415 (306)**	89%	47	nd	30.5	nd		No
	Treatments used (prior to trial, including surgery)							
Tx	nasal CPAP (121/306, 40%)							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	306	RDI 56	100% excessive daytime sleepiness	nd	100%	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

F. INTERVENTIONS

	Intervention Category	Specific Intervention	Description	
1	Surgery	UPPP	Done if "Type 1": oropharynx (soft palate) obstruction	n=10
2		UPPP + MO/GAHM	Done if "Type 2": oropharynx/hypopharynx obstruction	n=233
3		MO/GAHM*	Done if "Type 3": hypopharynx (base of tongue) obstruction	n=6
			Also nasal surgery if nasal deformity	
		Phase II MMO**	Done if 6 mo post-op PSG "failure" (not RDI<20 and at least 50% reduction)	1+MMO: n=? 2+MMO: n=24 3+MMO: n=?

* Mandibular osteoptomy/genioglossus advancement with hyoid myotomy/suspension
** Maxillary and mandibular advancement osteotomy

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			UPPP+GAHM	UPPP±GAHM then MMO		
	Postoperative bleeding requiring general anesthesia	Postoperative	3/233 (1.3%)	0/91		
	Long-term problems in speech or swallowing	mean 9 mo	0/233			
	Transient anesthesia of cheek and chin	nd		91/91		
	Motor nerve deficits	nd		0/91		
	Post-operative infection	Postoperative		0/91		

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments
It is not at all clear how the various numbers of patients add up to 306 or whether all patients are accounted for or whether all included patients received phase I surgery.

A.

Author, Year	Riley 1997			**Intervention 1**	Multiple OSA surgeries
PMID*	9419093	**RefID**	8734	**Intervention 2**	
Key Question(s)	KQ 5 cohort			**Intervention 3**	
Design †	Retrospective cohort			**Control**	
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	Exclusion	AHI Criteria to Dx OSA	Enrollment Years	Multicenter?	Country	Funding source
OSAS surgery			1994-1995			

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	Other, % (specify)	Is this a Special Population? (which?)
Tx	**182 (182)** **210 procedures**	86%	48	nd	30.3			
	Treatments used (prior to trial, including surgery)							
Tx	CPAP 117 (64%)							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	182	RDI 42.3±30.6						
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

F. INTERVENTIONS

	Intervention Category	Specific Intervention	Description	
1	Surgery	UPPP + GA + HS	n=132	
2		UPPP + GA	n=9	
3		UPPP	n=19	per Fujita 1981 Otolaryngol Head Neck Surg
		GA + HS	n=15	
		HS	n=10	per Riley 1994 Otolaryngol Head Neck Surg
		GA	n=7	per Riley 1993 Otolaryngol Head Neck Surg
		UPPP+HS	n=2	
		MMO	n=16	modified LeForte I osteotomy and sagittal split osteotomy per Riley 1993 J Oral Maxillofac Surg

GA, mandibular osteotomy with genioglossus advancement
HS, hyoid myotomy and suspension
MMO, maxillary and mandibular advancement osteotomy

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1				
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			All			
	Bleeding	3-7 days	4/210 procedures (1.9%)	2 from UPPP site, 2 from mandibular osteotomy		
	Infection		5/210 (2.4%)	3 MMO (and GA), 1 HS, 1 MMO		
	Seroma		3/210 (1.4%)			
	Arrhythmia		4/210 (1.9%)	new onset AFib, no previous history		
	Unstable angina		1/210 (0.5%)	Required CABG, previous negative CAD evaluation		
	Death		0/210			

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Stuck, 2003			**Intervention 1**	RF procedures
PMID*	12797590	**RefID**	4861	**Intervention 2**	
Key Question(s)	KQ 5 cohort			**Intervention 3**	
Design †	Retrospective cohort			**Control**	
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**
temperature-controlled radiofrequency procedures (Somnoplasty®)		>0 for surgery	1998-2002	No	Germany	nd

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**Other, % (specify)**	**Is this a Special Population? (which?)**
Tx	**322 (497 sessions)**	80%	48 (range 9-77)	nd	27.7 (range 18-40)	nd	Obstructive sleep apnea 200 (62%) Upper airway resistance syndrome 64 (20%) Primary snoring 43 (13%)	Not all sleep apnea
	Treatments used (prior to trial, including surgery)							
Tx								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:		20.5±18.5 (range 0-85)	nd	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

F. INTERVENTIONS

	Intervention Category	Specific Intervention	Description
1	Surgery	Somnoplasty® (Somnus generator model S2) Temperature-controlled RF procedures	Turbinate hypertrophy: 2-3 lesions 500 J Soft palate: 3-4 lesions 450/600 J Tongue base: 4-6 lesions 400-700 J

G. CO-INTERVENTIONS

Co-intervention	Description	
Septoplasty, UPPP, uvulopalatal flap, tonsillectomy, hyoid suspension	nd Some patients	
For CPAP:	**Describe the frequency of the initial education follow-up**	

Table I. *Type and number of interventions performed*

Type of intervention	*n*
RFVTR of the tongue base	179
RFVTR of the soft palate	30
RFVTR of inferior turbinates	10
Combined RFVTR of tongue base and soft palate	97
RFVTR of tongue base + nasal surgery	31
RFVTR of tongue base + oropharyngeal surgery	35
RFVTR of tongue base + hyoid suspension	11
RFVTR of tongue base + nasal surgery + oropharyngeal surgery	50
RFVTR of tongue base + oropharyngeal surgery + hyoid suspension	22
RFVTR of tongue base + nasal surgery + oropharyngeal surgery + hyoid suspension	13
RFVTR of the tongue base combined with surgery not affecting the upper airway	19

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Complication	Minor complication		Not requiring specific treatment
2		Moderate		Specific treatment and/or hospital admission required
3		Severe		Surgical intervention required and/or life-threatening event
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	n/N	%	
			RF			
Stuck 2003	Intraoperative complication (including bleeding or mucosal damage)	Intraoperative	all	0/497 sessions		
Germany	Airway compromise	3-8 days	all	0/497		
12797590	Minor complication	3-8 days	all	5/497	1.0%	
	Moderate complication	3-8 days	all	4/497	0.8%	
	Severe complication	3-8 days	all	1/497	0.2%	
	Tongue base ulceration (no specific treatment)		Tongue+nose RF: 1 Isolated tongue RF: 2	3		
	Soft palate mucosa ulceration (no specific treatment)		Isolated soft palate RF	1		
	Dysphagia requiring hospital admission (IV steroids and antibiotics)		Isolated tongue RF	4		none received prophylactic antibiotics
	Temporary hypoglossal nerve palsy		Isolated tongue RF	1		
	Tongue base abscess (requiring I&D, temporary tracheotomy)		Isolated tongue RF	1		none received prophylactic antibiotics
	Long-term complications	>8 days		0/422 sessions		Among patients with >8 day follow-up

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments
Complication rates decreased over time (from 1999 through 2002)

Key Question 5
Multiple Comparisons

A.

Author, Year	Barnes , 2004			**Intervention 1**	CPAP
PMID*	15201136	**RefID**	4054	**Intervention 2**	MAS
Key Question(s)	5			**Intervention 3**	
Design †	Cross over			**Control**	Placebo
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA At least 2 teeth in upper and lower jaws on both sides >18yrs	Minimum blood oxygen saturation <75% in REM and 80% in non REM Significant coexisting disease(Dm, unstable ischemic heart diseases) Sleepiness unsafe and requiring urgent treatment	5-30	nd	y	Australia	nd	Y(ESS)		y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

Eligibility criteria and other study design extracted from supplemental online material and its references

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) >140/90mmHg**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Tx2								
Cx								
Total	**104 (80)**	79.8	47(0.9)	nd	31.1(0.5)	14	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	0	nd	nd	nd	nd	nd		n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Treatment2:								
Control:								
Total:	80	21.3(1.3)	10.7(0.4)	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	5-30		Standard AASM	Standard AASM	snoring	same	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Sullivan Elite, ResMed Limited, Sydney, Australia	
2	Oral appliance	MAS	Medical Dental Sleep Appliance, RJ & VK Bird, Melbourne, Australia	Made from dual laminate splinting material hooked at the jaws to cause manidublar advancement
3				
Control	placebo	placebo		Placebo Lactose tablet
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measure	AHI	3 months	
2	Sleep study measure	Arousal index	3 months	
3	Sleep study measure	ODI	3 months	
4	Sleep study measure	Mino2sat	3 months	
5	Sleepiness measures	ESS	3 months	
6	Psych scale	Beck Depression Inventory	3 months	
7	Sleep quality	FOSQ mean score, Social Outcome domain	3 months	
8	QOL	Sf36 mean score	3 months	
9	Sleep study measure	Stage 3 and 4	3 months	
10	Sleep study measure	REM	3 months	
11	Sleep study measure	Sleep efficiency	3 months	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (ΔcPAP – Δ control)*			Net Δ /Difference* (ΔMAS – Δ control)*			Net Δ /Difference* (ΔCPAP – Δ MAS*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P	Value	SE*	P	Value	SE*	P
Barnes, 2004 Australia 15201136	AHI	/hr	**Tx**	CPAP	3 months	80	21.3	1.3	4.8	0.5	-16.5		0.001	-15.5		0.001	-6.3		0.001	-9.2		<0.05
			Tx2	MAS		80	21.3	1.3	14.0	1.1	-7.3		0.001									
			Cx	Placebo	3 months	80	21.3	1.3	20.3	1.1	-1		NS									
	Arousal index		**Tx**	CPAP	3 months	80	22.0	1.2	18.3	0.9	-3.7		0.01	-6.9		0.001	-1.4		NS	-5.5		<0.05
			Tx2	MAS		80	22.0	1.2	23.8	1.2	1.8		NS									
			Cx	Placebo	3 months	80	22.0	1.2	25.2	1.1	3.2		NS									
	ODI(4%o2 desaturation)	%	**Tx**	CPAP	3 months	80	12.4	1.5	1.6	0.2	-10.8		0.001	-10.9		0.001	-4.4		0.001	-6.5		<0.05
			Tx2	MAS		80	12.4	1.5	8.1	1.3	-4.3		0.001									
			Cx	Placebo	3 months	80	12.4	1.5	12.5	1.6	0.1		NS									
	Mino2sat	%	**Tx**	CPAP	3 months	80	86.7	0.6	91.9	0.3	5.2		0.001	6.5		0.001	2.4		0.001	4.1		<0.05
			Tx2	MAS		80	86.7	0.6	87.8	0.4	1.1		NS									
			Cx	Placebo	3 months	80	86.7	0.6	85.4	0.6	-1.3		NS									
	ESS		**Tx**	CPAP	3 months	80	10.7	0.4	9.2	0.4	-1.5		0.001	-1		0.001	-1		0.001	0		NS
			Tx2	MAS		80	10.7	0.4	9.2	0.4	-1.5		0.001									
			Cx	Placebo	3 months	80	10.7	0.4	10.2	0.4	-0.5		NS									
	Beck Depression Inventory		**Tx**	CPAP	3 months	80	9.2	0.5	6.7	0.5	-2.5		0.001	-1		NS	-0.8		NS	-0.2		NS
			Tx2	MAS	3 months	80	9.2	0.5	6.9	0.5	-2.3		0.001									
			Cx	Placebo		80	9.2	0.5	7.7	0.6	-1.5		0.01									
	FOSQ social outcome domain		**Tx**	CPAP	3 months	80	3.1	0.1	3.3	0.1	0.2		0.001	0		NS	0		NS	0		NS
			Tx2	MAS		80	3.1	0.1	3.3	0.1	0.2		0.001									
			Cx	Placebo	3 months	80	3.1	0.1	3.3	0.1	0.2		0.01									
	Sf36 mean score		**Tx**	CPAP	3 months	80	69.4	1.3	74.1	1.2	4.7		0.001	2.7		<0.05	2.3		NS	0.4		NS
			Tx2	MAS		80	69.4	1.3	73.7	1.2	4.3		0.001									
			Cx	Placebo	3 months	80	69.4	1.3	71.4	1.4	2		NS									
	Stage 3 and 4	%	**Tx**	CPAP	3 months	80	17.9	1.2	20.7	1.1	2.8		0.001	2.2		<0.05	1.6		NS	0.6		NS
			Tx2	MAS	3 months	80	17.9	1.2	20.1	1.1	2.2		<0.05									
			Cx	Placebo		80	17.9	1.2	18.5	1.2	0.6											
	REM	%	**Tx**	CPAP	3 months	80	18.8	0.7	18.9	0.5	0.1		NS	0		NS	0.9		NS	-0.9		NS
			Tx2	MAS	3 months	80	18.8	0.7	19.8	0.6	1		NS									
			Cx	Placebo	3 months	80	18.8	0.7	18.9	0.6	0.1		NS									
	Sleep efficiency	%	**Tx**	CPAP	3 months	80	79.5	1.1	82.1	0.8	2.6		<0.05	1.4		NS	1.3		NS	0.1		NS

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (ΔcPAP – Δ control)*			Net Δ /Difference* (ΔMAS – Δ control)*			Net Δ /Difference* (ΔCPAP – Δ MAS*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P	Value	SE*	P	Value	SE*	P
			Tx2	MAS	3 months	80	79.5	1.1	82.0	1.0	2.5		<0.01									
			Cx	Placebo	3 months	80	79.5	1.1	80.7	0.9	1.2		NS									

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
CPAP	8.2	Time commitments, relocated, unable to tolerate , illness
MAS	14.1	Teeth unsuitable, time commitments, unable to tolerate, relocated, unrelated illness, lost weight and felt better, lost to follow up
Placebo	8.2	Time commitments , wanted CPAP, subject illness

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	y	n		y	y	y	y	y	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	y	nd	y			y
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)		**B**								

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Cartwright, 1991			**Intervention 1**	
PMID*	1798889	**RefID**	4126	**Intervention 2**	
Key Question(s)	KQ5 Positional			**Intervention 3**	
Design †	RCT			**Control**	
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Sleep apnea Male Positionality of SA	nd	≥12.5	nd	No	US	Gov't	nd	No	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**% Ideal Body Weight**	**SBP>104**	**DBP>100**	**AFib/AFlutter, %**	**CVD †, % (specify)**
TRD	**15 (15)**		50		1.20	27%	13%		
PA	**15 (15)**		49		1.35	40%	47%		
TRD+PA	**15 (15)**		46		1.31	20%	13%		
Cx	**15 (15)**		50		1.28	20%	27%		
Total	**60 (60)**	100		nd				nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**		**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx									
Cx									
Total	nd	nd	nd	nd	nd	nd		nd	No
	Treatments used (prior to trial, including surgery)								
Tx									
Cx									
Total	nd								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Side AHI	Back AHI	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
TRD	15	27.36±17.64	7.95±9.70	50.79±19.33						
PA	15	33.25±21.30	9.73±9.74	62.53±30.05						
TRD+PA	15	30.70±14.54	13.95±13.04	63.90±25.59						
Cx	15	26.69±13.31	7.72±8.86	87.29±59.72						
Total:					nd	nd	nd	nd	nd	

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify) "Nasal pathology scale (0-8)" ‡		Other characteristics
	TRD	4.40	
	PA	3.40	
	TRD+PA	3.73	
	Cx	4.47	

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

‡ Right and left nasal airway were rated as normal, mildly, moderately, or severely obstructed. This was converted to a scale of 0-8.

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	12.5		nd	nd	nd	NA	Positionalality (not defined)

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	Tongue retaining device (TRD)		nd
2	Positional therapy	Posture alarm (PA)		Auditory beep if supine >15 seconds
3	Combination	TRD + PA		
Control	No additional intervention			
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.

If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description
Good health habits for sleep apnea	Weight loss, exercise, no evening alcohol, sleep on side
Weekly phone call	
For CPAP:	**Describe the frequency of the initial education follow-up**

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study	AHI	8 wk	
2	Sleep study	AHI (categorical)		<5.5
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Cartwright, 1991	AHI <5.5	Tx	TRD	8 wk	9	15								
US		Tx	PA		8	15								
1798889		Tx	TRD+PA		11	15								
		Cx	Cx		9	15								

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ (Δ test – Δ control)*		
							Value	SD	Value	SD	Value		P Final v Final	Value	SD/SE*	P
Cartwright, 1991	AHI (total)		Tx	TRD	8 wk	15	27.36	17.64	11.38	15.05	-15.98		0.01 (t=2.85, df=14)	+0.80		
US			Tx	PA		15	33.25	21.30	20.83	29.25	-12.42		0.08 (t=1.88, df=14)	+4.36		
1798889			Tx	TRD+PA		15	30.70	14.54	7.87	12.27	-22.83		<0.001 (t=5.24, df=14)	-6.05		
			Cx	Cx		15	26.69	13.31	7.72 †	9.91	-16.78		<0.01 (t="524"†, df=14)			
										ANOVA NS						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper
† 6.28, P<0.001 based on reported raw data. But mean = 7.66 (not 7.72

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	Also data for "Side AHI" and "Back" AHI

Pearson (r) correlations of 5 variables with total AHI. (see D for definition of nasal patency)

TABLE 8. *The relation of five factors to posttreatment total A + HI*

	All cases	TRD	PA	Both	HH
A + HI pre (severity)	0.378**	0.095	0.527*	0.172	0.524*
A + HI lateral	0.369**	0.555*	0.464	0.172	0.777**
Initial weight	0.289*	0.098	0.270	0.491*	0.246
Weight change	0.107	0.045	0.010	−0.584*	0.010
Nasal patency	0.021	0.573*	−0.145	−0.210	0.303

* $p < 0.05$.
** $p < 0.01$.

