Appendix A. Search Strategies

Table A-1. Treatment / Intervention
Interface: PubMed; Database: Medline

	Search	Records
1	"Child Development Disorders, Pervasive"[Mesh]	22690
2	(autistic[tiab] OR autism[tiab] OR asperger[tiab] OR asperger's[tiab] OR aspergers[tiab] OR pervasive development[tiab] OR pervasive developmental[tiab] OR pdd[tiab]) NOT medline[sb]	5613
3	#1 OR #2	28303
4	therapy[sh] OR therapeutics[mh] OR psychotherapy[mh] OR treatment outcome[mh]	7271756
5	(treatment[tiab] OR therapy[tiab] OR intervention[tiab] OR “control group”[tiab] OR randomized[tiab] OR outcome[tiab] OR randomized[tiab] OR efficacy[tiab] OR effectiveness[tiab] OR comparison[tiab] OR compared[tiab] OR trial[tiab] OR “pilot study”[tiab]) NOT medline[sb]	794459
6	#4 OR #5	8058741
7	#3 AND #6	9859
8	(newspaper article[pt] OR comment[pt] OR case reports[pt] OR review[pt] OR practice guideline[pt] OR news[pt] OR editorial[pt] OR historical article[pt] OR meta-analysis[pt] OR legal cases[pt] OR published erratum[pt] OR congresses[pt])	5128288
9	#7 NOT #8	6801
10	#9 limited to ("2010/01/01"[Date - Publication] : "3000"[Date - Publication])	3894
Key: [mh] Medical Subject Heading; [tiab] title/abstract word; [pt] publication type; [sh] subheading; [dp] publication date; [la] language; [pt] publication type.		

Table A-2. Medication
Interface: EBSCOhost; Database: CINAHL

	Search	Records
1	(MH "Autistic Disorder")	10,856
2	(MH "Child Development Disorders") OR (MH "Child Development Disorders, Pervasive")	2,067
3	"autism"	8,856
4	#2 AND #3	511
5	#1 OR #4	11,134
6	(MH "Psychopharmacology") OR (MH "Central Nervous System Agents+")	92,105
7	(MM "Autistic Disorder/DT")	237
8	#6 OR #7	92,210
9	#5 AND #8	493
10	#9 limited to 2010-2015	215
11	#10 limited to English language	214

Table A-3. Medication
Interface: OVID; Database: EMBASE

	Search	Results
1	exp autism/	43068
2	exp autism/dt [Drug Therapy]	2497
3	exp *autism/dt [Drug Therapy]	1766
4	exp central nervous system agents/	1386129
5	exp *central nervous system agents/	734471
6	exp *autism/	28323
7	5 and 6	1213
8	3 or 7	2307
9	limit 8 to (english language and yr="2010")	116

Appendix B. Screening and Risk of Bias Assessment Forms

Medical and Sensory-Related Therapies for Children with Autism Spectrum Disorder Abstract Review Form

1. Addresses <u>intervention approach and outcomes</u> for young children (2-12 years) with ASD.

□ Yes □ No □ Cannot Determine

If answer to question 1 is NO, this form is complete. Please submit and proceed to next abstract.

2. Original research (does not include systematic reviews and meta-analyses)

□ Yes □ No □ Cannot Determine

3. Is this a comparative study (includes a treatment and comparison group)?

□ Yes □ No □ Cannot Determine

4. Addresses one of the following:

□ Behavioral intervention involving training parents
□ Sensory or auditory-focused intervention (e.g., sensory or auditory integration, weighted vest, therapeutic swinging, snoezelen room)
□ Medical/pharmacologic intervention, including vitamins/supplements, hyperbaric oxygen, electroconvulsive therapy, transcranial magnetic stimulation
□ Music therapy
□ Educational intervention
□ Complementary and alternative medicine (acupuncture, massage, etc.)
□ Allied health intervention (non-sensory/auditory-related such as language, exercise, animal-assisted)
□ Other behavioral intervention (e.g., social skills, CBT, early intensive intervention)
□ Other
□ Severe/challenging behavior (e.g., elopement, property destruction, self/other injury, severe aggression)
□ Cannot determine

5. Eligible study size (at least 10 total participants in target population)

□ Yes □ No □ Cannot Determine

5a. Record total N with ASD:

Medical and Sensory-Related Therapies for Children with Autism Spectrum Disorder Full Text Review Form

1. Study population is children with autism between the ages of 2 and 12 years (mean+SD ≤12 yrs, 11 months)

□ Yes □ No □ Cannot Determine

2. Original research (does not include systematic reviews and meta-analyses)

□ Yes □ No □ Cannot Determine

3. Is this a comparative study (includes a treatment and comparison group)?

□ Yes □ No □ Cannot Determine

4. Does this study address:

□ Medical intervention
□ Sensory intervention
□ Other intervention
□ Not an intervention study

5. Eligible study size (at least 10 total participants in RCT; 20 total participants in target population for observational studies)

□ Yes □ No □ Cannot Determine

5a. Record total N with ASD:

_____

6. Reports an outcome of interest for individuals with ASD:

□ Yes □ No □ Cannot Determine

Comments:

_____

If excluded, retain for review of references or background/contextual questions?

□ Background □ Review of References □ Other

Medical and Sensory-Related Therapies for Children with Autism Spectrum Disorder Risk of Bias Form

1. Did the study employ a group design?

□ Yes □ No

2. Were the groups randomly assigned?

□ Yes □ No □ Comments _____

3. Was there an appropriate comparison group?

□ Yes □ No or NR □ Comments _____

4. If an RCT, was randomization done correctly?

□ Yes
□ No
□ NR
□ NA (non-RCT)
□ Comments _____

5. Was a valid diagnostic approach for ASD used within the study, or were referred participants diagnosed using a valid approach?

□ A. clinical DSM-IV/5-based diagnosis + ADI-R and/or ADOS
□ B. [clinical DSM-IV/5-based diagnosis + other] OR [ADOS + other, such as SRS, CARS, SCQ, CAST, ASSQ, OR STAT, MCHAT for under 30 months]
□ C. Only clinical DSM-IV/5-based diagnosis OR Only ADOS
□ D. Neither clinical DSM-IV/5-based diagnosis NOR ADOS
□ Comments _____

6. Was the sample clearly characterized (e.g., information provided to characterize participants in terms of impairments associated with their ASD, such as cognitive or developmental level)?

□ Yes □ No or NR □ Comments _____

7. Were inclusion and exclusion criteria clearly stated?

□ Yes □ No or NR □ Comments _____

8. Do the authors report attrition?

□ Yes □ No □ Comments _____

9. Were characteristics of drop-out group evaluated for differences with the participant group as a whole?

□ Yes
□ No or NR
□ NA or minimal attrition
□ Comments _____

10. Was the intervention fully described?

□ Yes □ No or NR □ Comments _____

11. For behavioral/non-medical studies, was treatment fidelity monitored in a systematic way?

□ Yes
□ No or NR
□ NA
□ Comments _____

12. Did the authors measure and report adherence to the intended treatment process?

□ Yes □ No or NR □ Comments _____

13. Did the authors report differences in or hold steady all concomitant interventions?

□ Yes □ No or NR □ Comments _____

14. Did outcome measures demonstrate adequate reliability and validity (including interobserver reliability for behavior observation coding)?

□ Yes □ No or NR □ Comments _____

15. Were the primary & secondary outcomes clearly specified a priori?

□ Yes □ No or NR □ Comments _____

16. Were outcome data collected from sources appropriate to the target outcome (e.g. parent report, teacher report, direct behavior observation)?

□ Yes □ No or NR □ Comments _____

17. Were outcomes coded by individuals blinded to the intervention status of the participants?

□ Yes □ No or NR □ Comments _____

18. Was an appropriate statistical analysis used?

□ Yes □ No □ Comments _____

19. a. For RCTs, was there an intent-to-treat analysis?

□ Yes
□ No
□ NA
□ Comments _____

20. b. For negative studies, was a power calculation provided?

□ Yes
□ No
□ NA
□ Comments _____

21. c. Did the study correct for multiple testing?

□ Yes
□ No
□ NA
□ Comments _____

22. d. For observational studies, were potential confounders and effect measure modifiers captured?

□ Yes
□ No
□ NA
□ Comments _____

23. e. For observational studies, were potential confounders and effect measure modifiers handled appropriately?

□ Yes
□ No
□ NA
□ Comments _____

24. Were outcomes measured in at least one context outside of the treatment setting?

□ Yes □ No or NR □ Comments _____

25. Were outcomes measured in natural environments to assess generalization?

□ Yes □ No or NR □ Comments _____

26. Were follow-up measures of outcome conducted to assess maintenance of skills at least 3 months after the end of treatment?

□ Yes
□ No or NR
□ NA
□ Comments _____

27. Comments

_____

Appendix C. Excluded Studies

Reasons for Exclusion

X-1 Does not address interventions or outcomes of interest
X-2 Not original research
X-3 Does not include an appropriate comparison group
X-4 Does not meet sample size criterion
X-5 Not in English or not obtainable

1. John MECfCD, Communications S. AHRQ Comparative Effectiveness Reviews. Therapies for Children With Autism Spectrum Disorders: A Review of the Research for Parents and Caregivers. Comparative Effectiveness Review Summary Guides for Consumers. Rockville (MD): Agency for Healthcare Research and Quality (US); 2005.

2. John MECfCD, Communications S. AHRQ Comparative Effectiveness Reviews. Therapies for Children With Autism Spectrum Disorder: A Review of the Research for Parents and Caregivers. Comparative Effectiveness Review Summary Guides for Consumers. Rockville (MD): Agency for Healthcare Research and Quality (US); 2005.

3. John MECfCD, Communications S. AHRQ Comparative Effectiveness Reviews. Comparative Effectiveness of Therapies for Children With Autism Spectrum Disorders. Comparative Effectiveness Review Summary Guides for Clinicians. Rockville (MD): Agency for Healthcare Research and Quality (US); 2007.