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. MAJOR ADVERSE EVENTS

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
	nd					

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	nd	No	Yes	No	nd	Yes (all)	No Comparison of final values, but pt-level data reported	NA	Yes	No (some results numbers are wrong)

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	No ("Positionality" not clear)	No	No (TRD?)	Yes	No	NA	NA	NA

Reasons for drop-outs:	NA
Other Issues:	
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Lam, 2007			**Intervention 1**	Conservative management plus Mandibular advancement device (OA)
PMID*	17121868	**RefID**	3499	**Intervention 2**	Conservative management plus CPAP (CPAP)
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	Conservative management (CM)
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSAS AHI≥5-40 ESS >9(for those with AHI 5-20)	Sleepiness which contributes risk to self or others Unstable medical diseases Other sleep disorders Previous surgery of upper airway except for nasal problems Pregnant women	5-40	nd	n	Hong Kong	nd	Y(ESS)	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
MDA	**34(34)**	76	45(2)		27.3(0.6)	Morning systolic127.1 Morning diastolic76.2 Evening systolic131.9 Evening diastolic77.8		
CPAP	**34 (34)**	79	45(1)		27.6(0.6)	Morning systolic127.9 Morning diastolic77.0 Evening systolic130.9 Evening diastolic78.0		
Cx	**33(33)**	79	47(2)		27.3(0.6)	Morning systolic125.5 Morning diastolic74.2 Evening systolic127.2 Evening diastolic73.5		
Total	**101(101)**			nd			nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SEM. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI (SE)*	Epworth (SE)*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
MDA	34	20.9(1.7)	12(1)					
CPAP	34	23.8(1.9)	12(1)					
Control:	33	19.3(1.9)	12(1)					
Total:	101			nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	5-40		AASM	AASM	nd	nd	nd

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	Conservative management plus Mandibular advancement device (OA)		Tailored made non adjustable oral appliance, mde from dental acrylic. Function was to hold the mandible in a forward position with vertical opening.
2	PAP	Conservative management plus CPAP (CPAP)	Repironics, ARIA LX (Atlanta, Georgia)	
3				
Control	Physical therapy	Conservative management (CM)		Advice on sleep hygiene measures plus weight loss program for overweight patients BMI≥23)
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleepiness measure	ESS	10 weeks	
2	Sleep study measure	AHI	10 weeks	
3	Sleep study measure	Min o2 sat	10 weeks	
4	Sleep study measure	Arousal index	10 weeks	
5	Sleep quality	SAQLI	10 weeks	Calgary sleep apnea quality of life index
6	QoL	SF 36	10 weeks	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*			
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P	comparison
Lam 2007 Hong Kong 17121868	ESS		**Tx**	CM+OA	10 weeks	34	12	1	9	1	-3					<0.05	CPAP vs OA
			Tx2	CM+CPAP	10 weeks	34	12	1	7	1	-5					<0.05	CM vs CPAP
			Cx	CM	10 weeks	33	12	1	10	1	-2						
	AHI		**Tx**	CM+OA	10 weeks	34	20.9	1.7	10.6	1.7	-10.3					<0.001	CM vs OA
			Tx2	CM+CPAP	10 weeks	34	23.8	1.9	2.8	1.1	-21					<0.001	CM vs CPAP
			Cx	CM	10 weeks	33	19.3	1.9	20.5	2.5	1.2					<0.001	CM vs OA
	Min o2 sat	%	**Tx**	CM+OA	10 weeks	34	73.8	1.9	81.0	1.6	7.2					NS	
			Tx2	CM+CPAP	10 weeks	34	75.0	1.4	87.2	2.9	12.2						
			Cx	CM	10 weeks	33	76.1	2.6	77.4	2.0	1.3						
	Arousal index		**Tx**	CM+OA	10 weeks	34	24.5	2.2	21.6	2.5	-2.9					<0.05	CM vs CPAP
			Tx2	CM+CPAP	10 weeks	34	21.6	1.7	16.3	1.8	-5.3						
			Cx	CM	10 weeks	33	23.5	2.2	28.8	2.5	5.3						
	SQALI	summary score (A-D)[a]	**Tx**	CM+OA	10 weeks	34	5.0	0.2	5.6	0.1	0.6					<0.05	CPAP vs OA
			Tx2	CM+CPAP	10 weeks	34	5.0	0.1	5.9	0.1	0.9					<0.001	CM vs OA
			Cx	CM	10 weeks	33	5.1	0.1	5.0	0.1	-0.1					<0.001	CM vs CPAP
	SQALI	summary score (A-E)[a]	**Tx**	CM+OA	10 weeks	34			5.5	0.1						<0.05	CM vs CPAP
			Tx2	CM+CPAP	10 weeks	34			5.5	0.2						<0.05	CM vs OA
			Cx	CM	10 weeks	33			5.0	0.1							

* Delete or correct the incorrect value/item. If change, highlight yellow. [a] A:daily functioning, B: social interactions, C: emotional, D: symptoms E: Treatment related symptom

** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Lam 2007 Hong Kong 17121868	SF 36	Physical function	10 wk	OA	34	CPAP	34						
		Physical function	10 wk	OA	34	CM	33						
		Physical function	10 wk	CM	33	CPAP	34	CPAP	Net difference	6.9	0	100	<0.05
		Bodily pain	10 wk	OA	34	CPAP	34	CPAP	Net difference	15.7	0	100	<0.001
		Bodily pain	10 wk	OA	34	CM	33						
		Bodily pain	10 wk	CM	33	CPAP	34	CPAP	Net difference	11.7	0	100	<0.05

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	nd	nd	y	y	n	y	

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	y	nd	na	na

Reasons for drop-outs:	
Other Issues:	
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Ryan, 2009			**Intervention 1**	humidified CPAP
PMID*	19961025	**RefID**	125	**Intervention 2**	steroid CPAP
Key Question(s)	5			**Intervention 3**	
Design †	RCT			**Control**	CPAP
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA with AHI ≥10; successful CPAP titration study; adequate nasal breathing	prior CPAP; required bilevel CPAP; supplemental O2; malignancy; psychiatric illness; regular narcotics, sedatives, or psychoactive meds	≥10	nd	no	Ireland	industry supplied CPAP devices and steroid	yes; 38 per group	no	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx1	**42**	95	50		35.3±6.1			
Tx2	**42**	95	48		33±5.3			
Cx	**39**	92	48		35.1±6.4			
Total	**123 (112)**	94	49	nd	34.4	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx1		31						
Tx2		31						
Cx		21						
Total	nd	28 (current)	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx1								
Tx2								
Cx								
Total	no prior CPAP							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	42	36±20	13±6					
Tx2	42	35±21	13±6					
Control:	39	36±22	12±5					
Total:	123	35.7	12.7	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
nd	nd	nd	nd	nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP + heated humidfication	humidifier HA 50 (Breas Medical, Sweden) + PV10 (Breas Medical)	
2	PAP	CPAP + nasal steroid	fluticsasone 50 mcg 2x daily (Glaxo Wellcome, spain) + PV10	
3				
Control	PAP	dry CPAP only	PV10	
For CPAP:		**How was the Pressure selected?**	nd	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	QoL	SF-36; Mini Rhinoconjunctivitis QoL	baseline, 4 wk	MiniRQLQ (14 items in 5 domains; 0 (no impairment) to 6 (severely impaired))
2	Sleepiness measures	Epworth	baseline, 4 wk	
3	Compliance	mean h per night use	4 wk	
4				

* QoL; ; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Ryan, 2009 Ireland 19961025	Epworth		**Tx1**	humidified CPAP	4 wk	42 (?)	13	6	8	6				-2	1.22	ANOVA P=0.694
			Tx2	steroid + CPAP	4 wk	42 (?)	13	6	9	5						
			Cx	dry CPAP	4 wk	39 (?)	12	5	9	5						
Ryan, 2009 Ireland 19961025	Compliance	h per night	**Tx1**	humidified CPAP	4 wk	42 (?)	NA		5.21	1.84				0	0.275	NS
			Tx2	steroid + CPAP	4 wk	42 (?)	NA		5.66	1.68						
			Cx	dry CPAP	4 wk	39 (?)	NA		5.21	1.66						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Intervention 3		Favors**		If Significant Difference		
				Name	N	Name	N	Name	N	Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P
Ryan, 2009 Ireland 19961025	SF-36		4 wk	humidified CPAP	42 (?)	steroid + CPAP	42 (?)	dry CPAP	39 (?)	0				
Ryan, 2009 Ireland 19961025	MiniRQLQ	activity limitations	4 wk	humidified CPAP	42 (?)	steroid + CPAP	42 (?)	dry CPAP	39 (?)	0				
		practical problems								0				
		eye limitations								0				
		nose symptoms								humidifier vs. steroid (P=0.008)	1.27±1.15 vs. 2.16±1.48 vs. 1.56±1.22 (ANOVA, P=0.009)	6	0	
		other symptoms								0				

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
nasal CPAP	10/123	5 intolerant to treatment; 5 unknown reasons
	1/123	myocardial infarction 10 d after enrollment
dry CPAP or humidity CPAP	8/81	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
u	nd	nd	y	n	nd	y	y/n	n	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	n	y				

Reasons for drop-outs:	
Other Issues:	no details on randomization; no adjustment for multiple comparisons
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Whyte, 1988			**Intervention 1**	Acetazolamide
PMID*	3067313	**RefID**	16941	**Intervention 2**	Protriptyline
Key Question(s)				**Intervention 3**	
Design †	Cross over(Medication)			**Control**	Placebo
Extractor	NO			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Patients who failed to respond to weight reduction and alcohol avoidance OSAHS AHI>15 At least two supporting sleep apnea symptoms(daytime somnolence, recurrent nocturnal awakening, unsatisfying nocturnal sleep)	nd	>15	nd	n	UK	nd	n	y	y
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx								
Cx								
Total	**10(10)**	80	34-67 years	nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	n
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:								
Control:								
Total:	10	>15	nd	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	>15		10secs	≥ 50% reduction in thoraco abdominal movement	Excessive daytime sleepiness Recurrent nocturnal awakenings	na	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Medication	Acetazolamide 250mg twice daily for one week then 250 mg 4 times daily for 1 week		
2	Medication	Protryptyline 20mg at night for 2 weeks		
3				
Control	Placebo	Placebo		nd
For CPAP:		**How was the Pressure selected?**		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1		Arousals	2weeks	
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD*	Value	SD/SE*	P	Value	SD/SE*	P
Whyte, 1988 UK 3067313	Arousals		Tx	Acetazolamide	2weeks				26	26						
			Tx	Protriptyline	2weeks				21	11						
			Cx	placebo	2weeks				16	10						
	AHI		Tx	Acetazolamide	2weeks				26	20						
			Tx	Protriptyline	2weeks				46	23						
			Cx	placebo	2weeks				50	26						
	Sleep efficiency		Tx	Acetazolamide	2weeks				~80							
			Tx	Protriptyline	2weeks				~82							
			Cx	placebo	2weeks				~70							
	REM		Tx	Acetazolamide	2weeks				23	8						
			Tx	Protriptyline	2weeks				18	12						
			Cx	placebo	2weeks				19	8						
	Stage 3 and 4		Tx	Acetazolamide	2weeks				~15							
			Tx	Protriptyline	2weeks				~14							
			Cx	placebo	2weeks				~15							

* some figures were approximated from tables
Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			Protriptyline	Acetazolamide		
Whyte, 1988 UK **3067313**	Dose dependent dry mouth		2/10	Present(no data on number affected)		
	Visual upset		1/10			
	Urinary symptoms		1/10			
	Paraesthesia			8/10		

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	n	y	y	y	n	y	na	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	n	Y(no information on exclusion criteria, not sure how 10 patients were selected)	y	y	?	na	n	nd

Reasons for drop-outs:	
Other Issues:	
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Woodson, 2003			**Intervention 1**	CPAP
PMID*	12825037	**RefID**	4977	**Intervention 2**	RFA (tongue & palate)
Key Question(s)	KQ 5 CPAP/RFA/Placebo			**Intervention 3**	
Design †	RCT			**Control**	Sham RFA
Extractor	EMB			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA AHI 10-30 18-65 y Daytime somnolence	BMI >34 Prior surgery or CPAP Other sleep disorder Tonsillar hypertrophy Nasal or supraglottic obstruction ASA class IV/V Claustrophobia Latex allergy Pregnancy Major depression or nonstablized psychiatric disorder Drug or EtOH abuse Accident due to sleepiness	10-30 (or 5-40) [two parts of methods section disagree with each other]	nd	Yes	US	Industry	Yes 30/arm (1/SRT)	Yes (to RFA) CPAP patients not blinded	Yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx: CPAP	**30 (28)**	75	52	nd	29.1	nd	nd	nd
Tx: RFA	**30 (29)**	90	49		27.7			
Sham RF	**30 (30)**	70	46		28.5			
Total			P=0.04					
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	0 (eligibility)	nd	0 (eligibility)	nd	Restricted eligibility
Cx								
Total								
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	No CPAP or surgery							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Tx: CPAP	27	19.8±9.9	12.6±5.0	nd	nd	nd	nd	
Tx: RFA	29	21.3±11.1	11.9±4.6					
Sham RF	30	15.4±7.8	11.6±3.5					
Total		P=0.06						

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify)	Other characteristics
No	Neck circumference normal (~41 cm) Upper airway volume 73.6 cm^3	

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Home Autoset PDS or PSG	>5		Cessation of inspiratory airflow ≥10 sec	Reduction of airflow ≥10 sec with 4% desat or EEG arousal		Separate (auto-titrate)	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	nCPAP	Autoset T	
2	RFA	Temperature controlled RF tissue ablation		5 tongue and 2 palate sessions planned, at 4 week intervals Nonoverlapping lesions in 2 (1000 J) or 3 (750 J) sites. Target 85º C, Max 10 W. 1 midline (650 J) and 2 lateral (325 J) soft palate lesions per session
3				
Control		Sham RFA		Similar process for tongue only (3 "lesions"). No energy delivered. 3 sessions. Same anesthesia, medications, and probe insertion
For CPAP:		**How was the Pressure selected?**	Titrated unattended over ≥3 nights with AutoSet T device	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
None		
For CPAP:	**Describe the frequency of the initial education follow-up**	nd. Seen at 1, 2 & 4 wk to troubleshoot & increase compliance

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Physical/Psychomotor	Slowest reaction time (SRT)	8 wk	Mean of slowest 10% of reaction times on the Psychomotor Vigilance Task (PVT-192). Analyzed as 1/SRT (larger values better).
2	QoL	Functional Outcomes of Sleep Questionnaire (FOSQ)		
3	QoL	Symptoms of Nocturnal Obstruction and Related Events (SNORE25) [Same as OSA Patient Oriented Severity Index]		
4	Sleepiness	Epworth Sleepiness Scale		
	QoL	SF-36 MCS & PCS		
	Sleep measure	AHI		
	Sleep measure	Minimum O2 saturation		
	Sleep measure	Total arousal index		
	Adverse events	Pain, swallowing problems	1 & 3 wk post-surgery	10 cm VAS (0=no pain, normal swallow)
	Adverse events	self-reported	8 wk	

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed Base/Final	Baseline		Effect Size (F mean - Base mean)/ (Base SD) + improve ≥0.5 = ≥"moderate"		Change (Final – Baseline)			Net Δ (Δ test – Δ control)		
							Value	SD	Value		Value	SD	P	Value	95% CI	P
Woodson, 2003	AHI	/hr	Tx	CPAP	8 wk	27/	19.8	9.9			nd					
US			Tx	RFA		29/24	21.3	11.1	0.38		-4.5	13.8	NS	-2.7	(-9.9, 4.5)	NS
12825037			Cx	Sham RF		30/28	15.4	7.8	0.24		-1.8	11.5	NS			
	Min SaO2	%	Tx	CPAP	8 wk	27/	86.0	6.4			nd					
			Tx	RFA		29/24	86.3	7.6	-0.08		-0.6	4.6	NS	-1.2	(-3.8, 1.4)	NS
			Cx	Sham RF		30/28	88.3	3.9	0.15		0.6	4.7	NS			
nl <10	ESS		Tx	CPAP	8 wk	27/25	12.6	5.0	0.44		-2.3	5.2	0.02	-1.4	(-3.8, 1.1)	NS
			Tx	RFA		29/26	11.9	4.6	0.50		-2.1	3.9	0.005	-1.2	(-3.1, 0.8)	NS
			Cx	Sham RF		30/28	11.6	3.5	0.27		-1.0	3.1	NS	0.20	(-2.39,2.80)	NS
nl>17.8	FOSQ		Tx	CPAP	8 wk	27/25	16.0	2.6	0.61		1.5	2.1	0.02	1.2	(0.1, 2.3)	0.02
			Tx	RFA		29/26	16.5	2.0	0.66		1.2	1.6	0.005	0.9	(-0.1, 1.9)	0.04
			Cx	Sham RF		30/28	16.8	2.1	0.18		0.4	2.0	NS	-0.29	(-1.35, 0.77)	NS
	SNORE25		Tx	CPAP	8 wk	27/	1.5	0.6	0.46		-0.30	0.52	0.005	-0.09	(-0.39, 0.21)	NS
			Tx	RFA		28/	1.6	0.7	0.65		-0.43	0.56	<0.001	-0.22	(-0.53, 0.09	0.08
			Cx	Sham RF		30/	1.6	0.7	0.31		-0.21	0.56	0.06	-0.13	(-0.44, 0.18)	NS
Norm 50	SF36 MCS		Tx	CPAP	8 wk	27/24	47.2	10.5	0.22		2.0	6.1	NS	1.7	(-1.8, 5.2)	NS
			Tx	RFA		28/24	46.4	9.4	0.32		2.9	7.3	0.08	2.5	(-1.4, 6.4)	NS
			Cx	Sham RF		30/27	46.7	9.8	0.04		0.4	6.4	NS	0.83	(-3.07, 4.74)	ns
Norm 50	SF36 PCS		Tx	CPAP	8 wk	27/24	50.7	6.7	0.02		0.1	7.7	0.08	-1.4	(-5.8, 3.0)	NS
			Tx	RFA		28/24	50.1	8.3	0.06		0.5	6.8	NS	-1.0	(-5.1, 3.1)	NS
			Cx	Sham RF		30/27	19.9	8.0	0.18		1.5	7.8	NS	0.38	(-3.86, 4.62)	NS
nl≥2.88	1/SRT	1/msec	Tx	CPAP	8 wk	28/19	2.77	0.66	0.30		0.18	0.60	NS	0.12	(-0.26, 0.51)	NS
			Tx	RFA		29/23	2.71	0.69	0.42		0.32	0.57	0.006	0.27	(-0.09, 0.62)	0.07
			Cx	Sham RF		29/25	2.88	0.55	0.09		0.05	0.66	NS	-0.15	(-0.22, 0.52)	NS

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper
RFA versus (minus) CPAP

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
Tx: CPAP	4/30 (13%)	1 withdrew prior to intervention, 2 found to have AHI>40, 1 lost to follow-up
Tx: RFA	4/30 (13%)	1 withdrew prior to intervention, 1 found to have AHI<5, 2 lost to follow-up
Sham RF	2/30 (7%)	1 withdrew prior to intervention, 1 lost to follow-up

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			CPAP	RFA	Sham RFA	
Woodson, 2003	Hematomas (% sessions)	1, 3 wk	NA	2.3% (3/26)	3.5% (3/28)	
US	Ulcerations (% of sessions)	same	NA	0.8% (1/26)	0	
12825037	Infections (% of sessions)	same	NA	0	0	
	(Pain & swallowing VAS reported but not extracted; hard to interpret)					
	Nasal dryness, congestion, bleeding or sinusitis	8 wk	38% (8/21)			
	Delayed sleep or subjective sleep fragmentation		43% (9/21)			
	Noise inconvenience and/or spouse objection		33% (7/21)			
	Aerophagia, Chest wall discomformt, or mouth breathing		33% (7/21)			
	Skin or eyes complaint		38% (8/21)			
	Total subjects affected by CPAP		95% (20/21)			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
Yes	Yes	Yes	Yes	Yes, but not CPAP	Yes	Yes	Yes (but not for baseline imbalances)	Yes	Not baseline imbalances	Except for AHI eligibility
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	No. AHI	No	Yes	No. Not scales	No (for CPAP)	Yes	NA			NA
Reasons for drop-outs:	See above									
Other Issues:	Extensive statistical methods section raises confidence that important issues were considered and dealt with appropriately									
Overall Quality (A, B, C)	**A (with caveat about AHI eligibility criteria)**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Questions 5 & 7
(Study with data for both questions)

A.