4. John MECfCD, Communications S. AHRQ Comparative Effectiveness Review. Comparative Effectiveness of Therapies for Children With Autism Spectrum Disorder. Comparative Effectiveness Review Summary Guides for Clinicians. Rockville (MD): Agency for Healthcare Research and Quality (US); 2007.

5. Silva LM, Ayres R, Schalock M. Outcomes of a pilot training program in a qigong massage intervention for young children with autism. Am J Occup Ther. 2008 Sep-Oct;62(5):538-46. PMID: 18826014. X-3

6. Keino H, Funahashi A, Keino H, et al. Psycho-educational Horseback Riding to Facilitate Communication Ability of Children with Pervasive Developmental Disorders. J Equine Sci. 2009;20(4):79-88. doi: 10.1294/jes.20.79. PMID: 24833971. X-1, X-3

7. . Extending trust. Nature Neuroscience. 2010 August;13(8):905. doi: http://dx.doi.org/10.1038/nn0810-905. PMID: 2010410948.X-1

8. . For the record. Journal of Reproductive Medicine. 2010;55(1-2):2A-A 1p. PMID: 105160564. Language: English. Entry Date: 20100409. Revision Date: 20150711. Publication Type: Journal Article.X-1, X-2

9. . Aripiprazole effective in treating irritability in autistic youth. Brown University Child & Adolescent Psychopharmacology Update. 2010;12(2):4-5 2p. PMID: 105306069. Language: English. Entry Date: 20100312. Revision Date: 20150711. Publication Type: Journal Article. Journal Subset: Biomedical. X-2, X-6

10. . Briefly noted. Mental Health Weekly. 2010;20(7):7-8 2p. PMID: 105120514. Language: English. Entry Date: 20100402. Revision Date: 20150711. Publication Type: Journal Article.X-1, X-2

11. . Oxytocin improves social interaction in autistic patients. Brown University Child & Adolescent Psychopharmacology Update. 2010;12(4):7-8 2p. PMID: 105162352. Language: English. Entry Date: 20100521. Revision Date: 20150711. Publication Type: Journal Article. Journal Subset: Biomedical.X-1, X-2

12. . Keep your eye on. Brown University Child & Adolescent Behavior Letter. 2010;26(4):2- 1p. PMID: 105155628. Language: English. Entry Date: 20100507. Revision Date: 20150711. Publication Type: Journal Article. Journal Subset: Biomedical.X-1, X-2

13. . Drug & device news. Medical Malpractice Law & Strategy. 2010;27(8):5- 1p. PMID: 105201156. Language: English. Entry Date: 20100709. Revision Date: 20150711. Publication Type: Journal Article. Journal Subset: Biomedical.X-1, X-2

14. . Clozapine for aggression in adolescent autism. Brown University Child & Adolescent Psychopharmacology Update. 2010;12(5):8- 1p. PMID: 105193002. Language: English. Entry Date: 20150227. Revision Date: 20150711. Publication Type: Journal Article.X-1, X-2

15. . NAC effective for self-injurious behavior in 4-year-old with ASD. Brown University Child & Adolescent Psychopharmacology Update. 2010;12(5):7-8 2p. PMID: 103840426. Language: English. Entry Date: 20150227. Revision Date: 20150710. Publication Type: Journal Article. Journal Subset: Biomedical.X-1, X-2, X-3, X-4

16. . Divalproex sodium for irritability in autism. Brown University Child & Adolescent Psychopharmacology Update. 2010;12(7):7- 1p. PMID: 105045860. Language: English. Entry Date: 20100827. Revision Date: 20150711. Publication Type: Journal Article.X-1, X-2

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19. . Medication plus behavioral intervention for aggression in autism. Brown University Child & Adolescent Psychopharmacology Update. 2010;12(8):4-5 2p. PMID: 105068473. Language: English. Entry Date: 20101001. Revision Date: 20150711. Publication Type: Journal Article. Journal Subset: Biomedical. X-1, X-2, X-3

20. . Mental health. Nursing Times. 2010;106(31):7- 1p. PMID: 105077539. Language: English. Entry Date: 20101001. Revision Date: 20150711. Publication Type: Journal Article.X-1, X-2

21. . Current world literature. Curr Opin Neurol. 2010 Apr;23(2):194-201. doi: 10.1097/WCO.0b013e328338cade. PMID: 20216346.X-1, X-2

22. . Massachusetts & New Hampshire. Insurance; autism spectrum disorders. Ment Phys Disabil Law Rep. 2010 Sep-Oct;34(5):812. PMID: 21197720.X-1

23. . Autism spectrum disorders and the gut. Consensus recommendations for evaluation and treatment. Harv Ment Health Lett. 2010 Apr;26(10):4. PMID: 20499455.X-1, X-2, X-3

24. . Autism spectrum disorders. Diagnosis and management involve time and patience. Harv Ment Health Lett. 2010 Sep;27(3):4-5. PMID: 20941863.X-1

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Appendix D. Risk of Bias Ratings