Author, Year	Damjanovic, 2009			**Intervention 1**	CPAP – intensive support
PMID*	19129293	**RefID**	3203	**Intervention 2**	CPAP – standard support
Key Question(s)	5, 7			**Intervention 3**	APAP – intensive support
Design †	RCT			**Intervention 4**	APAP – standard support
Extractor	si			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
newly diagnosed OSAS; AHI ≥15	resp failure; central sleep apnea; severe mental or psychological impairment	≥15	nd	n	Germany	nd	n	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx 1	**25**	80	59.4	nd	30.5±1.2 (SE)	nd	nd	nd
Tx 2	**25**	68	57.6	nd	31.2±1.0 (SE)	nd	nd	nd
Tx 3	**25**	84	54.9	nd	31.8±1.2 (SE)	nd	nd	nd
Tx 4	**25**	80	57.8	nd	30.8±0.8 (SE)	nd	nd	nd
Total	**100**	78	57.4	nd	31.1	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx	nd	nd	nd	nd	nd	nd	nd	
Cx	nd	nd	nd	nd	nd	nd	nd	
Total	nd	nd	nd	nd	nd	nd	nd	
	Treatments used (prior to trial, including surgery)							
Tx	nd							
Cx	nd							
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Intensive support	50	43.8±3.6 (SE)	10.1±0.6(SE)	nd	nd	nd	nd	nd
Standard support	50	43.6±3.4 (SE)	7.4±0.8 (SE)	nd	nd	nd	nd	nd
Total:	100	43.7±24.76(SD)	8.8±5.18	nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
PSG	≥15	nd	nd	nd	nd	separate night	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP – intensive support	AutoSet Spirit (ResMed, Australia)	fixed CPAP (pressure with the lowest RDI during PSG); optimal mask fit, use of moisturizers as indicated, early identification of low compliance, educational support, and counseling; visits at 1, 2, 4, 5, and 6 mo
2	PAP	CPAP – standard support	AutoSet Spirit (ResMed	fixed CPAP (pressure with the lowest RDI during PSG)
3	PAP	APAP – intensive support	AutoSet Spirit (ResMed	auto titrate CPAP; optimal mask fit, use of moisturizers as indicated, early identification of low compliance, educational support, and counseling; visits at 1, 2, 4, 5, and 6 mo
4	PAP	APAP – standard support	AutoSet Spirit (ResMed	auto titrate CPAP
For CPAP:		**How was the Pressure selected?**	pressure with the lowest RDI during PSG	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	1, 2, 4, 5, and 6 mo in the intense support group

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Sleep study measures	AHI	3 mo, 9 mo	
2	Sleepiness measures	Epworth	3 mo, 9 mo	
3	Compliance	h used per sleep time; days used	9 mo	Data were downloaded from CPAP device. Compliance data were obtained as follows: retention rate was calculated from the number of patients who returned for follow-up divided by the total number of patients; daily usage was calculated from the total number of hours divided by the total number of days used; the days the device was actually used were divided by the total number of days, in order to obtain the percentage; and the portion of individual sleep time spent with appropriate mask pressure was calculated from the daily usage in hours divided by patients' self-estimated sleep time, which they gave at the interview. Compliance parameters were set to zero when patients did not appear for their follow-up visit.
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P
Damjanovic, 2009 Germany 19129293	AHI		Tx	Intensive support	3 mo	46	43.8	3.6	5.6	0.7	-38.2		<0.01	-0.6		
			Cx	Standard support	3 mo	46	43.6	3.4	6.0	1.0	-37.6		<0.01			
Damjanovic, 2009 Germany 19129293	AHI		Tx	Intensive support	9 mo	44	nd	nd	3.5	0.8			<0.01			

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P
			Cx	Standard support	9 mo	34	nd	nd	5.9	1.6			<0.01			
Damjanovic, 2009 Germany 19129293	Epworth		**Tx**	Intensive support	3 mo	46	10.1	0.6	7.8	0.7	-2.3					<0.05 (final value btw groups at same time point)
			Cx	Standard support	3 mo	46	7.4	0.8	5.5	0.6	-1.9					
Damjanovic, 2009 Germany 19129293	Epworth		**Tx**	Intensive support	9 mo	44	nd	nd	6.6	0.7			<0.01			
			Cx	Standard support	9 mo	34	nd	nd	5.8	0.6						
Damjanovic, 2009 Germany 19129293	AHI		**Tx**	auto CPAP	3 mo	46	41.8	3.5	4.8	0.7	-37	3.208	<0.01	1.8	4.563	0.693
			Cx	Fixed CPAP	3 mo	46	45.5	3.6	6.7	0.9	-38.8	3.245	<0.01			

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P
Damjanovic, 2009 Germany 19129293	AHI		**Tx**	auto CPAP	9 mo	34	41.8 (?) nd	3.5 (?) nd	3.6	0.8			<0.01	1.9	4.469	0.671
			Cx	Fixed CPAP	9 mo	44	45.5 (?) nd	3.6 (?) nd	5.4	1.4			<0.01			
Damjanovic, 2009 Germany 19129293	Epworth		**Tx**	auto CPAP	3 mo	46	8.5	0.8	5.9	0.7	-2.6		<0.05	-0.3	1.03	0.771
			Cx	Fixed CPAP	3 mo	46	9.3	0.7	7	0.7	-2.3		<0.05			
Damjanovic, 2009 Germany 19129293	Epworth		**Tx**	auto CPAP	9 mo	34	8.5 (?) nd	0.8 (?) nd	5.9	0.7			<0.05	0.1	1.03	0.923
			Cx	Fixed CPAP	9 mo	44	9.3 (?) nd	0.7 (?) nd	6.6	0.7			<0.05			
Damjanovic, 2009 Germany 19129293	h used per sleep time	%	**Tx**	intensive support	3 mo	50	NA	NA	79.6	5.4						
			Cx	standard support	3 mo	50	NA	NA	75.7	4.1						
Damjanovic, 2009 Germany 19129293	h used per sleep time	%	**Tx**	intensive support	9 mo	50	NA	NA	80.6	3.2						<0.05 (final value btw groups at same time point)
			Cx	standard support	9 mo	50	NA	NA	64.2	6.2						
Damjanovic, 2009 Germany 19129293	h used per sleep time	%	**Tx**	Fixed CPAP	3 mo	50	NA	NA	81.4	5.8						
			Cx	auto CPAP	3 mo	50	NA	NA	73.4	3.1						

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P
Damjanovic, 2009 Germany 19129293	h used per sleep time	%	**Tx**	Fixed CPAP	9 mo	50	NA	NA	72.1	5.2						
			Cx	auto CPAP	9 mo	50	NA	NA	72.5	5.0						
Damjanovic, 2009 Germany 19129293	daily usage	h	**Tx**	intensive support	3 mo	50	NA	NA	5.5	0.2						
			Cx	standard support	3 mo	50	NA	NA	5.4	0.3						
Damjanovic, 2009 Germany 19129293	daily usage	h	**Tx**	intensive support	9 mo	50	NA	NA	5.7	0.2						<0.05 (final value btw groups at same time point)
			Cx	standard support	9 mo	50	NA	NA	4.6	0.4						
Damjanovic, 2009 Germany 19129293	daily usage	h	**Tx**	auto CPAP	3 mo	50	NA	NA	5.4	0.2				0	0.039	1.00
			Cx	Fixed CPAP	3 mo	50	NA	NA	5.4	0.3						
Damjanovic, 2009 Germany 19129293	daily usage	h	**Tx**	auto CPAP	9 mo	50	NA	NA	5.2	0.4				0.1	0.06	0.098
			Cx	fixed CPAP	9 mo	50	NA	NA	5.1	0.3						
Damjanovic, 2009 Germany 19129293	Arousal Index		**Tx**	Intensive support	3 mo	46	33.9	2.9	14.6	1.4	-19.3			-2.4		NS

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SE*	Value	SE*	Value	SE*	P	Value	SE*	P
			Cx	Standard support	3 mo	46	31.1	3.5	14.2	1.5	-16.9		<0.01			
Damjanovic, 2009 Germany 19129293	Arousal Index		**Tx**	Intensive support	9 mo	44	33.9	2.9	12.3	1.5	-21.6		<0.01	-4.5		NS
			Cx	Standard support	9 mo	34	31.1	3.5	14	1.4	-17.1		<0.01			
Damjanovic, 2009 Germany 19129293	Arousal Index		**Tx**	auto CPAP	3 mo	46	30.6	3.3	12.3	1.3			<0.01	-0.2	3.94	0.96
			Cx	Fixed CPAP	3 mo	46	34.5	3.1	16.4	1.4			<0.01			
Damjanovic, 2009 Germany 19129293	Arousal Index		**Tx**	auto CPAP	9 mo	34	30.6 (?) nd	3.3 (?) nd	12.9	1.5			<0.01	3.6	3.924	0.359
			Cx	Fixed CPAP	9 mo	44	34.5 (?) nd	3.1 (?) nd	13.2	1.5			<0.01			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons
intensive support	12% at 9 mo	
standard support	32% at 9 mo	

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	n	nd	nd	n	y	n	NA	y
	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?			If a Crossover study, was the Washout period adequate?
	y	n	y	y	n	y				
Reasons for drop-outs:										
Other Issues:										
Overall Quality (A, B, C)	B									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Key Question 6
Predictors of Compliance

A. Source and Extractor

Author, Year	Hui, 2001			**Outcomes**	Compliance
PMID	11451834	**RefID**	5388		
Key Question(s)	KQ 6 (CPAP)			**Design †**	Prospective cohort
Extractor	EB			**Comments**	

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	Exclusion	AHI Criteria to Dx OSA	Study Years	Multicenter?	Prospective vs retrospective	Country	Funding source
Newly diagnosed OSA Completed questionnaire	nd	>10	1997-1998 (recruitment)	No	Prospective	Hong Kong	Gov't

C. BASELINE CHARACTERISTICS:

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
112 (112)	90%	46	(Chinese)	29.3	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" & TREATMENT AT BASELINE

All had Sleep Study?	Which?	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Yes	PSG	48±24	nd	nd	nd	nd	)	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		
Timing of Baseline (OSA Dx, Time of survey, Other):					Diagnosis			
Treatments Being Used:					CPAP only			

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Other
PSG	≥10		>10 sec	≥50% for >10 sec and >4% desat or an arousal	Self reported sleepiness	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	nasal autoCPAP	Aria CPAP (Respironics) with Autoset titration	
2				
3				
Control				
For CPAP:		**How was the Pressure selected?**	Auto, separate night. Initial education and brochure Afternoon session for training. Available for assistance x 1 night F/up at 1 and 3 mo	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	"Linear trend", correlation, t test
Multivariate	"Independent factors" analyzed by "univariate ANOVA"

H. PREDICTORS TESTED

	Category	Predictor	Definition	Time Point Measured	Strata	Tested in Univariable Analysis?	Tested in Multivariable Analysis?	Comment
1	Demographic	Age						
2	Habitus	BMI						
3	Sleep measure	AHI		Baseline	"high baseline AHI"			unclear if analyzed as continuous or categorical variable (and what was threshold)
4	Sleep measure	Min O2 sat		Baseline				
	Sleep measure	mean O2		Baseline				
	Sleep measure	Arousal index		Baseline				
	Sleepiness	ESS		Baseline				
	Demographic	Education level						
	CPAP	CPAP pressure		unclear				
	Financial	Self- or Govt-paid CPAP						
5								
6								
	Criteria Used to Test Predictors in Multivariable Analysis					nd		

I. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome	How Ascertained?
1	Compliance	Objective compliance (h/night)	1, 3 mo		CPAP recording
2					
3					
4					

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

J. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor				Follow-up	n Event	N Total	Pct	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Unit	Base	Final					Metric*	Result	95% CI	P	Metric*	Result	95% CI	P	Adjusted for:
Hui, 2001	Objective compliance (h/night)	AHI				1 mo	nd	nd						none	nd	nd	0.006	
Hong Kong		Snoring											0.03				0.11	
11451834		Frequent awakenings											0.01					
		Witnessed apneas											0.04					
		Other symptoms											NS					
		AHI				3 mo	nd	nd						none	nd	nd	0.004	
		Snoring											0.06				0.24	
		Frequent awakenings											0.11					
		Witnessed apneas											0.22					
		Other symptoms											NS					

* RR, OR, HR, RD

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	

Comments on Results	

L. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons
Implied 0/112		

M. QUALITY

Analytic method very unclear. “Independent factors” is not consistent with “univariate ANOVA”. Unclear if truly multivariate.
Outcome not well defined (analyzed continuous or categorical?)
Unclear if AHI analyzed as continuous or categorical.

Quality: C

A. Source and Extractor

Author, Year	Izci, 2005			**Outcomes**	Compliance
PMID	15733510	**RefID**	4403		
Key Question(s)	KQ 2 (mandibular)			**Design †**	Retrospective cohort
Extractor	EMB			**Comments**	

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Study Years**	**Multicenter?**	**Prospective vs retrospective**	**Country**	**Funding source**
Custom fit intra-oral mandibular repositioning splint (consecutive) Diagnostic sleep study Periodontal status adequate	Central sleep apnea TMJ problems, periodontal disease, maxillo-facial abnormalities, insufficient teeth	≥5	nd	No	Retrospective	Scotland	nd

C. BASELINE CHARACTERISTICS:

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
177 surveyed (144)	79%	51	nd	nd	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" & TREATMENT AT BASELINE

All had Sleep Study?	**Which?**	**AHI***	**Epworth***	**MSLT* †**	**Habitual Snoring ***	**Bed partner, %**	**Time Since Diagnosis**	**Other (specify)**
Yes	nd	23	10	nd	99%	"Marital situation" 80%	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
Non-apneic snorer (<5): 12 (8%) Apneic w/o sleepiness: 58 (40%) Mild OSA: 25 (17%) Moderate OSA: 26 (18%) Severe OSA: 23 (16%)						nd		
Timing of Baseline (OSA Dx, Time of survey, Other):				Time of MRS prescription				
Treatments Being Used:				50 (35%) had not tolerated or failed to comply with CPAP				

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Other
nd	≥5		nd	nd	Excessive daytime sleepiness, ESS>10	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	Oral appliance	Mandibular repositioning splint	Individually manufactured and fitted by one dentist	Goal: ~80% maximal comfortable mandibular protrusion with 2-4 mm of inter-dental clearance. Not titratable.
2				
3				
Control				
For CPAP:		**How was the Pressure selected?**	Standard education about device use, maintenance and possible side effects given. All patients followed-up until device was as effective as workable. Remoulding done when necessary.	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	Kaplan-Meier
Multivariate	None

H. PREDICTORS TESTED

	Category	Predictor	Definition	Time Point Measured	Strata	Tested in Univariable Analysis?	Tested in Multivariable Analysis?	Comment
1	Demographic	Age				Yes		
2	Demographic	Sex				**Yes**		
3	Demographic	Occupation				**Yes**		
4	Lifestyle	Marital situation				**Yes**		
5	Lifestyle	Marital satisfaction				**Yes**		
	Habitus	Number of teeth				**Yes**		
	Symptoms	Snoring		Baseline		**Yes**		
	Symptoms	Refreshment after sleep		Baseline		**Yes**		
	Symptoms	Daytime somnolence		Baseline		**Yes**		
	Symptoms	Driving problems		Baseline		**Yes**		
	Sleep measure	ESS		Baseline		**Yes**		
	Sleep measure	AHI		Baseline		**Yes**		
	Treatment	MRS/CPAP	?			**Yes**		
	Treatment	Changes in symptoms		≥1 mo of use		**Yes**		
	Treatment	Side effects		≥1 mo of use		**Yes**		
	Criteria Used to Test Predictors in Multivariable Analysis							

I. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome	How Ascertained?
1	Compliance	Self-reported MRS use	1-31 mo	Nights/week of use Hr/night of use	
2					
3					
4					

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

J. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor				Follow-up	n Event	N Total	Pct	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Unit	Base	Final					Metric*	Result	95% CI	P					
Izci, 2005	Compliance	Age				1-31 mo							NS					
Scotland		Sex											NS					
15733510		Occupation											NS					
		Marital situation											NS					
		Snoring											NS					
		Refreshment after sleep											NS					
		Daytime somnolence											NS					
		Driving problems											NS					
		ESS											NS					
		AHI											NS					
		CPAP failure or refusal											NS					
	Continued use	**Number of teeth <12**								OR	0.16	0.05, 0.53)	0.004					
		Less snoring (patient report)									0.05	0.02, 0.13	0.0001					
		Less breathing pauses (patient report)									0.20	0.04, 0.32	0.0001					
		Improved sleep quality (patient report)									0.03	0.008, 0.12	0.0001					
		Improved tiredness (patient report)									0.04	0.008, 0.17	0.0001					
		Less snoring (partner report)									0.15	0.04, 0.55	0.008					
		Less breathing pauses (partner report)									0.24	0.07, 0.85	<0.05					
		Improvement sleepiness (partner report)									0.18	0.04, 0.72	<0.03					
		Improvement partner sleep quality									0.23	0.07, 0.77	<0.04					
		Poor marital satisfaction before MRS									5.63	1.34, 24	<0.04					
	Stopping MRS	Difficulty falling asleep / frequent awakening									15	1.83, 123	0.005					
		Soreness, oral									19	2.39, 153	0.001					
		Soreness, jaw									9.4	1.11, 80	0.04					
		Difficulty breathing									1.23	1.05, 1.37	0.01					
		Non-retention									1.44	1.17, 1.78	0.0001					

* RR, OR, HR, RD

Bold: Pre-MRS predictors that were discussed in the text

Apparently, post-MRS use predictors (changes). Text and Table seem to say different things. Text makes more sense: Better response led to more continued use.

Unclear what the predictors are. Not adequately discussed in text.

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	

Comments on Results	

L. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons
33/177	19%	No response

M. QUALITY

Retrospective. Univariable analysis.
“Predictors” poorly defined. Unclear which are pre- and which are post-MRS use.
Text and table do not clearly say the same thing.
Unclear how to interpret differences between continued use results and stopping MRS results.

Quality: C

A. Source and Extractor

Author, Year	Krieger, 1996			**Outcomes**	Compliance
PMID	9122571	**RefID**	8473		
Key Question(s)	KQ 6 (CPAP)			**Design †**	Prospective cohort
Extractor	EMB			**Comments**	

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	Exclusion	AHI Criteria to Dx OSA	Study Years	Multicenter?	Prospective vs retrospective	Country	Funding source
PSG for suspected OSA CPAP	nd	NA	1984-1995 (PSG and evaluation)	No	Prospective	France	nd

C. BASELINE CHARACTERISTICS:

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
608 (608)		54	nd	31.9	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	nd	nd	nd	nd	nd	nd	

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" & TREATMENT AT BASELINE

All had Sleep Study?	Which?	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Yes	PSG	70	8.8	16.5	nd	nd	New diagnosis	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		
Timing of Baseline (OSA Dx, Time of survey, Other):					OSA Dx			
Treatments Being Used:					CPAP alone			

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Other
PSG	nd		nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	nd	
2				
3				
Control				
For CPAP:		**How was the Pressure selected?**	Separate night titration	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	Kaplan Meier
Multivariate	Stepwise multiple regression

H. PREDICTORS TESTED

	Category	Predictor	Definition	Time Point Measured	Strata	Tested in Univariable Analysis?	Tested in Multivariable Analysis?	Comment
1	Sleep measure	AHI		Pre-CPAP	≤15 >15	Yes	Yes	
2	Demographic	Age		Pre-CPAP	nd		Yes	
3	Sleep measure	MSLT		Pre-CPAP	nd		Yes	
4	Sleep measure	ESS		Pre-CPAP	nd		Yes	
5	Symptom	Respiratory score	Questionnaire: frequency and intensity of snoring, choking, witnessed apneas	Pre-CPAP	nd		Yes	
6								
	Criteria Used to Test Predictors in Multivariable Analysis							

I. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome	How Ascertained?
1	Compliance	Continued CPAP use	3.2 y (mean)	If CPAP use <3 hr/day by questionnaire, medical or technical intervention planned. If remained <1 hr/day, machine was withdrawn.	Clinical follow-up
2					
3					
4					

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

J. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor				Follow-up	n Event	N Total	Pct	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Unit	Base	Final					Metric*	Result	95% CI	P	Metric*	Result	95% CI	P	Adjusted for:
Krieger, 1996 France 9122571	Continued CPAP use	AHI≤15				3.2 y (mean)			>60% 3 y				<0.005				<0.05	
		AHI>15							>90% 3 y >85% 7 y									
		Age															<0.05	
		MSLT															NS	
		ESS															NS	
		Respiratory symptoms															NS	

* RR, OR, HR, RD

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	

Comments on Results	

L. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons
0		

M. QUALITY

No obvious selection bias
Probably no ascertainment bias
Predictors not defined adequately.
Statistical analysis not described adequately.

Quality: C

A. Source and Extractor

Author, Year	McArdle, 1999			**Outcomes**	Compliance
PMID	10194153	**RefID**	5589		
Key Question(s)	KQ 6 CPAP			**Design †**	Prospective cohort
Extractor	EMB			**Comments**	

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Study Years**	**Multicenter?**	**Prospective vs retrospective**	**Country**	**Funding source**
Booked for CPAP titration	Kyphoscoliosis, Neuromuscular disorders Refused titration, unable to tolerate during titration, refused to take CPAP home.	Varied over time. >5 or >15 CPAP required ≥30	1986-1997 (enrollment)	No	Prospective	Scotland	nd

C. BASELINE CHARACTERISTICS:

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
1211 (1103)	86%	Median 50 (IQR 43-58)	nd	Median 30 (27-35)	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	Current 32%	nd		nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" & TREATMENT AT BASELINE

All had Sleep Study?	**Which?**	**AHI***	**Epworth***	**MSLT* †**	**Habitual Snoring ***	**Bed partner, %**	**Time Since Diagnosis**	**Other (specify)**
Yes	PSG (84%) [EdenTec 12%, Autoset 2%, Oximetry alone 2%]	Median 31 (IQR 18-53)	12 (8-16) >10 60%	nd	98%	nd	nd (implied start at time of Dx)	Sleepiness while driving 36%
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
no						nd		

Timing of Baseline (OSA Dx, Time of survey, Other):	Time of CPAP prescription
Treatments Being Used:	nd

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Other
PSG	Varied over time. >5 or >15 CPAP required ≥30		No airflow with throracoabdominal movement x 10 sec	≥50% reduction in thoracoabdominal movement x 10 sec	≥2 major symptoms	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	Various machines (implied). Respironics mask ~2/3 Sullivan Bubble mask (ResMed) ~1/3 Full face mask in <10	
2				
3				
Control				
For CPAP:		**How was the Pressure selected?**	Manual titration on separate night (except 4% with split night) Also education given prior to titration. 2 weeks contact with nurse specialist. At reviews, if objective CPAP use <2 h, confronted with usage data to encourage increase use. If still <2 h at 1 month f/up visit, CPAP machine reclaimed.	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	Kaplan Meier (log rank)
Multivariate	Cox proportional hazards

H. PREDICTORS TESTED

	Category	Predictor	Definition	Time Point Measured	Strata	Tested in Univariable Analysis?	Tested in Multivariable Analysis?	Comment
1	Demographic	Sex			Female	Yes	Yes	
2	Demographic	Age		Baseline	≥50	**Yes**	**Yes**	
	Habitus	BMI		Baseline	≤30	**Yes**	**Yes**	
3	Sleep measure	ESS		Baseline	≤10	**Yes**	**Yes**	
4	Sleep measure	AHI		Baseline	<15 <30	**Yes**	**Yes**	
5	Sleep measure	Arousal index		Baseline	<32	**Yes**	**Yes**	
	Symptom	Snoring			Nonsnorer	**Yes**	**Yes**	
	Symptom	Apnea			No apneas	**Yes**	**Yes**	
	Symptom	Somnolence			No somnolence	**Yes**	**Yes**	
	Symptom	Driving problem			No driving problem	**Yes**	**Yes**	
	Comorbidity	COPD			Coexisting COPD	**Yes**	**Yes**	
6	CPAP setting	CPAP pressure		Baseline	<8 cm H2O	**Yes**	**Yes**	
	(CPAP)	(Usage)		3 mo	(Usage at 3 mo)	**Yes**	**Yes**	
	Demographic	Occupation				Yes	No (NS univariate)	
	Miscellaneous	Referral source				Yes	No (NS univariate)	
	Habitus	Collar size				Yes	No (NS univariate)	
	Lifestyle	EtOH consumption				Yes	No (NS univariate)	
	Lifestyle	Smoking				Yes	No (NS univariate)	
	Diagnosis	Diagnostic study type				Yes	No (NS univariate)	
	Diagnosis	CPAP titration method				Yes	No (NS univariate)	
	Criteria Used to Test Predictors in Multivariable Analysis							

I. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome	How Ascertained?
1	Compliance	Stop using CPAP	Median 22 mo (IQR 12-36) Max 139 mo 25% >3 y 6% >5 y	Either voluntarily or if using <2 h/night for at least 1 month	Interview, medical records
2					
3					
4					

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

J. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor				Follow-up	n Event	N Total	Pct	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Unit	Base	Final					Metric*	Result	95% CI	P	Metric*	Result	95% CI	P	Adjusted for:
McArdle, 1999	Stopping CPAP use	TOTAL				Median 22 mo	217	1103	20%	KM %	16% (12 mo) 32% (4 y)							
Scotland		Female		14%						HR	1.48		0.03	HR			NS	
10194153		Age ≥50 y		~50%							1.43		0.001				NS	
		BMI≤30		~50%							1.65		0.0003				NS	
		ESS ≤10		40%							1.89		<0.0001		1.92	1.41, 2.61	<0.001	Also: Use at 3 mo <2 h
		AHI <15		nd							2.29		<0.0001		2.48	1.79, 3.46	<0.001	
		AHI <30		~50%							2.26		<0.0001				NS	
		Arousal Ind<32		~50%							1.55		0.004				NS	
		Nonsnorer		2%							2.60		0.006		2.76	1.29, 5.95	0.009	
		No (witnessed) apneas		17%							2.25		<0.0001				NS	
		No somnolence		19%							2.23		<0.0001				NS	
		No driving problem		64%							2.25		<0.0001				NS	
		Coexisting COPD		10%							1.60		0.01				NS	
		Pressure <8 cm H2O		~50%							1.53		0.02				NS	

* RR, OR, HR, RD

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	
McArdle, 1999	Stopping CPAP use	AHI, continuous	Median 22 mo	Lower AHI predicted less compliance	
Scotland		ESS, continuous		Lower ESS predicted less compliance	
10194153					

Comments on Results	Reasons for patients stopping using CPAP: Lack of benefit 112/217 (52%) Discomfort (including noise and claustrophobia) 102/217 (47%) Cure as a result of weight loss, epistaxis, alternative diagnosis, unknown 28/217 (13%) (More than one reason in 20 patients

L. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons
56/1211	4.6%	Lack of followup data
(also 52 who refused CPAP initially)		

M. QUALITY

No obvious selection bias
No obvious ascertainment bias.
Proper statistical analyses. Well described.

Quality: A

A. Source and Extractor

Author, Year	Pepin, 2009			**Outcomes**	Compliance
PMID	19567496	**RefID**	3695		
Key Question(s)	KQ 6 (CPAP)			**Design †**	RCT (analyzed as prospective cohort)
Extractor	EMB			**Comments**	

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Study Years**	**Multicenter?**	**Prospective vs retrospective**	**Country**	**Funding source**
Newly diagnosed SA Age >18 y Referred for CPAP	Pregnant Medically unstable Predominantly central SA	≥15	nd	Yes	Prospective	France	Gov't Industry (Respironics)

C. BASELINE CHARACTERISTICS:

N enrolled (analyzed)	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
218 (218)	72%	56	nd	31 ≥30 kg/m^2: 57%	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	12% ("consumption")	nd	nd	nd	nd	nd	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" & TREATMENT AT BASELINE

All had Sleep Study?	**Which?**	**AHI***	**Epworth***	**MSLT* †**	**Habitual Snoring ***	**Bed partner, %**	**Time Since Diagnosis**	**Other (specify)**
Yes	PSG or portable	43.8	11.6	nd	nd	nd	~0	None
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
None						nd		None
Timing of Baseline (OSA Dx, Time of survey, Other):					Start of trial / CPAP			
Treatments Being Used:					CPAP alone			

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Other
In-lab PSG or Cardio-respiratory polygraphy	≥15		Apnea: >10 s Hypo: ≥30% reduction of airflow, 3% desaturation and/or microarousal	NA	Separate (all referred for CPAP)	None

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	C-Flex	C-Flex	
2	PAP	CPAP (C-Flex not activated)	C-Flex	
3				
Control				
For CPAP:		**How was the Pressure selected?**	2 nights with an autotitration device without C-Flex activated. Following the autotitration period, fixed CPAP was used at the pressure that was effective for > 90% of the night	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	
Multivariate	Logistic regression

H. PREDICTORS TESTED

	Category	Predictor	Definition	Time Point Measured	Strata	Tested in Univariable Analysis?	Tested in Multivariable Analysis?	Comment
1	Demographic	Sex					Yes (implied)	
2	Demographic	Age			per 10 y		Yes	
3	Habitus	BMI			continuous		Yes (implied)	
4	Sleep measures	Mean SaO2			continuous		Yes	
5	Sleepiness	Sleepiness domain of GrenobleSAQOL			continuous		Yes	
6		Implied also: Other PSG measures, including AHI Other domains of GrenobleSAQOL	5 questions in 40 question survey					
	Criteria Used to Test Predictors in Multivariable Analysis					nd		

I. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome	How Ascertained?
1	Compliance	Objective compliance		Not defined. Possibly h/night Or ≥4 h/night	CPAP recording
2					
3					
4					

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

J. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor				Follow-up	n Event	N Total	Pct	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Unit	Base	Final					Metric *	Result	95% CI	P	Metric *	Result	95% CI	P	Adjusted for:
Pepin, 2009	Objective compliance (continuous or categorical?)	Age	/10 y			3 mo								OR	0.9	0.54, 1.34	NS	3 month "noise", "feel resistance to exhalation", treatment domain of SAQOL
France		SaO2, mean	%												1.22	1.03, 1.45	0.02	
19567496		GrenobleSAQOL Sleepiness	scale unit?												1.13	1.04, 1.24	<0.01	

* RR, OR, HR, RD

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	

Comments on Results	

L. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons
0		implied

M. QUALITY

Outcome not clearly defined (continuous or categorical?)
Incomplete list of analyzed predictors
Mix of pre- and post-treatment predictors
Not clearly stated whether this is a multivariate analysis.

Quality: C

A. Source and Extractor

Author, Year	Wild, 2004			**Outcomes**	Compliance
PMID	15358707	**RefID**	4962		
Key Question(s)	KQ 6 (CPAP)			**Design †**	Prospective cohort
Extractor	EB			**Comments**	Separate study from McArdle, though done in same center.

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	Exclusion	AHI Criteria to Dx OSA	Study Years	Multicenter?	Prospective vs retrospective	Country	Funding source
Attending CPAP titration, diagnosed with OSAHS	Serious coincident illness or already participating in another research protocol	nd	nd (8 month period)	No	Prospective	Scotland	nd

C. BASELINE CHARACTERISTICS:

N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
162 (119 with full data)	79%	51	nd	33	nd	nd	nd
NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
nd	56% current	nd	nd	nd	nd	EtOH 8±11 units/week	No

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" & TREATMENT AT BASELINE

All had Sleep Study?	Which?	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Yes	PSG or home	45±35	13±5	nd	nd	82% married	New diagnosis (implied)	Min O2 sat 80±10% CPAP pressure 9±2
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
No						nd		
Timing of Baseline (OSA Dx, Time of survey, Other):				CPAP titration				
Treatments Being Used:				CPAP only				

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Other
PSG or home	nd	nd	nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

F. INTERVENTIONS*

	Intervention Category †	Specific Intervention ‡	Brand Name or Equivalent	Description
1	PAP	CPAP	nd	nd
2				
3				
Control				
For CPAP:		**How was the Pressure selected?**	nd (separate night) Pretitration training, home support at 2 weeks, formal f/up at 3 mo	

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. STATISTICAL ANALYSES PERFORMED

	METHOD
Univariate	Logistic regression
Multivariate	Logistic regression, forward stepwise

H. PREDICTORS TESTED

	Category	Predictor	Definition	Time Point Measured	Strata	Tested in Univariable Analysis?	Tested in Multivariable Analysis?	Comment
1	Psychological	Multidimensional locus of control scale	Wallston KA. Health Educ Monogr 1978; 6: 161–170. Internality: Believes locus of control is internal Chance: Believes chance or external factors determine health outcomes Powerful others: Control by powerful others (particularly health professionals) in health	Pre-titration	Cut at median			
2	Psychological	Health value scale	Lau RR. Health Psychol 1986; 5: 25–43. How much they value their health	Pre-titration	Cut at median			
3	Psychological	Generalized self-efficacy scale	Schwarzer R, ed. Self-efficacy: thought control of action. Hemisphere, 1992. Belief in their ability to respond to novel or difficult situations and deal with obstacles or setbacks	Pre-titration	Cut at median			
	Demographic	Age		Pre-titration				
	Demographic	Sex		Pre-titration				
	Habitus	BMI		Pre-titration				
	Lifestyle	EtOH intake		Pre-titration				
4	Lifestyle	Current cigarette use		Pre-titration				
	Lifestyle	Marital status		Pre-titration				
5	Sleep measure	AHI		Pre-titration				
	Sleep measure	minimum O2 sat		Pre-titration				
	Sleepiness	ESS		Pre-titration				
6	CPAP	Initial pressure after titration		Post-titration				
	Criteria Used to Test Predictors in Multivariable Analysis					Inclusion p<0.2; exclusion p>0.3		

I. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome	How Ascertained?
1	Compliance	Adherence	3 months	>3 h/night	CPAP time clock reading
2					
3					
4					

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Preference; Harms;

J. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Predictor				Follow-up	n Event	N Total	Pct	Unadjusted (reported)				Adjusted (reported)				
		Predictor	Unit	Base	Final					Metric*	Result	95% CI	P	Metric*	Result	95% CI	P	Adjusted for:
Wild, 2004	Adherence	Total				3 mo	nd	119										
Scotland		Internality (MLCS)												OR	1.064	nd	NS	With psychological variables
15358707		Powerful others (MLCS)													0.946	nd	NS	
		Chance (MLCS)											NS					
		Health value scale													1.396		0.02	
		Generalized self-efficacy scale											NS					
		Age											NS					
		Sex											nd					
		BMI	continuous, implied												1.103	nd	0.007	
		EtOH intake											NS					
		Current cigarette use											NS					
		Marital status											NS					
		AHI	continuous, implied												1.019	nd	0.02	
		minimum O2 sat											NS					
		ESS	continuous, implied												1.127		0.01	
		CPAP pressure	continuous, implied												0.80	nd	0.04	
		AHI													1.02		0.02	Without psychological variables
		CPAP pressure													0.82		0.05	
		BMI													1.09		0.02	
		ESS													1.09		0.04	

* RR, OR, HR, RD

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome	Predictor	Follow-up	Results	

Comments on Results	

L. REASONS FOR DROPOUT / POST HOC EXCLUSION FROM ANALYSIS

n/N	% Not Included in Analyses	Reasons
43/162	27%	Did not complete all questionnaire items

M. QUALITY

No obvious selection bias
No obvious ascertainment bias
Analyzed as a predictive model. Not fully clear results reporting. No data on adherence rate.

Quality: B

Key Question 7
Treatments for Compliance

A.

Author, Year	Antic, 2009			**Intervention 1**	Model A (the simplified nurse-led model of care)
PMID*	19136368	**RefID**	7046	**Intervention 2**	
Key Question(s)	7			**Intervention 3**	
Design †	RCT			**Control**	Model B (traditional physician-directed care)
Extractor	MC			**Comments**	Interventions not specifically to improve CPAP complaince

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Patients referred with a clinical suspicion of OSA. ESS score of 8 or more, history of snoring ''most nights'' or ''every night,'' age 18–75 years, and willing to trial CPAP.	unstable cardiovascular diseases (e.g. recent unstable angina, myocardial infarction, stroke or TIA within the previous 6 months or severe left ventricular failure), neuromuscular disease affecting or potentially affecting respiratory muscles, moderate to severe respiratory disease (i.e. breathlessness affecting activities of daily living) or documented hypoxemia or awake SaO2 <92% or psychiatric disease that limited the ability to give informed consent or complete the study	home oximetry with an oxygen saturation dip rate >27/hr at the >2% level. Prior study showed this cut-point gave the highest diagnostic sensitivity for PSG-determined AHI ≥30	March 2004 to September 2006	yes	Australia	Private and industry	Yes (noninferiority of nurse-led management compared with specialist-directed care with respect to change in ESS)	no	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Tx	**100 (90)**	72	49.9		35.1 ± 0.7 (SE)			
Cx	**95 (84)**	76	50.3		34.0 ± 0.6 (SE)			
Total	**195 (174)**			nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	none							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	100	n/a (home oximetry only)	13. ± 0.4 (SE)					
Control:	95	67.9 ± 2.82	13.4 ± 0.4 (SE)					
Total:	195			nd	nd	nd	0	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
All reported snoring most nights or every night								

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
home oximetry	an oxygen saturation dip rate >27/hr at the >2% level	nd	nd	nd	snoring most nights or every night	Model A (the simplified nurse-led model of care): home autotitration Model B (traditional physician-directed care): lab titration on a separate night after diagnostic PSG	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	Model A (the simplified nurse-led model of care)	Home diagnosis, CPAP titration with an autoadjusting positive airway pressure device to set a fixed CPAP pressure, and overall care supervised by a specialist nurse	Home autotitrating CPAP (Autoset T; ResMed, Sydney, Australia); CPAP device (S6 Elite lightweight; ResMed)		
2					
3					
Control	Model B (traditional physician-directed care)	In-laboratory PSG, hospital-based program of care	PSGs were conducted using Compumedics E Series equipment (Melbourne, Australia)p; CPAP device (S6 Elite lightweight; ResMed)		
Sleep apnea Intervention†‡:		**For CPAP, how was the pressure selected?**	Model A: fixed CPAP pressure was determined a priori. Model B: titration of CPAP pressure to abolish snoring, oxygen desaturation and apneas and hyponeas. fixed CPAP pressure was determined a priori.		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	compliance	CPAP adherence	nd	Measured by in-built compliance meter for the 3 month duration of the trial
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SE	Value	SD/SE*	P	Value	SE	P
Antic, 2009 Australia 19136368	CPAP compliance	hr/night	Tx	Model A (nurse-led care, home care)	3 mo	94			4.11	0.28				-0.45	0.41	NS
			Cx	Model B (traditional, physician-led care)	3 mo	83			4.56	0.30						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	The authors stated that "the mean adherence figures included data from 8 patients (4 in each group) who did not use CPAP during the 3 months of follow-up but returned for final assessment."