Table D-1. Risk of bias assessments

First Author Year	Group Design	Random Assignment	Appropriate Comparison Group	Correct Randomization	Systematic Diagnostic Approach	Clear Sample Characterization	Clear Inclusion/ Exclusion Criteria	Attrition Reported	Drop out Characteristics Evaluated	Intervention Fully Described	Treatment Fidelity Monitored	Treatment Adherence Measured and Reported	Concomitant Interventions Held Steady/ Reported	Outcome Measures Reliable and Valid	Primary Outcomes Specified *a priori*	Outcome Data Collected From Appropriate Sources	Outcomes Coded Blindly	Appropriate Statistical Analysis	Rating
Aman 2015[1-11]	+	+	+	+	++	+	+	+	+	+	+	+	+	+	+	+	+	+	Low
Amatachaya 2015[12, 13]	+	+	+	+	+	-	+	-	NA	+	NA	+	+	+	+	+	+	-	Moderate
Arnold 2012[14]	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	-	Low
Akhondzadeh 2010[15]	+	+	+	+	-	-	+	NA	NA	+	NA	-	-	+	+	+	+	-	Moderate
Akhondzadeh 2008[16]	+	+	+	+	-	-	+	+	NA	+	NA	-	+	+	+	+	+	+	Moderate
Arnold 2006 [17]	+	+	+	-	+	+	+	+	-	+	NA	-	+	+	+	+	+	-	moderate
Al Ayadhi 2013[18]	+	+	+	-	+	-	-	+	NA	+	-	-	+	+	+	+	+	-	High
Asadabadi 2013[19]	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	-	Low
Bent 2014[20]	+	+	-	+	-	+	+	+	NA	+	NA	+	+	+	+	+	+	-	Moderate

First Author Year	Group Design	Random Assignment	Appropriate Comparison Group	Correct Randomization	Systematic Diagnostic Approach	Clear Sample Characterization	Clear Inclusion/ Exclusion Criteria	Attrition Reported	Drop out Characteristics Evaluated	Intervention Fully Described	Treatment Fidelity Monitored	Treatment Adherence Measured and Reported	Concomitant Interventions Held Steady/ Reported	Outcome Measures Reliable and Valid	Primary Outcomes Specified *a priori*	Outcome Data Collected From Appropriate Sources	Outcomes Coded Blindly	Appropriate Statistical Analysis	Rating
Bent 2011[21]	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	+	Low
Bertoglio 2010[22]	+	+	+	-	++	+	+	+	NA	+	NA	+	+	+	+	+	+	-	Low
Cortesi 2012[23]	+	+	+	+	++	+	+	+	+	+	NA	+	+	+	+	+	+	-	Low
Chez 2003[24]	+	+	+	-	+	+	+	+	+	+	NA	-	+	+	+	+	+	-	Moderate
Dadds 2014[25]	+	+	+	-	+	+	+	+	-	+	NA	+	+	+	-	+	+	-	Low
Duffy 2014[26]	+	-	-	NA	+	-	+	-	NA	+	NA	+	+	-	+	-	-	-	High
Findling 2014[27]	+	+	+	-	++	+	+	+	-	+	NA	-	+	+	+	+	+	+	Low
Fahmy 2013[28]	+	+	+	-	-	+	+	+	-	+	NA	-	-	+	-	+	+	-	Moderate
Ghanizadeh 2014[29]	+	+	+	-	++	+	+	+	-	+	NA	+	+	+	+	+	+	+	Low
Geier 2011[30]	+	+	+	-	-	-	-	+	-	+	NA	+	+	+	+	+	+	-	High
Granpeesheh 2010[31]	+	+	+	-	++	-	+	+	-	+	NA	+	+	+	+	+	+	+	Low

First Author Year	Group Design	Random Assignment	Appropriate Comparison Group	Correct Randomization	Systematic Diagnostic Approach	Clear Sample Characterization	Clear Inclusion/ Exclusion Criteria	Attrition Reported	Drop out Characteristics Evaluated	Intervention Fully Described	Treatment Fidelity Monitored	Treatment Adherence Measured and Reported	Concomitant Interventions Held Steady/ Reported	Outcome Measures Reliable and Valid	Primary Outcomes Specified *a priori*	Outcome Data Collected From Appropriate Sources	Outcomes Coded Blindly	Appropriate Statistical Analysis	Rating
Ghaleiha 2015[32]	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	-	Low
Ghaleiha 2013[33]	+	+	+	+	++	+	+	+	-	+	NA	+	+	+	+	+	+	+	Low
Ghaleiha 2013[34]	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	-	Low
Ghaleiha 2013[35]	+	+	+	+	++	+	+	+	-	+	NA	+	+	+	+	+	+	-	Low
Ghanizadeh 2015[36]	+	+	+	+	++	-	+	+	-	+	NA	-	+	+	+	+	+	+	Low
Ghanizadeh 2013[37]	+	+	+	+	++	-	+	+	-	+	NA	-	+	+	+	+	+	+	Low
Hyman 2015[38]	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	-	Low
Handen 2011[39]	+	+	+	-	++	+	+	+	NA	+	NA	+	+	+	+	+	+	+	Low
Hollander 2010[40]	+	+	+	-	++	+	+	+	-	+	NA	+	+	+	+	+	+	+	Low
Hardan 2012[41]	+	+	+	+	++	+	+	+	-	+	NA	+	+	+	+	+	+	-	Low
Hasanzadeh 2012[42]	+	+	+	+	++	+	+	+	NA	+	NA	-	+	+	+	+	+	-	Low
King	+	+	+	-	+	+	+	+	NA	+	NA	-	+	+	+	+	+	-	Moderate