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	y	y	n	y	n	y	n	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	n (for compliance outcome)	NA	n		

Reasons for drop-outs:	Unwilling to continue with CPAP (n=11), depressive illness (n=2), unknown (n=8). No differences between groups.
Other Issues:	Different CPAP titrations between groups by study design. This trial was no focusing on compliance.
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Bradshaw, 2006			**Intervention 1**	Oral hypnotic agent (zolpidem), 10 mg
PMID*	17099012	**RefID**	3109	**Intervention 2**	
Key Question(s)	5; 7			**Intervention 3**	
Design †	RCT			**Control**	Ctrl 1: Placebo pill Ctrl 2: Standard care (no zolpidem or placebo pill)
Extractor	MC			**Comments**	

* or Cochrane number

† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Consecutive patients referred for initiation of CPAP treatment; age ≥18 years, an AHI ≥5, an Epworth sleepiness scale≥10, and willingness to try CPAP.	Previously used CPAP, a known allergy or intolerance the study medication, or involved in an operational (ie, military) assignment that might preclude nightly use of CPAP or planned follow-up	≥5	April 2001 and June 2003	no	US	no source of external funding	Yes (difference of 1 h in CPAP usage per night)	Yes (for Tx and placebo control groups) No (for standard care group)	Yes (for Tx and placebo control groups) No (for standard care group)
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	24 (24)	100	40.25		32.40 ± 4.82			
Cx1 (placebo)	24 (24)	100	36.08		30.47 ± 5.39			
Cx2 (standard care)	24 (24)	100	38.04		33.52 ± 4.98			
Total	72 (72)	100	38.13	nd	32.13 ± 7.37	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx1 (placebo)								
Cx2 (standard care)								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx1 (placebo)								
Cx2 (standard care)								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	24 (24)	32.61 ± 25.12	13.94 ±2.45					
Cx1 (placebo)	24 (24)	38.09 ± 25.65	14.75 ± 2.81					
Cx2 (standard care)	24 (24)	54.75 ± 28.02 (P=0.012 between groups)	14.41 ±3.22					
Total:	72 (72)	42.82 ± 27.60	15.38 ± 3.51	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
AHI	≥40 or ≥20 with oxygen desaturation ≤75% over the first 2 h of sleep (lab), or dividing the number of apneas and hypopneas by total study time (home)	nd	Cessation of oronasal airflow for at least 10 s with evidence of ongoing ventilatory effort	A reduction of oronasal airflow by at least one third with an associated oxygen desaturation ≥4%.	nd	Both	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	zolpidem	Zolpidem 10 mg	Zolpidem	14 days	
2					
3					
Control 1	Placebo pill	Placebo pill		14 days	
Control 2	Standard care	Standard treatment with no zolpidem or placebo pill		14 days	Patients in the standard care has more severe OSA based no AHI, and were not blinded
Sleep apnea Intervention†‡: CPAP: standardized "one-on-one" CPAP training session utilizing a checklist of topics that included nasal mask fitting, review of machine function and maintenance, and viewing of a commercially produced video ("Rise and Shine"; Respironics; Murrysville, PA) that explained the benefits of CPAP therapy		**For CPAP, how was the pressure selected?**	• zolpidem group (polysomnography, n =10; split-night study, n =11; cardiopulmonary homestudy, n =3) • placebo pill group (polysomnography, n =10; split-night study, n =8; cardiopulmonaryhome study, n =6) • standard care group (polysomnography, n =7; split-night study, n =13; and cardiopulmonary home study, n =4)		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	CPAP use – hours/night	Internally recorded CPAP usage data for each of the 28 days	For 1 patient in the zolpidem group, only the total number of days used and the average use per night were available. For 2 patients in the placebo pill group, <28 days of data were available (11 days and 7 days, respectively). These subjects were presumed not to have used CPAP on days with missing data and were included in the analysis according to the intention-to-treat principle. Arbitrarily chose a cutoff of 10 min to determine whether CPAP had been used on a particular day. Any usage <10 min was counted as a day not used.
2	Compliance	Number of patients with mean CPAP use > 4 h	Same as above	
3	Compliance	Number of patients receiving CPAP >70% of nights	Same as above	
4	Compliance	Number of patients with both mean > 4 h and using > 70% of nights	Same as above	
5	Harms	Adverse medication effect		
6	General symptom scales	ESS	At baseline and follow-up after day 28	Subjective sleepiness. Higher ESS scores indicate greater sleepiness, and a cut point of 10 is often used to distinguish normal (<10) from excessive (≥10) daytime sleepiness.
7	General symptom scales	FOSQ	At baseline and follow-up after day 28	26-item functional outcomes of sleep questionnaire. Scores were reported by subcategory (activity level, vigilance, intimacy, general productivity, and social outcomes) and summed to give a "global" score. Higher FOSQ scores indicate better function.

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Bradshaw, 2006 US 17099012	Number of patients with mean CPAP use > 4 h	**Tx**	Zolpidem	4 weeks	17	24				NS (between groups)				
		Cx1	Placebo pill	4 weeks	13	24								
		Cx2	Standard care	4 weeks	17	24								
Bradshaw, 2006 US 17099012	Number of patients receiving CPAP >70% of nights	**Tx**	Zolpidem	4 weeks	16	24				NS (between groups)				
		Cx1	Placebo pill	4 weeks	13	24								
		Cx2	Standard care	4 weeks	20	24								
Bradshaw, 2006 US 17099012	Number of patients receiving CPAP >70% of nights	**Tx**	Zolpidem	4 weeks	14	24				NS (between groups)				
		Cx1	Placebo pill	4 weeks	12	24								
		Cx2	Standard care	4 weeks	15	24								

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference		
							Value	SD/SE*	Value	SD	Value	SD/SE*	P	Value	SD/SE*	P
Bradshaw, 2006 US 17099012	CPAP use	hr/night	**Tx**	Zolpidem	Days 1-14	24			11.08	3.66						NS (between groups)
			Cx1	Placebo pill	Days 1-14	24			9.54	4.60						
			Cx2	Standard care	Days 1-14	24			12.13	3.23						
Bradshaw, 2006 US 17099012	CPAP use	hr/night	**Tx**	Zolpidem	Days 15-28	24			9.50	4.62						NS (between groups)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference		
							Value	SD/SE*	Value	SD	Value	SD/SE*	P	Value	SD/SE*	P
			Cx1	Placebo pill	Days 15-28	24			8.29	5.15						
			Cx2	Standard care	Days 15-28	24			10.79	3.88						
Bradshaw, 2006 US 17099012	ESS score		**Tx**	Zolpidem	28 days	24	15.63	2.81	9.63	4.83			<0.001			NS (between groups)
			Cx1	Placebo pill	28 days	24	14.79	3.65	8.21	5.54			<0.001			
			Cx2	Standard care	28 days	24	15.71	4.04	9.00	5.77			<0.001			
Bradshaw, 2006 US 17099012	FOSQ global score		**Tx**	Zolpidem	28 days	24	13.94	2.45	16.60	2.63			<0.001			NS (between groups)
			Cx1	Placebo pill	28 days	24	14.75	2.81	17.45	2.54			<0.001			
			Cx2	Standard care	28 days	24	14.41	3.22	17.26	3.04			<0.001			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	For FOSQ activity, vigilance, intimacy, productivity, and social scales: none of these scores were statistically significantly different between groups at

	baseline or at follow-up. For all scales, the changes within group were all statistically significant. Baseline FOSQ productivity score was borderline significantly higher in placebo group than zolpidem and standard care group (p=0.061 between groups)

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention
			Zolpidem, 10 mg			
Bradshaw, 2006 US 17099012	Any adverse event associated with medications	28 days	A sleep walking event occurred after 2nd night			

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	y (for Tx and placebo control groups) n (for standard care group)	y (for Tx and placebo control groups) n (for standard care group)	y	y	NA	N (for comparison to standard care group)	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	NA	y		

Reasons for drop-outs:	No dropout
Other Issues:	Patients in the standard care had more severe OSA based on AHI, and were not blinded. The authors stated that one could make the argument that the higher AHI in the standard care group might have lead to greater CPAP usage, thereby masking a beneficial effect of zolpidem in patients with less severe disease.
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Chervin, 1997			**Intervention 1**	Telephone calls from one of the investigators
PMID*	9231954	**RefID**	4144	**Intervention 2**	Literature containing educational information on CPAP and guidelines for CPAP use
Key Question(s)	7			**Intervention 3**	
Design †	RCT			**Control**	Standard care (no additional intervention to improve compliance)
Extractor	MC			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Adult OSA patients from the Sleep Disorders Clinic with bilevel positive airway pressure; no signs of cognitive deficit; had electronic hour meters in their CPAP machines.	Lost to follow-up; impossible CPAP reading data	nd	July and August 1995	no	US	nd	no	nd	no
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
TEL calls	**(12)**	67	53.8					
Literature	**(14)**	71	52.9					
Cx	**(7)**	43	45.7					
Total	**40 (33)**	64	51.7	nd	nd	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
TEL calls								
Literature								
Cx								
Total	nd	nd	nd	nd	nd	nd		no
	Treatments used (prior to trial, including surgery)							
TEL call								
Literature								
Cx								
Total	All subjects were recruited after visiting a sleep medicine physician. Physicians gave all subjects verbal explanations of what CPAP does, the expected benefit, and the need for regular CPAP use, and no modification of this practice was instituted during the study period							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
TEL call	12	57.2 ± 48.7	11.5 ± 5.5	4.5 ± 2.6				
Literature	14	54.3 ± 33.7	12.4 ± 5.3	6.6 ± 3.4				
Control:	7	27.3 ± 25.3	7.8 ± 2.9	6.5 ± 5.5				
Total:	33	49.4 ± 38.9	10.9 ± 5.1	6.0 ± 3.9	nd	nd	nd	

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify)	Other characteristics
nd	nd	New to vs. continuous CPAP: TEL call: 5/7 Literature: 3/11 Control: 2/5 Total: 10/22

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
nd	nd	nd	nd	nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	Telephone calls	1 telephone call each week (5-9 days) from one of the investigators. During these calls subjects were asked whether thy had any problems with CPAP and were encouraged to use it nightly. Subjects who reported problems were put in contact with appropriate individual.	N/A	One phone call every 5 to 9 days for 1 to 2.5 months	
2	Literature	One pamphlet, designed for patient education and available through the American Sleep Disorders Association, entitled "Sleep Apnea and Snoring"; one-half-page document written by the authors and entitled "Guidelines for CPAP (or BiPAP) Use".	N/A	N/A	
3					
Control	Standard care	Usual information provided our clinic physicians and home care companies	N/A	N/A	

Sleep apnea Intervention†‡: CPAP (REMstar Choice, Respironics, Inc., Murrysville, PA). One subject in each of the three groups used the Healthdyne Quest (healthdyne, Inc., Marietta, GA), and 4 subjects used four other types of machines made by the same two companies.	**For CPAP, how was the pressure selected?**	Not reported Note: Patients were either new to CPAP or continuing on it. CPAP settings (i.e. titrated effective CPAP pressure) were similar between groups.

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	CPAP use hr/night	Hour meter readings on CPAP machines were read by patients at initiation of the study and again when they were contacted by phone 1 to 2.5 months later	The number of hours of CPAP use were recorded by built-in counters on CPAP machine, and was then divided by the number of days elapsed between the two readings to obtain the mean number of hours of use of CPAP per night
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference		
							Value	SD/SE*	Value	SD	Value	SD/SE*	P	Value	SD/SE*	P
Chervin, 1997 US 9231954	CPAP use	hr/night	**Tx 1**	**TEL call**	1-2.5 mo	12			5.7	2.3						0.02 (between groups)
			Tx 2	**Literature**	1-2.5 mo	14			7.1	1.8						
			Cx	**Standard care**	1-2.5 mo	7			4.4	3.4						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	There was an interaction effect with "new to' vs. "continuing on it" CPAP status (p = .004); the increase in compliance with intervention was greater for new CPAP users than for continuing users. The complete regression model used 3 explanatory variables: group, new versus continuing on CPAP, and an interaction term.Results remained significant even when the data from the one control subject who did not use CPAP at all were excluded.

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	n	nd	n	n	NA	n	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	n	y	y	y	NA	y		

Reasons for drop-outs:	Impossible to reach by phone to establish counter readings (n=5) and counter readings reported by the patients were physically impossible (n=2)
Other Issues:	Mixed patients who were new to and those who had been using CPAP together. Likely had deferential dropout rate across groups although data were not clearly reported. Patients' characteristics were poorly reported. The distribution of patients was a little bit different between groups although not statistically significant. Variable follow-up duration with unexplained reasons. Unclear whether patients were followed-up in the same manner across all groups but it is very likely that phone call group had more complete follow-up (due to the nature of follow-up method)
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	DeMolles, 2004			**Intervention 1**	Telephone-linked communications for CPAP (TLC-CPAP) + usual care
PMID*	15258478	**RefID**	4198	**Intervention 2**	
Key Question(s)	7			**Intervention 3**	
Design †	RCT			**Control**	Usual care
Extractor	MC			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Adults starting nasal CPAP therapy through a collaborating home care company; English-speaking, have a physician diagnosis of OSAS, and have polysomnography demonstrating >15 episodes of apnea or hypopnea per hour of sleep	Prior CPAP use	nd	nd	no	US	Government	no	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**15 (15)**		49.8		38.0 ± 12.2			
Cx	**15 (15)**		42.0		38.1 ± 7.0			
Total	**30 (30)**	nd		nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	No prior CPAP use							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	15 (15)	41.8 ± 38.1						Sleep Symptom Checklist (developed by Scottish national Sleep Lab) = 23.7 ± 7.0
Control:	15 (15)	38.1 ± 40.1						25.3 ± 9.1
Total:	30 (30)		nd	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
physician diagnosis and polysomnography	nd	nd	nd	nd	polysomnography demonstrating >15 episodes of apnea or hypopnea per hour of sleep	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	Telephone-linked communications for CPAP (TLC-CPAP)	Subjects assigned to the TLC intervention group were trained to use TLC. TLC technology is a computer-based telecommunications system that functions as an at-home monitor, educator, and counselor to improve health-related behaviors. The patients respond by using the touchtone keypad of their telephones. The TLC-CPAP content is based on patterns of CPAP adherence and side-effect profiles identified in prior studies. Reinforcement of the need for regular CPAP use was provided at the end of the dialogue (except when a patient had been instructed by a physician to discontinue CPAP), reminding the patient that CPAP use would likely reduce daytime sleepiness and could also have the additional benefit of reducing the risk of cardiovascular disease.	nd	patients were asked to make their first TLC-CPAP call 3 days after starting CPAP therapy (3-day call) and thereafter weekly (1-week call) for a total of 2 months	
2					
3					
Control	Usual care	nd			
Sleep apnea Intervention†‡: CPAP		**For CPAP, how was the pressure selected?**	nd		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	Average nightly CPAP use (hr) at the effective mask pressure over 2 months	Patients were asked to make their first TLC-CPAP call 3 days after starting CPAP therapy (3-day call) and thereafter weekly (1-week call) for a total of 2 months.	After the confirmed identification of the user, TLC began with an assessment of the frequency and duration of CPAP use during the previous week (except for the first call, in which 3 days' use were collected).
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference		
							Value	SD/SE*	Value	SD	Value	SD/SE*	P	Value	SD/SE*	P
DeMolles, 2004 US 15258478	Average nightly CPAP use	hr/night	**Tx**	TLC-CPAP + usual care	2 mo	15			4.4	3.0						0.076
			Cx	Usual care	2 mo	15			2.9	2.4						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	Given the prescribed calling plan, patients would have made an average of 9.3 calls during the trial, but in fact they made an average of 7.9 calls to the system (85%).

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	no	nd	y	y	NA	n	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	n	NA	nd				
Reasons for drop-outs:	No dropout									
Other Issues:	How CPAP use data were collected was not described (self-reported or downloaded from CPAP machine?). The follow-up of patients assigned to the usual care group was not described. Usual care was not described.									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Fletcher, 1991			**Intervention 1**	Telephone reinforcement about OSA and nCPAP use
PMID*	2024846	**RefID**	6194	**Intervention 2**	
Key Question(s)	7			**Intervention 3**	
Design †	Randomized, cross-over study			**Control**	Monthly call but no reinforcement
Extractor	MC			**Comments**	There are two parts of study in this paper. Only 2nd part is a randomized, cross-over study.

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
OSA patients; new CPAP user	nd	nd	nd	nd	US	Device industry, and government	no	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**11 (10)**							
Cx	**11 (10)**							
Total	**11 (10)**	100	51.6	nd	Ideal BW = 158 ± 20 %	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd		no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	10							
Control:	10							
Total:	10	49 ± 26	nd	nd	nd	nd	nd	

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify)	Other characteristics
nd	nd	

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
"polysomnographic diagnosis of OSA"	nd	nd	nd	nd	nd	Separate nights	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	Telephone reinforcement	Positive reinforcement consisted of telephone discussions with the patients about the severity of the disease, complications of apnea, the benefits of CPAP, and suggestions about minimizing side effects.	N/A	Telephone reinforcement about OSA and nCPAP use during the first 3 months (weekly for 3 wk then monthly for 2 months).	
2					
3					
Control	Monthly call but no reinforcement	Monthly call but asked only for the hour reading on CPAP machine's Hobb's meter and to report side effects of the therapy and perceived level of improvement from pre-therapy symptomatology.	N/A	Once per month for 3 months	
Sleep apnea Intervention†‡: CPAP with mask		**For CPAP, how was the pressure selected?**	Separate night following diagnosis of OSA in the lab.		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description
For CPAP:	**Describe the frequency of the initial education follow-up**

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	CPAP use hr/night	Unscheduled calls and during clinic checkups.	Self-reported readings over the telephone with some verifications by machine downloaded data during clinic checkups.
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference		
							Value	SD/SE*	Value	SD	Value	SD/SE*	P	Value	SD/SE*	P
Fletcher, 1991 US 2024846	CPAP use	hr/night	Tx	Telephone reinforcement	3 mo	10 (cross-over study)			5.95	2.74						NS
			Cx	Control monthly call	3 mo	10			6.04	2.77						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	No patient failed to use the machine at least part-time, but 4 patients did not use it on a nightly basis.

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	NA	y	nd	nd	n	y	NA	y	n
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	n	unclear	y	y	NA	y	n			No washout
Reasons for drop-outs:	Moved from the area shortly after taking CPAP machine home and no data were available.									
Other Issues:	Patient characteristics and selection were not reported clearly. The number of subjects analyzed was reported differently in Table 1 and in the text. Mainly relied on self-reported readings for CPAP use. Very small sample size may be underpowered.									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Holmdahl, 2009			**Intervention 1**	Outpatient follow-up visits by a specialist nurse (a simplified model)
PMID*	19179111	**RefID**	173	**Intervention 2**	
Key Question(s)	7			**Intervention 3**	
Design †	RCT			**Control**	Standard care follow-up visits
Extractor	MC			**Comments**	The aim of this study was to study a simplified model for follow-up visits by a specialist nurse compared with the current standard of physician-led visits regarding patient satisfaction. The goal was not to improve compliance.

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Adult patients with obstructive sleep apnoea syndrome. Predominantly diagnosed with predominantly moderate (ODI > 15–25 and/or AHI > 15) or severe (ODI > 25 and/or AHI > 30) OSAS, judged by a senior physician to be in stable condition that allowed for yearly follow-up, with planned continued treatment with CPAP. CPAP treatment should have also been used for a minimum of one year and without complications since the initiation.	Chronic respiratory disease, or any other complicating condition necessitating regular contact with a physician	ODI ≥4% and/or AHI ≥5	nd	no	Sweden	Private	Yes (reduction in patient satisfaction)	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**100 (95)**	80	58		34 ± 4.9	SBP/DBP: 150/88		
Cx	**100 (89)**	89	59		35 ± 5.3	150/86		
Total	**200 (184)**			nd			nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	Yes (CPAP-treated patients with OSAS in a stable condition)
	Treatments used (prior to trial, including surgery)							
Tx	Years of CPAP use: 5 (1-11) y							
Cx	Years of CPAP use: 5 (1-12) y							
Total	CPAP treatment had been used for a minimum of one year and without complications since the initiation.							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	100							
Control:	100							
Total:	200	>15	nd	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
Diagnosed by the use of polygrafy (Breas Sc 20, Breas Medical AB, Sweden)	>15	>15	moderate (ODI > 15–25 and/or AHI > 15) or severe (ODI > 25 and/or AHI > 30)	nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	Outpatient follow-up visits by a specialist nurse	Follow-up consisted of a yearly outpatient visit by a specialist nurse following a structured protocol. Criteria for consulting a physician were established, consisting mainly of newly developed symptoms related to the diagnosis of OSAS or CPAP treatment, other medical events, or on request from the patient.	N/A	Yearly for 2 years	
2					
3					
Control	Standard care follow-up visits	Yearly interview and examination by a physician and measurements of oxygen saturation during sleep using oximetry, either during an overnight hospital stay or at the patient's home using portable equipment.	N/A	Yearly for 2 years	In both groups a specially trained physiotherapist checked the CPAP equipment, assessed the time of use, and corrected any problems with the nasal mask and/or other devices related to the CPAP equipment
Sleep apnea Intervention†‡: CPAP		**For CPAP, how was the pressure selected?**	All patients used a CPAP device with fixed pressure. The pressure was determined from the results of the polygraf examination. It was then applied and adjusted so that it gave a saturation curve of at least 90% during sleep, a stable pulse curve, and was acceptable to the patient.		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	more than 6 h use of CPAP equipment per night	Yearly for 2 years	Unclear but likely to be self-reported CPAP use
2	Compliance	More than 4 h use of CPAP equipment per night	Yearly for 2 years	Unclear but likely to be self-reported CPAP use
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Holmdahl, 2009 Sweden 19179111	>6 h CPAP use per night	**Tx**	Outpatient follow-up visits by a specialist nurse	2 yr	72	95	%	76		NS				
		Cx	Standard follow-up visits	2 yr	66	89	%	74						
Holmdahl, 2009 Sweden 19179111	>4 h CPAP use per night	**Tx**	Outpatient follow-up visits by a specialist nurse	2 yr	90	95	%	95		NS				
		Cx	Standard follow-up visits	2 yr	83	89	%	93						

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
			Tx													
			Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	y	y	nd	nd	n	y	NA	nd	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	n	NA	nd		

Reasons for drop-outs:	Intervention group (n=5): did not received allocated intervention (n=2), death (n=1), lost to follow-up (n=1); did not answer the questionnaire (n=1) Control group (n=11): did not received allocated intervention (n=3), death (n=1), moved out of area (n=2); discontinued CPAP treatment (n=2); refused (n=3)
Other Issues:	More patients dropped out in the control group and only completers in the analyses. How CPAP use data were collected was not reported but likely to be self-reported data. How CPAP was titrated was not clearly reported but all patients had used CPAP >1 year prior to this study.
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments
The goal of the study intervention was not to improve compliance.

A.

Author, Year	Hoy, 1999			**Intervention 1**	Intensive educational programs and nursing support
PMID*	10194151	**RefID**	5386	**Intervention 2**	
Key Question(s)	7			**Intervention 3**	
Design †	RCT			**Control**	Usual support
Extractor	MC			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Patients with sleep apnea/hypopnea syndrome (SAHS) defined by >15 apneas plus hypopneas/h of sleep as revealed by routine polysomnography, plus either daytime sleepiness or two other major symptoms of the syndrome. No prior CPAP therapy; no coexisting COPD, asthma, or neurologic problems, and all lived within 50 miles of Edinburgh.	nd	>15	nd	no	UK	private	no	yes	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**40 (40)**				32 ± 6			
Cx	**40 (40)**				33 ± 6			
Total	**80 (80)**	97.5	51	nd	33 ± 7	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd		
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	No prior CPAP therapy							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	40	58 ± 31	13 ± 6					
Control:	40	59 ± 31	13 ± 6					
Total:	80	58 ± 33		nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		
nd						no coexisting COPD, asthma, or neurologic problems		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
routine polysomnography plus major symptoms	>15	nd	nd	nd	either daytime sleepiness or two other major symptoms of the syndrome	Separate nights	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	Intensive support	All of the features for the standard support protocol, plus 1) initial CPAP education was given in the patient's home; 2) an additional 2 nights (3 nights in total) of CPAP titration in the sleep center in an effort to resolve early problems encountered with CPAP; 3) sleep nurses made home visits to the patient and the patient's partner at 7, 14, and 28 d and at 4 mo after CPAP initiation, in order to minimize problems with treatment	N/A	4 mo	
2					
3					
Control	Usual support	After undergoing baseline polysomnography, each patient was given a full explanation of the need for and benefits of CPAP therapy by a sleep physician and a sleep nurse. This was reinforced by a 20-min video education program. The patients went home with their CPAP units, and were asked to report any side effects immediately by using a 24-h telephone line to the sleep nurses. The nurses contacted the patients by telephone on Days 2 and 21 to try to identify and resolve any problems with CPAP. The patients were then seen in the hospital by the CPAP nurse and by a sleep physician at 1, 3, and 6 mo after the full night titration study, and any problems with CPAP that the patients had encountered were treated appropriately.	N/A	N/A	
Sleep apnea Intervention†‡: CPAP (ResMed, Sydney, Australia)		**For CPAP, how was the pressure selected?**	Separate night		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	CPAP use, h/hight	At each clinic visit (1, 3, and 6 mo)	Patients' CPAP use data were downloaded to a personal computer using ResMed SCAN software
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference		
							Value	SD/SE*	Value	SE	Value	SD/SE*	P	Value	SD/SE*	P
Hoy, 1999 UK 10194151	CPAP use	hr/night	**Tx**	Intensive support	6 mo	40			5.4	0.3						0.003
			Cx	Usual support	6 mo	40			3.8	0.4						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	39 of the patients were classified as self-referrals and 41 as partner referrals. The self-referred patients had a higher mean Epworth score than did the partner-referred patients (p< 0.01). Eighteen of the self-referred patients were randomized to the intensive support and 21 to the control group. • CPAP usage was higher (p=0.002) in the patients who self-referred than in those whose referrals were initiated by a partner (6-mo mean: self-referred: 5.3 ± 0.4; partner-referred: 4.0 ± 0.4 [mean ± SEM]). • Overall, duration of CPAP therapy had no effect on CPAP use, but there was an interaction (p= 0.04) between duration of CPAP use and referral group, indicating a decline in CPAP use with time in the partner-referred group.

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	y	nd	y	y	NA	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	NA	y		

Reasons for drop-outs:	Seven of the 80 patients (4 receiving standard and 3 intensive support) were unavailable for daytime function retesting at 6 mo - 4 patients in the standard support group had stopped using CPAP - 1 patient in the intensive support group died of lung carcinoma diagnosed after randomization, 1 stopped using CPAP, and 1 defaulted from daytime testing at 6 months All patients were analyzed (ITT)
Other Issues:	
Overall Quality (A, B, C)	**A**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Hui, 2000			**Intervention 1**	Augmented education and support
PMID*	10807830	**RefID**	5369	**Intervention 2**	
Key Question(s)	7			**Intervention 3**	
Design †	RCT			**Control**	Basic education and support
Extractor	MC			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Symptomatic patients with newly diagnosed OSA.	nd	≥10 events/h of sleep as shown by overnight polysomnography	nd	no	Hong Kong	government	no	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**54 (45)**				28.4 ± 0.6 (SE)			
Cx	**54 (52)**				30.2 ± 0.9 (SE)			
Total	**108 (97)**	90	45	nd	30 ± 8	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx					Digital span: 19 Digital symbol: 71			
Cx					Digital span: 20 Digital symbol: 75			
Total	nd	nd	nd	nd		nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	54	52 ± 3 (SE)	11.6 ± 0.7 (SE)					
Control:	54	45 ± 4 (SE)	13.9 ± 0.6 (SE)					
Total:	108	48 ± 24		nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
AHI plus self-reported sleepiness	≥10	nd	as cessation of airflow for >10 s	Reduction of airflow ≥50% for >10 s plus an oxygen desaturation of > 4% or an arousal	self-reported sleepiness	Separate nights	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	Augmented support	In addition to the basic support, extra education on OSA and CPAP by physicians via a locally produced 15-min videotape was given to each patient. Respiratory nurses also reinforce knowledge about OSA and provide solutions for potential problems with the use of CPAP during an additional 15-min education session. The patients were reviewed early by physicians at week 1 and week 2. The respiratory nurses also followed up these patients by phone on day 1 and day 2, and at weeks 1, 2, 3, 4, 8, and 12 to help sort out any technical problem and encourage the use of CPAP	N/A	N/A	
2					
3					
Control	Basic support	Each patient was given a 10-min CPAP education program by a respiratory nurse who explained the basic operation and care of the CPAP device and mask. A brochure on OSA and CPAP treatment in Chinese was given to each patient during the education session. After CPAP titrations, patients subsequently were followed up by physicians and nurses at the CPAP clinic at 1 month and 3 months to deal with any problem with the CPAP device or mask fit, and CPAP pressure was adjusted if necessary	N/A	N/A	
Sleep apnea Intervention†‡: auto-titrating CPAP- Aria CPAP device (Respironics; Murrysville, PA)		**For CPAP, how was the pressure selected?**	overnight AutoSet CPAP titration study		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	CPAP use, hr/night (objective)	At 1 mo and 3 mo follow-up	Aria CPAP data downloaded into a personal computer using the Respironics Encore software (Respironics). The time spent at effective pressure was recorded as the objective compliance.
2	Compliance	CPAP use, hr/night (self-report)	At 1 mo and 3 mo follow-up	Self report CPAP use
3	Compliance	Compliance rate	At 1 mo and 3 mo follow-up	as at least 4 h of CPAP use per night for ≥70% of the nights per week
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Hui, 2000 Hong Kong 10807830	Compliance rate	**Tx**	Augmented support	3 mo		54	%	71	63.16, 78.84	NS				
		Cx	Basic support	3 mo		54	%	74	66.16, 81.84					

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference		
							Value	SD/SE*	Value	SE	Value	SD/SE*	P	Value	SD/SE*	P
Hui, 2000 Hong Kong 10807830	Objective CPAP use	hr/night	**Tx**	Augmented support	3 mo	45			5.3	0.3						NS
			Cx	Basic support	3 mo	52			5.3	0.2						
Hui, 2000 Hong Kong 10807830	Subjective CPAP use	hr/night	**Tx**	Augmented support	3 mo	54			6.5	0.2						NS
			Cx	Basic support	3 mo	54			6.3	0.2						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	nd	nd	n	y	NA	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	y	y	y	NA	y		

Reasons for drop-outs:	All the patients returned for follow-up, but there was a technical problem with the Aria/Encore software, resulting in missing CPAP compliance data for 11 of the 108 patients
Other Issues:	Recruitment was not described. Missing more objective CPAP use data in the intervention group than the control group due to technical problems.
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Jean Wiese, 2005			**Intervention 1**	Educational videotape
PMID*	15716221	**RefID**	4408	**Intervention 2**	
Key Question(s)	7			**Intervention 3**	
Design †	RCT			**Control**	No intervention
Extractor	MC			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
>20 years of age, an RDI of >4 obstructed events per hr of sleep, and new diagnosis of OSA.	nd	>4	nd	no	US	nd	no	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**51 (37)**	50.9	49.4		37.7 ± nd			
Cx	**49 (24)**	55.1	47.3		38.3 ± nd			
Total	**100 (61)**			nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ** **	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx		25.5 (not defined)						
Cx		49						
Total	nd		nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	51	9.6 ± nd	13.1 ± 5.9					Mean number of apneas: 44.7
Control:	49	8.9 ± nd	12.78 ± 6.11					43.1
Total:	100			nd	nd	nd	nd	

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify)	Other characteristics
Mean duration of symptoms (yr): Treatment: 6.3 Control: 4.8	nd	Subjects in the control group were significantly more likely to be smokers than those in the treatment group. Thus, smoking status was adjusted in the analysis

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
nd	>4	nd	nd	nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	Educational videotape	~15-min videotape depicted 2 male blue-collar workers discussing their sleep problems, with 1 describing what sleep apnea was in common language, what CPAP was, what CPAP felt like on a sensory basis, and how it had helped them.	N/A	15 minutes	
2					
3					
Control	No intervention to improve compliance	Patients was interviewed and completed questionnaires during the initial visit	N/A	N/A	During the initial visit, patients in both group received explanations of OSA and CPAP by both a physician and a respiratory therapist.

Sleep apnea Intervention†‡: CPAP	**For CPAP, how was the pressure selected?**	nd

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	CPAP use	At the scheduled 4-week return visit	Machine-recorded data. Hours of CPAP use.
2	Compliance	Rate of compliance with CPAP		measured by return to clinic at 4 weeks.
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Jean Wiese 2005 15716221	return to clinic at 4 weeks	**Tx**	Educational videotape	1 mo		51	%	72.9		0.0174				
		Cx	No intervention			49		48.9						

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
			Tx													
			Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	• Lost to follow-up rate (note: the study authors called this rate of compliance with CPAP use) was significantly higher in the control group than the treatment group (57.1% vs. 27.1%, P=0.0174). The authors stated that "CPAP hour usage (mean=4.15, SD=2.38) was not associated with the treatment video in the group of patients returning for their 4-week appointment. • The authors said " the usefulness of the hour CPAP usage data is limited because 13 of the 57 patients who returned for their 1-mo clinic visit had unusable machine-recorded data."

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	n	nd	nd	n	n	NA	n	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	n	n	y	n	NA	nd				

Reasons for drop-outs:	27.1% lost-to follow-up rate in treatment group; 51.1% lost-to follow-up rate in control group. No reasons were given.
Other Issues:	Useless study
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Lewis, 2006			**Intervention 1**	Extra early support
PMID*	16564210	**RefID**	3517	**Intervention 2**	
Key Question(s)	7			**Intervention 3**	
Design †	RCT			**Control**	Standard care
Extractor	MC			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Adults with sleep apnoea-hypopnoea syndrome (SAHS) immediately prior to their first in-patient night of CPAP (auto-titration). All had symptoms of tiredness, most had raised scores on the ESS, and all had a positive (limited-channel) home sleep study. All were CPAP-naïve.	nd	>10	nd	no	UK	nd	no	yes	no
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**36 (30)**		50.1		37.0 v 5.9			
Cx	**36 (25)**		52.6		35.9 ± 6.1			
Total	**72 (55)**	86	51.4	nd	36.4 ± 6.0	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	No prior CPAP use prior study							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	36	47.3 ± 26.5	15.8 ± 4.2					
Control:	36	37.7 ± 26.2	15.5 ± 4.5					
Total:	72	42.5 ± 26.6	15.7 ± 4.3	nd	nd	nd	Nd	

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify)	Other characteristics
nd	nd	Mean total side effects score (immediately after 1st night using CPAP at auto-titration; self-reported), which concerning "nasal stuffiness, dry mouth, difficulty breathing, mask discomfort, headache, machine noise, frequent awakening, inconvenience, and other): Treatment= 6.6; Control=8.7 (P=0.08 between groups)

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
nd	nd	nd	nd	nd	Tiredness; a positive (limited-channel) home sleep study	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	**Extra early support**	Intensive support were lent a 20-min educational video (© ResMed) that explained the pathogenesis, risks and treatment for SAHS. A research assistant telephoned patients between 2 and 5 days after CPAP was issued and led them through a 10-min, semistructured interview (details omitted) to identify any early problems and offered advice as necessary. Patients were allocated an extra appointment to see a sleep physician within 7–14 days after being issued CPAP. Each consult lasted 10–20 min and consisted of a clinical review and specific questions and support regarding the merits of CPAP.	N/A	See description	
2					
3					
Control	Standard care	Patients were provided with a telephone number to call for support within office hours. Each consult lasted 10–20 min and consisted of a clinical review and specific questions and support regarding the merits of CPAP.	N/A	10-20 min	In both groups, a sleep physician reviewed patients at 1, 6 and 12 months.
Sleep apnea Intervention†‡: Auto-titrating CPAP		**For CPAP, how was the pressure selected?**	Auto-titriation. CPAP pressure (cm H_2O) was significantly different between groups: Treatment: 11.2; control 9.9 (P=0.02)		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	CPAP use per night	1, 6 and 12 months	Calculated from cumulative hours (by the hidden timer) at each assessment, taking into account any self-reported non-use, e.g. due to chest infections, holidays, etc.
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline (1 mo)		Final		Change (Final – Baseline)			Difference		
							Value	95% CI (estimated from figure)	Value	95% CI (estimated from figure)	Value	SD/SE*	P	Value	SD/SE*	P
Lewis, 2006 UK 16564210	CPAP use	hr/night	Tx	Extra early support	12 mo	36 (1 mo) / 30	5.2	4, 5.6	4.6	3.7, 5.5						nd
			Cx	Standard care	12 mo	32 (1 mo) / 30	5.4	4.3, 5.7	5.1	4.1, 6.2						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	n	y	n	n	y	NA	n	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	n	y	y	y	NA	y				
Reasons for drop-outs:	Lost to follow-up									
Other Issues:	Patient recruitment process was not described. Likely a convenience sample. At every time point (1, 6, and 12 months), the intervention group had fewer patients who did not attend follow-up. At 12 months, 31% (11/36) in the control group not attending, compared to 17% (6/36) in the intervention group (P=0.17) not attending for review. Analyses were for completers only. The authors sated that in control group mean use increased from 4.5 hours at 6 months to 5.1 hours at 12 months, largely because patients who previously used the machine less frequently, failed to attend and were then missing.									
Overall Quality (A, B, C)	**C**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Massie, 2003			**Intervention 1**	Nasal pillows
PMID*	12684301	**RefID**	4552	**Intervention 2**	Nasal mask
Key Question(s)	7			**Intervention 3**	
Design †	Randomized Cross-over			**Control**	Self-control (cross-over design)
Extractor	MC			**Comments**	Patients were not informed that the study was designed to assess compliance, but they were debriefed at the conclusion of the study regarding compliance monitoring.