First Author Year	Group Design	Random Assignment	Appropriate Comparison Group	Correct Randomization	Systematic Diagnostic Approach	Clear Sample Characterization	Clear Inclusion/ Exclusion Criteria	Attrition Reported	Drop out Characteristics Evaluated	Intervention Fully Described	Treatment Fidelity Monitored	Treatment Adherence Measured and Reported	Concomitant Interventions Held Steady/ Reported	Outcome Measures Reliable and Valid	Primary Outcomes Specified *a priori*	Outcome Data Collected From Appropriate Sources	Outcomes Coded Blindly	Appropriate Statistical Analysis	Rating
2001[43]																			
Kent 2013[44, 45]	+	+	+	+	++	+	+	+	-	+	NA	-	+	+	+	+	+	+	Low
King 2013[46, 47]	+	+	+	+	++	+	+	+	+	+	NA	+	+	+	+	+	+	+	Low
Klaiman 2013[48]	+	+	+	+	++	-	+	+	-	+	NA	+	+	+	+	+	+	-	Low
Lv 2013[49]	+	-	-	NA	++	-	+	+	NA	+	NA	+	+	+	+	+	-	+	High
Lemonnier 2012[50]	+	+	+	-	++	+	+	+	NA	+	NA	-	+	+	+	+	+	-	Moderate
Mankad 2015[51]	+	+	+	+	++	+	+	+	-	+	NA	+	+	+	+	+	+	-	Low
McCracken 2014[52-55]	+	+	+	+	++	+	+	+	-	+	NA	-	+	+	+	+	+	+	Moderate
Mohammadi 2013[56]	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	+	Low
Marcus 2011[57-63]	+	+	+	+	++	+	+	+	-	+	NA	+	+	+	+	+	-	+	Low
Munasinghe 2010[64]	+	+	+	-	-	-	+	+	-	+	NA	+	+	+	+	+	+	-	Moderate

First Author Year	Group Design	Random Assignment	Appropriate Comparison Group	Correct Randomization	Systematic Diagnostic Approach	Clear Sample Characterization	Clear Inclusion/ Exclusion Criteria	Attrition Reported	Drop out Characteristics Evaluated	Intervention Fully Described	Treatment Fidelity Monitored	Treatment Adherence Measured and Reported	Concomitant Interventions Held Steady/ Reported	Outcome Measures Reliable and Valid	Primary Outcomes Specified *a priori*	Outcome Data Collected From Appropriate Sources	Outcomes Coded Blindly	Appropriate Statistical Analysis	Rating
Navarro 2015[65]	+	+	+	+	++	+	+	+	NA	+	NA	+	-	+	+	+	+	-	Low
Nikoo 2014[66]	+	+	+	+	+	+	+	+	-	+	NA	-	+	+	+	+	+	+	Moderate
Nagaraj 2006[67]	+	+	+	+	+	+	+	+	-	+	NA	-	+	+	+	+	+	-	Moderate
Pusponegoro 2015[68]	+	+	+	+	+	+	+	+	-	+	+	+	-	+	+	+	+	+	Moderate
Pearson 2013[69]	+	+	+	-	++	+	+	+	NA	+	NA	+	+	+	+	+	+	+	Low
Rezaei 2010[70]	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	+	Low
Rossignol 2009[71]	+	+	+	+	++	+	+	+	+	+	NA	-	+	+	+	+	+	-	Low
Scahill 2013 [2, 3, 72]	+	+	+	+	++	+	+	+	+	+	+	+	+	+	+	+	+	+	Low
Sampanthavivat 2012[73]	+	+	+	+	+	-	+	+	NA	+	NA	+	-	+	+	+	+	-	Moderate
Shea 2004[74, 75]	+	+	+	-	+	+	+	+	-	+	NA	+	+	+	+	+	+	-	Moderate

First Author Year	Group Design	Random Assignment	Appropriate Comparison Group	Correct Randomization	Systematic Diagnostic Approach	Clear Sample Characterization	Clear Inclusion/ Exclusion Criteria	Attrition Reported	Drop out Characteristics Evaluated	Intervention Fully Described	Treatment Fidelity Monitored	Treatment Adherence Measured and Reported	Concomitant Interventions Held Steady/ Reported	Outcome Measures Reliable and Valid	Primary Outcomes Specified *a priori*	Outcome Data Collected From Appropriate Sources	Outcomes Coded Blindly	Appropriate Statistical Analysis	Rating
Saad 2015[76]	+	+	+	+	++	+	-	+	NA	+	NA	-	+	+	+	+	+	-	Moderate
Scahill 2015[77]	+	+	+	+	++	+	+	+	+	+	NA	+	+	+	+	+	+	+	Low
Shan 2015[78]	+	+	+	-	-	-	+	+	-	+	NA	-	-	+	-	+	-	-	High
Voigt 2014[79]	+	+	+	+	++	+	+	+	-	+	NA	+	+	+	+	+	+	+	Low
Van der Meer 2013[80-83]	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	-	Low
Wink 2014[84]	+	-	+	NA	+	+	-	-	-	+	-	+	+	+	+	-	+	+	Moderate
Wright 2011[85]	+	+	+	+	++	+	+	+	-	+	NA	+	+	+	+	+	+	-	Low
Whiteley 2010[86, 87]	+	+	+	-	++	+	+	+	-	+	NA	+	+	+	+	+	-	-	Moderate

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APPENDIX E. Applicability Summary Tables

Table E-1. Antipsychotics

Domain	Description of applicability of evidence compared to question
Population	Studies typically included participants recruited from non-primary care populations (university/academic-affiliated clinics, research centers), which may limit applicability to the wider population; participants in randomized controlled trials (RCT)s had an average age of 9.6 and 9.3 years in the treatment and comparison groups, respectively and included more male subjects (83.0% in treatment groups and 83.6% in control). Three studies provided IQ data, with the majority of subjects with IQs in the intellectual disability range. Studies reported use of concurrent medications but typically did not report on co-morbid conditions. Most of the studies report including children with at least moderate level of severity of ASD.
Intervention	Antipsychotics evaluated included risperidone and aripiprazole in dose ranges used in some children with autism spectrum disorder (ASD).
Comparators	RCTs compared treatment to placebo which is an appropriate comparator.
Outcomes	Studies primarily targeted outcomes related to problem behavior (irritability, hyperactivity) and repetitive behavior, which are significant concerns in the ASD population. Outcome measures used to assess change were appropriate; although the duration of studies was typically less than 6 months, and evaluation was typically immediately post-treatment. Studies reported adverse effects including sedation, weight gain, and extrapyramidal symptoms. It is unclear whether these short term harms and outcomes reflect longer-term outcomes.
Setting	Studies were conducted in the US, Canada, Iran, and India, primarily in academic clinics or research centers which may have yielded more selected populations.

Table E-2. Stimulants

Domain	Description of applicability of evidence
Population	Studies included children 5 to 14 years old with autistic disorder; 79%-89% male. Studies typically included children with cognitive impairment (IQ or DQ ≤ 70) and comorbidities including ADHD, ODD, OCD; with severity of the condition ≥ 4 on CGI. Use of concomitant medications ranged from none to 29%.
Intervention	Stimulants evaluated include different doses of methylphenidate (MPH) and guanfacine.
Comparators	The MPH trial and guanfacine trial included a placebo controlled comparison group, which was an appropriate comparison.
Outcomes	The MPH trial assessed outcomes in the short-term including hyperactivity/inattention and social behaviors. One of the MPH trials reported use of co-interventions. The dose and type of stimulant were similar to reports in the literature; the duration of treatment was 4 to 13 weeks with evaluation conducted immediately after treatment. Treatment episodes were associated with at least 1 side effect. MPH was superior to placebo on the targeted areas of outcome in 49% of participants. Study found no benefit of treatment on hyperactivity subscale scores in subgroup (age, IQ, diagnosis type or weight) analyses. Stimulants were not well-tolerated.
Setting	The MPH trial included drug-free children in 5 academic outpatient clinics in the US, likely representing a highly selected population. Guanfacine trial included children from clinic registries and referrals.

ADHD-Attention Deficit/Hyperactivity Disorder; ODD-Oppositional Defiant Disorder; OCD-Obsessive Compulsive Disorder; DQ-Developmental Quotient; CGI-Clinical Global Impression

Table E-3. Nutritional supplements

Domain	Description of applicability of evidence
Population	Studies included children ages 2-11 years with differing requirements for inclusion. Two omega-3 fatty acid studies targeted younger children (ages 3-8) with hyperactive behavior. The degree of intellectual disability was not well described in the studies.
Intervention	Nutritional supplements including omega-3 fatty acids, methyl B-12, peptizyde, N,N-dimethylglycine, digestive enzymes, docosahex-aenoic acid and levocarnitine.
Comparators	Comparator for all studies in this group was placebo.
Outcomes	Study outcomes included behavior, autism severity, communication, cognitive, and gastrointestinal symptoms and sleep disturbances. Data were collected using a wide range of assessment tools including CGI, ABC, CARS, SRS, BASC, GBRS, PDDBI, MCDI, PPVT, Stanford-Binet, hand muscle testing, ATEC, PIA-CV, Expressive Vocabulary test, Rescorla Language Development Survey, CBCL, and Childhood Psychiatric Rating Scale. Most studies were of 3 months duration (range 1 to 6 months). Outcomes were collected at end of treatment with no long term follow-up.
Setting	Five studies were conducted in the United States, two in Egypt and one each in the Netherlands and Australia