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Age 18-70 y, had an OSAHS diagnosis (AHI ≥15/h or AHI ≥5 plus daytime sleepiness), and had not received CPAP treatment previously.	Wake resting arterial oxygen saturation <90%, evidence of upper airway track infection or flu-like symptoms at the time of titration, elective surgery scheduled before end of the study, prior surgical intervention for OSAHS, or need bilevel positive airway pressure or supplemental oxygen.	≥15/h, or ≥5 plus daytime sleepiness	nd	no	US	Industry (device company)	no	yes	no
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	N enrolled (analyzed)	Male, %	Age, y	Race	BMI*	HTN, % (how defined?) or BP	AFib/AFlutter, %	CVD †, % (specify)
Nasal pillows	**(20)**	90	47.7		36.3 ± 6.8			
Nasal mask	**(19)**	74	49.8		35.5 ± 6.0			
Total	**42 (39)**	82	48.7	nd	35.9 ± 6.4	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Nasal pillows								
Nasal mask								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Nasal pillows								
Nasal mask								
Total	No prior surgery treatment for OSA							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Nasal pillows								
Nasal mask								
Total:	39	47.3 ± 35.4	12.8 ± 4.9	nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
AHI	≥15/h, or ≥5 plus daytime sleepiness	nd	nd	nd	nd	62% full night titration; 38% split night titration	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	Nasal pillows	Hands-on fitting by a registered polysomnographic technologist was performed. Medium-size nasal pillows were used first; nasal pillow size was reassessed after placement and changed if needed based on patient comfort and adequate seal.	Breeze; Mallinckrodt Co.; Minneapolis, MN	3 weeks	No washout period
2	Nasal mask	Fitted using the sizing gauge. Mask, headgear, and spacer adjustments were made with the interface in place based on patients' comfort and a proper fit was obtained. Patients were instructed not to make any changes.	Contour; Respironics; Murrysville, PA. Each nasal mask was equipped with the Simple Strap, Whisper-Swivel II exhalation port, and appropriate size spacer (Respironics).	3 weeks	No washout period
3					
Control					
Sleep apnea Intervention†‡: CPAP with heated humidity (HC100 humidifier; Fisher & Paykel; Auckland, NZ).		**For CPAP, how was the pressure selected?**	62% full night titration; 38% split night titration according to American Academy of Sleep Medicine standards.		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description
For CPAP:	**Describe the frequency of the initial education follow-up**

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	• Percentage of days used (PER) • Mean daily use for all day (TOT) • Mean daily use for days with use >0 min (UTL)	Compliance data were downloaded at each of the 2 follow-up visits	Compliance data were downloaded from the Mallinckrodt 418 A using SilverLining software, version 2.0 (Mallinckrodt Co.). The Mallinckrodt 418 A recorded sleep-disordered breathing during therapy, and reported an apnea index and a hyponea index.
2	Harms	Adverse effects	At each of the 2 follow-up visits	CPAP questionnaire (patient self report), including 12 problems (pressure from the mask, skin irritation from the mask, mask coming of the face, air leaks from the mask, putting on the mask, claustrophobia from the mask, machine noise, dry mouth or throat, dry or congested nose, headache, difficulty breathing, and chest discomfort.
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference		
							Value	SD/SE*	Value	SD	Value	SD/SE*	P	Value	SD/SE*	P
Massie, 2003 US 12684301	Percentage of days used (PER)	%	**Tx**	Nasal pillows	3 weeks	39 (cross-over study)			94.1	8.3						<0.05
			Cx	Nasal mask	3 weeks				85.7	23.5						
Massie, 2003 US 12684301	Mean daily use for all day (TOT)	Minutes per night total	**Tx**	Nasal pillows	3 weeks	39 (cross-over study)			322.6	85.7						NS
			Cx	Nasal mask	3 weeks				288.4	113.1						
Massie, 2003 US 12684301	Mean daily use for days with use >0 min (UTL)	Minutes per night total	**Tx**	Nasal pillows	3 weeks	39 (cross-over study)			336.7	77.4						NS
			Cx	Nasal mask	3 weeks				322.6	93.2						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
Massie, 2003 US 12684301	Adverse effects	**Tx**	Nasal pillows	3 weeks	"Nasal pillows was associated with fewer overall adverse effect (p<0.001). Individual-item analysis revealed significant differences for all questions pertaining to the interface (questions 1 to 6)."
		Cx	Nasal mask	3 weeks	

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	y	y	n	n	y	NA	NA	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	Y	N	Y	Y	NA	Y				n
Reasons for drop-outs:	1 patient traveled to Europe and was unable to use the equipment. An unrelated medical condition developed in one patient; he was dropped from the study but maintained on CPAP treatment. 1 patient was unavailable for follow-up.									
Other Issues:	No washout period									
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Meurice, 2007			**Intervention 1**	Reinforced education by the prescriber and by the homecare network (RP + RH)
PMID*	17157557	**RefID**	3597	**Intervention 2**	Reinforced education by the prescriber and standard care by the homecare network (RP + SH)
Key Question(s)	7			**Intervention 3**	Standard education by the prescriber and reinforced education by the homecare network (SP + RH)
Design †				**Control**	Standard education by the prescriber and by the homecare network (SP + SH)
Extractor	MC			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Full PSG confirming an AHI greater than 30/h of sleep;	nd	>30	nd	yes	France	nd		nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
RP+RH	**(27/23) at 3 mo/12 mo**		57.9		31.3 ± 5.1			
RP+SH	**(30/22)**		60.8		32.9 ± 6.7			
SP+RH	**(28/21)**		57.4		31.5 ± 5.8			
SP+SH	**(27/25)**		55.1		34.6 ± 6.4			
Total	**133 (112/91)**	nd		nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
RP+RH								
RP+SH								
SP+RH								
SP+SH								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
RP+RH								
RP+SH								
SP+RH								
SP+SH								
Total	No patient had prior sleep apnoea treatment							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
RP+RH	27	53.7 ± 24.7	12.4 ± 4.9					
RP+SH	30	59.6 ± 22.9	9.0 ± 5.4					
SP+RH	28	62.7 ± 27.7	11.6 ± 6.6					
SP+SH	27	55.2 ± 21.1	12.4 ± 4.8					
Total:	112			nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
AHI	>30	nd	nd	nd	nd	Separate night	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	Standard education by the prescriber (SP)	Oral explanation of OSA and CPAP treatment with a brief demonstration of use of the machine plus a supply of the manufacturers' literature	N/A	See description	Patients were randomized to one of four combinations of different education strategies designating the level of initial education input proposed either before leaving hospital, or at home by the homecare technician
2	Reinforced education by the prescriber (RP)	SP plus a written support on CPAP use and benefit. This included in-depth explanation of OSA and CPAP and its side effects. There was emphasis on the importance of compliance with written support material on CPAP use and a detailed demonstration of the equipment	N/A		
3	Standard education by the homecare network (SH)	A homecare visit to supply the CPAP machine, fit the mask and explain the technique of using the apparatus. The CPAP mechanism and the method of using the machine and mask were clearly explained. The patient was encouraged to ask questions and could phone at any time to resolve problems.	N/A		
4	Reinforced education by the homecare team (RH)	A home visit by a technician at installation and further visits for explanation at 1 week, 1 month, 2 and 3 months of treatment for repetition of education and problem-solving	N/A		
Sleep apnea Intervention†‡: CPAP, the choice of the machine used by the patients corresponded to the wishes of the prescribers.		**For CPAP, how was the pressure selected?**	Separate overnight CPAP titration, performed in the laboratory and supervised by experienced technicians. Patients were treated with constant pressure CPAP.		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	Mean daily compliance	at 3, 6 and 12 months	Calculated from readings of the hour-meter in the machine by technicians from the homecare associations.
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference		
							Value	SD/SE*	Value	SD	Value	SD/SE*	P	Value	SD/SE*	P
Meurice, 2007 France 17157557	CPAP daily compiance	hr/night	**Group1**	RP+RH	3 mo	27			5.6	2.4						NS
			Group2	RP+SH	3 mo	30			4.7	2.2						
			Group3	SP+RH	3 mo	28			5.1	2.5						
			Group4	SP+SH	3 mo	27			4.7	2.4						
Meurice, 2007 France 17157557	CPAP daily compiance	hr/night	**Group1**	RP+RH	12 mo	23			5.8	2.8						NS
			Group2	RP+SH	12 mo	22			6.3	2.2						
			Group3	SP+RH	12 mo	21			5.7	2.2						
			Group4	SP+SH	12 mo	25			5.5	2.4						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	nd	n/y (3 mo / 12 mo)	nd	nd	n	y	n	n	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	y	y	NA	y		

Reasons for drop-outs:	Left hospital with a CPAP machine but subsequently refused definitively to continue treatment. no statistical difference in drop-out rate between groups
Other Issues:	Not sure the distribution of patients for each center (total 7 centers). The authors did say all centers follow the same protocol.
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Palmer, 2004			**Intervention 1**	a home visit from a specialist nurse.
PMID*	14725828	**RefID**	4648	**Intervention 2**	
Key Question(s)	7			**Intervention 3**	
Design †	RCT			**Control**	a visit to a consultant led clinic
Extractor	MC			**Comments**	Authors said this was a pragmatic randomized trial to compare the effects of 2 methods of annual review of SAHS patients. This study was not targeting to improve compliance.

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
All patients who had been diagnosed with SAHS and had a CPAP machine on 1 October 2000 were identified. The sleep service is provided from Raigmore Hospital in Inverness where 432 patients were investigated for SAHS between 1995 and 2000. During patients' annual review, 174 patients were randomized. The study included all patients undergoing annual review between January and December 2001.	nd	nd	January and December 2001	yes	UK	Private	no	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Home visit	**87 (63)**	84	54					
Consultant clinic visit	**87 (63)**	87	55					
Total	**174 (126)**			nd	nd	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Home visit								
Consultant clinic visit								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Home visit	The mean duration of CPAP therapy = 2.99 yr							
Consultant clinic visit	2.89 yr							
Total								

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	79		8 ± 5					Symptom score devised by Douglas et al.: 14 ± 11
Control:	77		9 ± 6					17 ± 12
Total:	156			nd	nd	nd	nd	

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify)	Other characteristics
nd	nd	General health and role physical functioning of SF-36 were significantly better in nurse visit group than consultant clinic group of patients at baseline.

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
nd	nd	nd	nd	nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	a home visit from a specialist nurse	sleep services undertake annual review of their patients through a home visit from a specialist nurse	N/A	Once a year	not targeting to increase compliance
2					
3					
Control	a visit to a consultant led clinic	sleep services undertake annual review of their patients through a visit to a consultant led clinic	N/A	Once a year	not targeting to increase compliance
Sleep apnea Intervention†‡: CPAP		**For CPAP, how was the pressure selected?**	nd		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	CPAP use	At baseline and follow-up	patients were asked to provide the current meter reading on their CPAP equipment to allow calculation of hours of use
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ * (Δ test – Δ control)*		
							Value	SD	Value	SD	Value	SD	P	Value	SD/SE*	P
Palmer, 2004 UK 14725828	CPAP use	hr/day	Tx	Nurse home visit	3 mo	71/63 (baseline / follow-up)	4.91	2.85	5.93	2.67	0.66 (n=58)	1.71	0.004			NS
			Cx	Consultant clinic visit	3 mo	71/63	5.24	2.50	5.64	2.54	0.45 (n=61)	1.69	0.041			

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	nd	no	n	nd	nd	no	no	no	no	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	n	n	y				

Reasons for drop-outs:	11 patients, 4 in the nurse group and 7 in the consultant group returned their CPAP machine before they were due to receive their baseline questionnaire. 11 patients did not sent a follow-up questionnaire: 5 because they had returned their CPAP machines (3 in the nurse group and 2 in the consultant group); 6 for other reasons such as moved away, discontinued treatment due to other illness, or trial of a mandibular advancement device. 1 patient who returned the follow-up questionnaire had not returned the baseline and was not included in the analysis. 1 patient returned the CPAP machine after receiving the follow-up questionnaire
Other Issues:	General health and role physical functioning of SF-36 were significantly better in nurse visit group than consultant clinic group of patients at baseline. This study was not targeting to improve compliance. In addition to dropout, unusable CPAP use data were excluded from the analyses.
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Richards, 2007			**Intervention 1**	Cognitive behavioral therapy (CBT) + usual care
PMID*	17552379	**RefID**	3825	**Intervention 2**	
Key Question(s)	7			**Intervention 3**	
Design †	RCT			**Control**	Usual care
Extractor	MC			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Participants were recruited following diagnosis with OSA and referral for a CPAP-titration study.	inability to understand fluent English and previous use of CPAP	>5	March to July, 2005	no	Australia	Private; scholarships	Yes (mean nightly CPAP usage)	yes	yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**50 (48)**	92	56.1		30.4 ± 5.1			
Cx	**50 (48)**	80	56.2		30.1 ± 4.9			
Total	**100 (96)**			nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx						Depression Anxiety Stress Scale – Depression: 8.1		
Cx						7.8		
Total	nd	nd	nd	nd	nd		nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	50	27.6 ± 21.2	10.3 ± 5.0					
Control:	50	25.3 ± 23.1	10.6 ± 5.4					
Total:	100			nd	nd	nd	nd	
Other Clinical symptoms, % (specify)						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
AHI	>5	nd	nd	nd	nd	Unclear, but CPAP was titration in lab	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	Cognitive behavioral therapy (CBT) + usual care	Participants attended 2 one-hour sessions spaced 1 week apart with approximately 10 participants and their partners in each session, which was based on a CBT community model for insomnia treatment. Each session contains a standardized slide presentation and a 15-min video was presented of age-appropriate real-life male and female CPAP users ("role models") who described their personal experiences of learning to manage CPAP. An additional booklet, containing information about sleep, OSA/CPAP, and general health (exercise, diet, effects of alcohol) was provided.	N/A	2 one-hour sessions spaced 1 week apart	
2					
3					
Control	Usual care	1 standardized group education session (usually with 3 participants). The CPAP-titration process was explained, and participants were familiarized with both the equipment used and the procedure to be followed on the titration night. Possible side-effects encountered when using CPAP were highlighted, and all participants were strongly encouraged to contact staff to obtain relevant help and support. Participants were assessed and fitted with a comfortable well-sealed mask to be worn during the titration study	N/A	See description	
Sleep apnea Intervention†‡: CPAP: REMstar Pro CPAP (Respironics Inc., Murrysville PA) device with a data-storage Smart- Card.		**For CPAP, how was the pressure selected?**	In-laboratory manual titration. Participants had a routine half-hour appointment at the Sleep Investigation Unit (SIU) during the fourth week, unless earlier difficulties with therapy were encountered.		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.

† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.

‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	CPAP use	7 and 28 nights	The returned data cards were downloaded by staff at the CPAP distributor and automatically analyzed using the Encore Pro software (Respironics Inc., Murrysville PA). The maskon time for the period was calculated and divided by the number of nights (7 nights or 28 nights) to obtain a mean daily usage. Mean hours of CPAP usage (measured by mask-on time) at 28 days was the primary outcome, with secondary outcomes being the mean usage at 7 days and the proportion of adherers at 7 and 28 days
2	Compliance	Proportion using CPAP ≥ 4 hr/night at 28 days		
3	Compliance	Proportion using CPAP ≥ 6 hr/night at 28 days		
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Richard, 2007 Australia 17552379	Proportion using CPAP ≥ 4 hr/night at 28 days	**Tx**	CBT + usual care	28 days	37	48	OR	7.4	3.07, 19.6	<0.0001	6.9	2.8, 18.2	<0.0001	sex
		Cx	Usual care	28 days	15	48								
Richard, 2007 Australia 17552379	Proportion using CPAP ≥ 6 hr/night at 28 days	**Tx**	CBT + usual care	28 days	24	48				0.0005				
		Cx	Usual care	28 days	7	48								

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference		
							Value	SD/SE*	Value	SD	Value	SD/SE*	P	Value	SD/SE*	P
Richard, 2007 Australia 17552379	Mean CPAP use (mask-on time) over 28 days	hr/night	**Tx**	CBT + usual care	28 days	48			5.38	2.55						<0.0001
			Cx	Usual care	28 days	48			2.51	2.70						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	Attendance of the bedpartner was only recorded for the CBT group. There was no difference in adherence rates (≥ 4 hours per nightly usage at 28 days between those participants without a partner attending [n = 9; 90%] and those with a partner present [n = 28; 74%] [P = 0.4] Logistic regression modeling to explore predictors for CPAP adherence at 28 days: Psychological factors did not contribute to the model. Treatment group and sex were included in the final model. Adjusted for the effect of sex, participants in the CBT group were 6.9 times more likely to adhere to CPAP than the treatment as usual group (adjusted odds ratio 6.9, CI 2.8-18.2). There was no significant group-by-sex interaction (P = 0.8).

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	y	y	y	y	n	y	NA	y	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	NA	y				
Reasons for drop-outs:	Withdrew because moved overseas or required bilevel ventilation (n=1 in each group); usage data lost (n=1 in each group).									
Other Issues:	4 (8%) and 17 (34%) patients in CBT and usual care group, respectively, did not take CPAP machine home after titration (P=0.002). I assume these patients were included in the analyses but basically counted as 0 usage time. This is probably the primary reasons that there were significant differences in the CPAP usage outcomes between groups.									
Overall Quality (A, B, C)	**A**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments
Good reporting

A.

Author, Year	Smith, 2009			**Intervention 1**	Audio-based habit (instruction+music) intervention
PMID*	18829212	**RefID**	3825	**Intervention 2**	
Key Question(s)	7			**Intervention 3**	
Design †	RCT			**Control**	Same audio-based, habit-promoting focused on a neutral health topic
Extractor	MC			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Adult patients who received a first-time medical diagnosis of OSA. Specifically patients were enrolled with an AHI ≥20.	positive screening for drug or alcohol abuse (which interferes with sleep) and for depression requiring hospitalization	≥20	nd	no	US	Government	no	nd	yes
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**55 (55)**	63.6	63		18.5-29: 15.8% 30-39: 59% >40: 22.5%			
Cx	**42 (42)**	51.5	63		18.5-29: 20% 30-39: 61.8% >40: 18.2%			
Total	**97 (97)**			nd		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx						32.2	Patients with 2 medical diagnoses (most freq. either high BP, CHF or DM) plus OSA: 40.4%	
Cx						29.6	38.7%	
Total	nd	nd	nd	nd	nd			no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	none							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	55	52.3 (nd) 20-39: 60.4% >40: 39.6%						
Control:	42	47.3 (nd) 20-39: 58.8% >40: 41.2%						
Total:	97		nd	nd	nd	nd	nd	

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify)	Other characteristics
nd	nd	

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
AHI	≥20	nd	nd	nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	Habit-promoting experimental audio intervention: CPAP everyday	The CPAP intervention packet called, ''Get In the Habit of CPAP Every Day,'' included audiotaped music along with softly spoken directions for using CPAP nightly. The audio music guided patients in preparing the CPAP machine at bedtime and in creating a relaxing environment in congruence with music and lyrics. The 20-min audio provides instructions for putting on the CPAP mask comfortably, correctly connecting air hoses and relaxing despite the ventilation equipment positive air pressure and noise. The intervention packet had informational handout sheets, CPAP use reminder placards and a 4-week diary for recording CPAP use.	N/A	20 min nightly	
2					
3					
Control	Placebo control intervention: vitamins every day	This placebo intervention was used to mimic the daily activities in the experimental treatment condition including an audiotape. And the placebo packet information handouts are the same format and length but contain content on the neutral health topic of daily vitamin intake from meals. The reminder placards and 4-week diary were the same format except instructions were for writing about daily vitamin intake from food.	N/A	nd	"this placebo controls for the time patients implement the intervention each day and the ''attention'' from the nurses administering the intervention"

Sleep apnea Intervention†‡: Auto-titrating CPAP	**For CPAP, how was the pressure selected?**	Prescribed (sleep lab determined) pressure. No other descriptions.