CGI-Clinical Global Impression; ABC-Aberrant Behavior Checklist; CARS-Childhood Autism Rating Scale; SRS-Social Responsiveness Scale; BASC-Behavioral Assessment System for Children; GBRS; Global Rating Scale; PDDBI-Pervasive Developmental Disorders Behavior Inventory; MCDI- MacArthur Communicative Development Inventory; PPVT-Peabody Picture Vocabulary Test; ATEC-Autism Treatment Evaluation Checklist; PIA-CV-Parent Interview for Autism-Clinical Version; CBCL-Child Behavior Checklist

Table E-4. Dietary interventions

Domain	Description of applicability of evidence
Population	Study participants ranged in age from 2 to 12 years, with no information available about co-morbidities, except one study that included children with severe maladaptive behavior. Severity of autism was not well described and the degree of intellectual disability was not well characterized in most studies. One GFCF study required participants to be concurrently enrolled in a comprehensive ABA program. Use of concomitant medications was not noted in most studies. One study recruited children with known allergies or food intolerances.
Intervention	Gluten-free casein-free diet, gluten and dairy diet, raw and boiled camel milk.
Comparators	Comparators included gluten dairy-free diet, usual diet, placebo and cow milk.
Outcomes	Outcomes included autism severity scores, problem behaviors including maladaptive behavior, sleep, and gastrointestinal symptoms. Assessments used in the studies included ADOS, CARS, Gilliam Autism Rating Scale (GARS), Ritvo-Freeman Real Life rating scales, ADHD-IV scale, Conner's Behavior Rating scale, VABS, Pervasive Developmental Disorder Behavior Inventory, sleep diaries, and Gastrointestinal symptom severity index. Three studies were of very short duration ranging from 1 to 4 weeks while one study had follow-up after 30 weeks and another lasted for 2 years.
Setting	Studies were conducted in academic medical centers located in the United States (2), Belgium (1), Denmark (1), and Saudi Arabia (1).

CARS-Childhood Autism Rating Scale; ADOS-Autism Diagnostic Observation Schedule; ADHD-IV-Attention Deficit/Hyperactivity Disorder-IV scale; VABS-Vineland Adaptive Behavior Scales; GFCF-Gluten-free, casein-free; ABA-Applied Behavioral Analysis

Table E-5. Risperidone adjuncts

Domain	Description of applicability of evidence compared to question
Population	Studies typically included participants with autism spectrum disorder (ASD) recruited from non-primary care populations (university/academic-affiliated clinics, research centers), which may limit applicability to the wider population; participants had an average age in a range between 3-16 years and included 17-23 subjects in the treatment arm to 14-24 in the placebo arm with more male subjects (73% in treatment groups and 75% in control). Three studies reported including subjects with cognitive impairment while majority did not mention the intellectual disability status. Most of the studies included subjects with severe disruptive symptoms and typically did not report comorbidity status or use of concomitant medications or therapies.
Intervention	Risperidone adjuncts evaluated included celecoxib, Ginkgo biloba, memantine , topiramate , riluzole, buspirone, N-acetyl cysteine, amantadine , pioglitazone, pentoxifylline and piracetam in children with ASD.
Comparators	Studies compared adjuncts to risperidone therapy to placebo added to risperidone.
Outcomes	Studies primarily targeted outcomes related to core and associated behavior symptoms (irritability, hyperactivity, lethargy/withdrawal, stereotypy and inappropriate speech) which are significant concerns in the ASD population along with global clinical improvement. Outcome measures used to assess change were appropriate; although the duration of studies was typically ≤10 weeks and evaluation was typically immediately post-treatment. Studies reported adverse effects including increased appetite, weight gain, and extrapyramidal symptoms. It is unclear whether these short term harms and outcomes reflect longer-term outcomes.
Setting	All the studies were conducted in Iran and primarily in academic clinics or research centers which may have yielded more selected populations.

Table E-6. Other--SRIs

Domain	Description of applicability of evidence compared to question
Population	Studies typically included participants recruited from non-primary care populations (university/academic-affiliated clinics), which may limit applicability to the wider population; RCTs included a total of 112 participants in treatment arms, and 115 participants in comparison arms with an average age range of 5-17 years in both groups; 77% to 84% male. Studies reported including subjects with cognitive impairment and use of other therapies (in one study) during intervention. The severity of autism ranged from 3-7 based on the CGI scale while none reported including subjects with specific comorbid conditions.
Intervention	Serotonin reuptake inhibitors (SRI)s evaluated include fluoxetine and citalopram, in dose ranges used in some children with ASD.
Comparators	RCTs compared treatment to placebo.
Outcomes	Studies primarily targeted outcomes related to repetitive behavior and problem behavior (irritability), significant concerns in the ASD population. Outcome measures used to assess change were appropriate; although evaluation typically occurred immediately after treatment. Studies reported harms including agitation, hyperactivity, inattention, decreased sleep, and diarrhea; it is unclear whether these short term harms and outcomes reflect longer-term outcomes.
Setting	All studies took place in the US in clinics affiliated with academic medical centers.