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	Adherence to CPAP	1, 3, and 6 months	4 or more hours per night and at least 9 of each 14 nights of ventilator use. Data from patient ventilator-timer recorders were used. The CPAP nightly use data were collected to differentiate between onset (1 month) and longer-term (3- and 6-month) adherence rates.
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
Smith, 2009 US 18829212	Adherence to CPAP	**Tx**	Habit-promoting experimental audio intervention	1 mo	49	55	%	89		<0.01				
		Cx	Placebo control intervention	1 mo	23	42		54.9						
Smith, 2009 US 18829212	Adherence to CPAP	**Tx**	Habit-promoting experimental audio intervention	6 mo	41	55	%	74.5		NS				
		Cx	Placebo control intervention	6 mo	30	42		71.4						

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Net Δ /Difference* (Δ test – Δ control)*		
							Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
			Tx													
			Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	No subjects had dropped out of the study at 1month post-intervention. Per the intent-to-treat analysis all dropouts remained in each analysis. Dropouts lost to contact were counted as nonadherent

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	y	n	nd	y	y	y	NA	y	y

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	y	y	y	NA			

Reasons for drop-outs:	2 subjects dropped from the experimental and 1 from placebo group at 3 months (total = 3). 11 subjects dropped from the experimental and 13 from the placebo group at 6 months (total = 24). Subjects who dropped out from the study (numbers listed below) had either stopped using CPAP, had less than 4 h of CPAP use, or were lost to contact.
Other Issues:	Per the intent-to-treat analysis all dropouts remained in each analysis. Dropouts lost to contact were counted as nonadherent.
Overall Quality (A, B, C)	**B**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Stepnowsky, 2007			**Intervention 1**	wireless telemonitoring of CPAP compliance
PMID*	17513285	**RefID**	3842	**Intervention 2**	
Key Question(s)	7			**Intervention 3**	
Design †	RCT			**Control**	Usual care
Extractor	MC			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Patients newly diagnosed with OSA who met all the following criteria: diagnosis of moderate-to-severe OSA, defined as an AHI ≥ 15 events per hour; naive to CPAP therapy; stable sleep environment (operationally defined as a permanent address, requisite for wireless monitoring); and at least 18 years of age.	Allergies or sensitivity to the mask or mask material; previous use of any other PAP device (eg, bi-level PAP, auto-adjusting PAP); current use of prescribed supplemental oxygen; or significant comorbid medical conditions that would prevent the patient from completing the protocol. Lived in a geographically unsuitable region (ie, outside of the wireless network coverage area)	≥ 15	Oct. 2004 to August 2006	no	US	Industry and private	Yes (CPAP use)	nd	no
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**21 (20)**		60		33.3 ± 4.9			
Cx	**24 (20)**		58		30.5 ± 5.1			
Total	**45 (40)**	98	59	61% were Caucasian, 15% Black, 10% Filipino, 7% Hispanic, 2% Asian or Pacific Islander, and 5% other		nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	none							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	21	44.8 ± 17.9	13.7 ± 5.8					
Control:	24	37.6 ± 14.3	11.7 ± 4.4					
Total:	45			nd	nd	nd	nd	nd
Other Clinical symptoms, % (specify						**Airway characteristics, % (specify)**		**Other characteristics**
nd						nd		

* Mean±SD. If median, SE, range, IQR, or other, specify these.

† Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
AHI	≥ 15	nd	nd	nd	nd	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)

† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	Telemonitored Clinical Care	ResTraxx Data Center, the patient and data management website designed for 24/7 access to telemonitored compliance and efficacy data. Collaborative management refers to the joint decision making and partnership between provider and patient and is characterized by communication, negotiation, and consideration of important patient factors and preferences. Patients in this group had their objective flow generator data monitored as frequently as needed per specified clinical pathways throughout the active 2-month treatment period. The frequency and nature of the clinical interactions depended on both the objectively measured nightly data values and subjective patient reports.	ResTraxx Data Center	2 months	
2					
3					
Control	Usual care	a 1-week telephone call after CPAP initiation and a 1-month in-office follow-up visit by CPAP clinic staff	N/A	See description	
Sleep apnea Intervention†‡: CPAP: AutoSet Spirit flow generator unit (ResMed Corp, Poway, CA) set to fixed-mode pressure, which was equipped with the HumidAire 2i heated humidifier (ResMed Corp, Poway, CA). Each participant was provided a compatible nasal or full-face mask; nasal pillows were not used.		**For CPAP, how was the pressure selected?**	Fixed prescribed pressure. The initial set-up visit consisted of sleep apnea education, sleep study review, and CPAP instruction and mask-fitting. During this visit, a study staff member educated the patient about sleep apnea and explained the patient's baseline sleep study results. Each patient was then instructed on how to use CPAP and was fitted for a mask. The patient wore the mask while the CPAP unit was set at the prescribed pressure for approximately 10 minutes for mask adjustment and assessment of pressure tolerance.		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	CPAP use	Nightly	All CPAP flow generators used in the study were outfitted with a ResTraxx wireless transmitter (ResMed Corp, Poway, CA) to allow the remote data collection of compliance and efficacy information for both groups. While the patient sleeps, data are collected. The next day, the de-identified data are transmitted to a computer server. Compliance is measured objectively via a device-internal clock counter
2		% night with CPAP use >4 hr		
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	SD	P btw	Result	95% CI	P btw	Adjusted for:
Stepnowsky, 2007 US 17513285	% night with CPAP use >4 hr	**Tx**	Telemonitored Clinical Care	2 mo		20	%	52	27	NS				
		Cx	Usual care	2 mo		20	%	37	34					

* RR, OR, HR, RD

J. RESULTS (continuous measures) **(Yellow highlighting indicates that values were calculated from reported data)**

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference		
							Value	SD/SE*	Value	SD	Value	SD/SE*	P	Value	SD/SE*	P
Stepnowsky, 2007 US 17513285	CPAP use (all days)	hr/night	**Tx**	Telemonitored Clinical Care	2 mo	20			4.1	1.8						0.07
			Cx	Usual care	2 mo	20			2.8	2.2						
Stepnowsky, 2007 US 17513285	CPAP use (days used)	hr/night	**Tx**	Telemonitored Clinical Care	2 mo	20			5.0	1.8						NS
			Cx	Usual care	2 mo	20			3.8	2.3						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)
QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	y	y	nd	nd	n	y	NA	y	y
	Were Eligibility Criteria Clear? (y/n)	**Was Selection Bias Likely (if yes, explain below)? (y/n)**	**Were Interventions Adequately Described? (y/n)**	**Were the Outcomes Fully Defined? (y/n)**	**Did the Analyses Account for Compliance? (y/n/NA)**	**If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)**	**If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?**			**If a Crossover study, was the Washout period adequate?**
	y	n	y	y	NA	n				
Reasons for drop-outs:	Did not received intervention (n=5). No lost to follow-up.									
Other Issues:										
Overall Quality (A, B, C)	**B**									

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

A.

Author, Year	Taylor, 2006			**Intervention 1**	Telemedicine support
PMID*	16565867	**RefID**	3877	**Intervention 2**	
Key Question(s)	7			**Intervention 3**	
Design †	RCT			**Control**	Usual care
Extractor	MC			**Comments**	

* or Cochrane number
† RCT; Randomized Cross-over; NRCS, prospective; NRCS, retrospective; Cross-over, nonrandomized; Cohort, prospective; Cohort, retrospective

B. ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

Inclusion	**Exclusion**	**AHI Criteria to Dx OSA**	**Enrollment Years**	**Multicenter?**	**Country**	**Funding source**	**Power calculation? (specify outcome)**	**Blinding, patient**	**Blinding, outcome assessor**
Patients diagnosed with OSAS who were prescribed CPAP.	Previously treated with nasal CPAP or other therapies such as an oral appliance or surgery for OSAS	>4	October 2002 and March 2003	no	US	Private	no	nd	nd
If NRCS, details about how was study adjusted (eg, matching, statistical adjustment):									

C. BASELINE CHARACTERISTICS:

Group	**N enrolled (analyzed)**	**Male, %**	**Age, y**	**Race**	**BMI***	**HTN, % (how defined?) or BP**	**AFib/AFlutter, %**	**CVD †, % (specify)**
Tx	**56 (47)**	66	45.8	African-American: 42% Causasian: 49% Hispanic: 5% Asian: 2% Other: 2%				
Cx	**58 (49)**	71	44.6	African-American: 40% Causasian: 60%				
Total	**114 (96)**				nd	nd	nd	nd
	NIDDM, %	**Smokers, % (define)**	**GERD, %**	**MVA ‡ etc, %**	**Cognitive Function ****	**Depression, %**	**Other Comorbidities, % (specify)**	**Is this a Special Population? (which?)**
Tx								
Cx								
Total	nd	nd	nd	nd	nd	nd	nd	no
	Treatments used (prior to trial, including surgery)							
Tx								
Cx								
Total	nd							

* Mean±SD. If median, SE, range, IQR, or other, specify these.
† Including CVD, CAD, IHD, previous MI, previous stroke, etc.
‡ Motor vehicle accident.
** Either score on a test (which test?) or % with cognitive dysfunction

D. OSA "SEVERITY" AT BASELINE

	N analyzed	AHI*	Epworth*	MSLT* †	Habitual Snoring *	Bed partner, %	Time Since Diagnosis	Other (specify)
Treatment:	56	Mild: 31% Moderate 35% Severe: 34%	14.2 ± 4.3					
Control:	58	Mild: 25% Moderate 27% Severe: 48%	14.1 ± 4.0					
Total:	114			nd	nd	nd	nd	

Other Clinical symptoms, % (specify)	Airway characteristics, % (specify)	Other characteristics
All had excessive daytime sleepiness	nd	

* Mean±SD. If median, SE, range, IQR, or other, specify these. † Multiple Sleep Latency Test

E. DEFINITION OF OBSTRUCTIVE SLEEP APNEA

Test Used	AHI	ODI	Definition of Apnea	Definition of Hypopnea*	Symptoms	Split night or separate nights †	Other
AHI and symptom	>4	nd	nd	nd	excessive daytime sleepiness	nd	

* Definition used to define AHI (usually 3% or 4% decline in O_2 saturation)
† Was introduction of CPAP done on the same night as diagnosis (split night) or was CPAP titration done on a separate night?

F. INTERVENTIONS*

	Intervention aim to increase compliance	Description	Brand Name or Equivalent	Intervention Duration	Comment
1	Telemedicine support	The intervention group received a prescheduled number of questions that were provided via a home computer called the "Health Buddy." The Health Buddy OSAS Library was customized with information and suggested interventions. The library comprised preprogrammed questions and answers in a patient–provider dialogue covering four general aspects of OSAS care: symptom management, health behavior, knowledge, and general questions. The patient's responses to these questions were monitored daily by the sleep medicine practitioner. Each possible response was stratified into a high-, medium-, or low-risk category. The stratified responses were color coded on the ICare Desktop for ease of interpretation. A set of guidelines indicated the appropriate course of action for each of the three response categories.	nd	See description	
2					
3					
Control	Usual care	A scheduled clinic visit 1 month after initiating nasal CPAP and any subsequent clinic visits felt necessary by the care provider to manage OSAS. Subjects in the control group were also able to access the sleep medicine practitioner through the use of telephone consultation and walk-in visits in addition to the scheduled clinic visits.	N/A	One clinic visit	
Sleep apnea Intervention†‡: CPAP		**For CPAP, how was the pressure selected?**	nd		

* If a cointervention (eg, education) is used in all patients, enter info in G, not here.
If an intervention has multiple components (that are all different than in other study arms) enter each on a separate row and renumber the 1st column as needed.
† PAP; Oral appliance; Surgery; Positional therapy; Physical therapy; Bariatric surgery; Weight loss program; Exercise program; No Treatment; Other.
‡ PAP: CPAP (fixed); Auto-titrating CPAP; Bilevel PAP; C-Flex; with/without Humidity (hot or cold)

G. CO-INTERVENTIONS

Co-intervention	Description	
For CPAP:	**Describe the frequency of the initial education follow-up**	

H. OUTCOMES (all outcomes listed should match one-for-one with outcomes in results sections)

	Outcome Category*	Specific Outcome	Time points measured	Definition of Outcome
1	Compliance	CPAP use	30-day follow-up visit	Documented by downloading the automated data recorder in the CPAP device. Nasal CPAP use was presented as duration (average hours of CPAP use) and frequency (the proportion of CPAP use of at least 4 h on all of the days monitored) over 30 days of observation.
2				
3				
4				

* QoL; Sleepiness measures; General symptom scales; Psych scale; Cognitive scale; Physical scale; Accidents; Sleep quality; Work days lost; Death; CVD events; NIDDM; Sleep study measures; Compliance; Harms;

I. RESULTS (dichotomized or categorical outcomes) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
							Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
		Tx												
		Cx												

* RR, OR, HR, RD

J. RESULTS (continuous measures) (Yellow highlighting indicates that values were calculated from reported data)

Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change (Final – Baseline)			Difference		
							Value	SD/SE*	Value	SD	Value	SD/SE*	P	Value	SD/SE*	P
Taylor, 2006 US 16565867	CPAP use	hr/night	**Tx**	Telemedicine support	30 days	47			4.29	2.15						NS
			Cx	Usual care	30 days	49			4.22	2.05						

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

J.1. RESULTS (summary of continuous measures)

QoL (except as above), Cognitive function, Executive function, Psychological tests, Physical function tests

Author, Year Country PMID	Test/Scale	Subscale	Follow-up	Intervention 1		Intervention 2		Favors**	If Significant Difference				
				Name	N	Name	N		Analysis***	Net Effect	Test Range "Worst"	Test Range "Best"	P

* If more than 2 interventions being tested in study
** Note which intervention statistically significantly favors the patient (net better score on test). If NS, type: 0
*** "Net Difference" or "Final Difference"

K. RESULTS (other reporting)

Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
		Tx			
		Cx			

Comments on Results	

L. REASONS FOR TREATMENT DISCONTINUATION or DROPOUT or LACK OF COMPLIANCE

Intervention	% Dropout	Reasons

SUBGROUPS: Eg, Subgroups = male/female; age group (<50, 50-70, >70); AHI <>15; others

M. SUBGROUP RESULTS (dichotomized or categorical outcomes)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	n Event	N Total	Unadjusted (reported)				Adjusted (reported)			
								Metric*	Result	95% CI	P btw	Result	95% CI	P btw	Adjusted for:
			Tx												
			Cx												

* RR, OR, HR, RD

N. SUBGROUP RESULTS (continuous measures)

Subgroup	Author, Year Country PMID	Outcome	Unit		Intervention	Follow-up	No. Analyzed	Baseline		Final		Change			Net Δ /Difference* (Δ test – Δ control)*		
								Value	SD/SE*	Value	SD/SE*	Value	SD/SE*	P	Value	SD/SE*	P
				Tx													
				Cx													

* Delete or correct the incorrect value/item. If change, highlight yellow.
** If data is presented graphically, please reference the appropriate figure in the primary paper

O. SUBGROUP RESULTS (other reporting)

Subgroup	Author, Year Country PMID	Outcome		Intervention	Follow-up	Results
			Tx			
			Cx			

Comments on Subgroup Results	

P. ADVERSE EVENTS (Any)

Author, Year Country UI	Adverse Event	Follow-up	Intervention	Intervention	Intervention	Intervention

Q. QUALITY

RCT (y/n)	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Dropout Rate <20% (y/n)	Blinded Patient (y/n/nd)	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis (y/n)	If Multicenter, Was this accounted for in analysis? (y/n/NA)	Were Potential Confounders Properly Accounted For? (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)
y	y	nd	y	nd	nd	n	y	NA		

	Were Eligibility Criteria Clear? (y/n)	Was Selection Bias Likely (if yes, explain below)? (y/n)	Were Interventions Adequately Described? (y/n)	Were the Outcomes Fully Defined? (y/n)	Did the Analyses Account for Compliance? (y/n/NA)	If CPAP Used, Was Pressure Titrated? † (y/n/nd/NA)	If a Crossover study with N<30, was a Power Analysis reported (and was N sufficiently large)?	If a Crossover study, was the Washout period adequate?
	y	y	y	y	NA	nd		

Reasons for drop-outs:	In usual care group: unwillingness to continue with CPAP therapy or to participants who were unable to return to the clinic or were unavailable by telephone within the 30-day observation period (n=8); CPAP use of less than 20 days (n=1) In intervention group: failure to activate the Health Buddy computer (n=7); did not use the Health Buddy for the full 30-day observation period (n=1); use an oral appliance as an alternative method of therapy (n=1)
Other Issues:	Only those patients who completed all 4 telemedicine questions daily over the 30-day observation period were included in the analysis. Patients who had difficulties to use telemedicine support were excluded from the analyses.
Overall Quality (A, B, C)	**C**

*non-randomized cannot be A, retrospective study is always C
N must be ≥30 per intervention in a parallel RCT for quality to be A. For a cross-over study, N≥10, so long as an adequate power analysis was reported.
Dropout must be <20% for quality to be A.
† as opposed to simply selecting a pressure for the patients.

R. SPECIFIC COMMENTS CONCERNING THE STUDY

Comments

Appendix E. Technical Expert Panel, Key Informants, and Domain Expert

Technical Expert Panel and other domain experts

Charles Atwood, MD
University of Pittsburgh Medical Center
Pittsburgh, PA

Pulmonology, Sleep medicine

Paul Dallas, MD
Carilion Clinic Internal Medicine
Roanoke, VA
American College of Physicians

Internist

Carolyn D'Ambrosio
Tufts Medical Center
Boston, MA

Pulmonology, Sleep medicine

Doug Owens, MD
Stanford University
Stanford, CA
American College of Physicians

Internist, Methodologist

Allan Pack, MD
University of Pennsylvania Medical Center
Philadelphia, PA

Respiratory Neurobiology

Michael J. Sateia, MD
Dartmouth Medical School
Lebanon, NH

Psychiatry, Sleep medicine

Walter E. Shaffer, MD
Division of Medical Assistance Programs
Salem, OR

Internist, Medicaid

Additional Key Informants

Benjamin Chambers
Stanford, CA

Patient representative

Edward Grandi
American Sleep Apnea Association
Washington, DC

Patient advocate

Leah Hole-Curry, JD
Washington State Health Technology Assessment Program
Olympia, WA

Susan Redline, MD
Brigham & Women's Hospital
Boston, MA

Pulmonology, Epidemiology

Amir Qaseem, MD PhD MHA
American College of Physicians
Philadelphia, PA

Methodologist

Paul Shekelle, MD
RAND / Southern California EPC
Santa Monica, CA
American College of Physicians

Methodologist

John W. Winkelman, MD, PhD
Brigham & Women's Hospital
Boston, MA

Psychiatry, Sleep medicine