RCT-Randomized Controlled Trial; CGI-Clinical Global Impression; ASD-Autism Spectrum Disorder

Table E-7. Other--Melatonin

Domain	Description of applicability of evidence
Population	Studies included children 4 to 10 years old with autistic disorder along with sleep problems; 80%-86% male. Studies typically did not include children with Fragile X syndrome or those with any co-morbid conditions and hence cannot be generalized. Use of concomitant medications was restricted even though one study reported use of risperidone by one child.
Intervention	Melatonin used alone or in combination with behavioral therapy.
Comparators	The trials included either a placebo or behavioral therapy alone as comparison groups, which were appropriate comparisons.
Outcomes	The melatonin trials ranged from 3 to 9 months in duration with the evaluation conducted immediately after treatment. Studies assessed outcomes in the short-term including sleep-wake patterns and sleep behaviors but did not report plasma levels of melatonin either before or after treatment. The dose used was similar to reports in the literature; treatment episodes were not associated with any significant side effect. Melatonin was superior to placebo on the targeted areas of outcome and the responses were better when combined with behavioral therapy in the short-term.
Setting	The melatonin trial included children from an Italian pediatric department as well as from four specialist centers in UK.

Table E-8. Other--Donepezil

Domain	Description of applicability of evidence
Population	Studies included children 2 to 17 years old with autistic disorder; with majority being male children (>90%). One study reported a total ADOS score ranging from 10.2 to 11.2; with IQ ranging from 73-146 while the other did not exclude children based on intelligence or language development level. Studies allowed use of concomitant medications but did not include children with co-morbid conditions.
Intervention	The acetylcholinesterase inhibitor used was donepezil hydrochloride.
Comparators	The trial included a placebo controlled comparison group, which was an appropriate comparison group.
Outcomes	The trials ranged from 10 to 12 weeks in duration with the evaluation conducted immediately after treatment. Studies assessed outcomes in the short-term including expressive, receptive language, autistic behaviors and cognitive functioning. The dose used was similar to reports in the literature; treatment episodes were most commonly associated with mood swings, lability, diarrhea, headache and fatigue as side effects. One trial also evaluated the effect of age, IQ and autism severity on treatment response and found no significant group difference.
Setting	Both the trials were conducted in USA.

ADOS-Autism Diagnostic Observation Schedule

Table E-9. Other--Bumetanide

Domain	Description of applicability of evidence
Population	Study participants ranged in age from 3 to 11 years with a wide range of disease severity among study participants. The Chinese study was restricted to younger children (2.5 to 6.5 years) who were concurrently enrolled in an ABA program. The degree of intellectual disability was not described. Concomitant medications were stopped prior to study entry in both studies. The placebo-controlled trial did allow use of melatonin.
Intervention	Bumetanide , 1 mg dose
Comparators	Placebo and no medical treatment in one study in which all participants were receiving ABA.
Outcomes	Outcomes included autism severity scores and symptoms. Assessments used in the studies included CARS, CGI, ADOS-G and ABC scales. Both studies were of 3 months duration. The placebo controlled trial also assessed subjects after a one month wash-out period post-intervention.
Setting	One placebo-controlled trial was conducted in France and the other study was done in China.

ABA-Applied Behavioral Analysis; CGI-Clinical Global Impression; CARS-Childhood Autism Rating Scale; ADOS-G-Autism Diagnostic Observation Schedule-Generic; ABC-Aberrant Behavior Checklist

Table E-10. Other--Hyperbaric oxygen therapy

Domain	Description of applicability of evidence
Population	Studies included children ages 2-14 years with autism. The degree of disease severity was not well categorized. Participants were overwhelmingly male in the two studies that reported gender (84% and 93%) The degree of intellectual disability was not reported in any of the studies. Concomitant behavioral and medication interventions were reported in all studies.
Intervention	Hyperbaric oxygen therapy- dosages ranged from 24% to 100% oxygen.
Comparators	Comparators for these studies included treatments of room air, sham air and free air flow.
Outcomes	Study outcomes included autism severity and change in behavior. Assessment tools used in the studies included CGI (used in all three trials), ATEC, ADOS, SRS, ABC. VABS, VMI-5, BRIEF, PPVT-III, RBS and direct observation of toy play sessions. The number of treatment sessions ranged from 20 up to 80 one hour treatments occurring over a three up to 15 week period of time. Outcomes were collected at end of treatment with no long term follow-up.
Setting	Two studies were conducted in the United States and one was performed in Thailand. Participants in one study were recruited from a large community based ABA provider.

CGI-Clinical Global Impression; ADOS-Autism Diagnostic Observation Schedule; ATEC-Autism Treatment Evaluation Checklist; SRS-Social Responsiveness Scale; ABC-Aberrant Behavior Checklist; VABS-Vineland Adaptive Behavior Scales; VMI-5-Visual-Motor Integration, Fifth Edition; BRIEF-Behavior Rating Inventory of Executive Functioning; PPVT-III-Picture Vocabulary Test-Third Edition; RBS-Repetitive Behavior Scale

Appendix F. Detailed Tables of Findings

Table F-1. Key Findings in Studies of Antipsychotics

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
Risperidone			
[a]Scahill 2015[1] RCT G1: Risperidone (2.5 mg/day), 57/55 G2: Placebo (NA), 27/26 21 months/2 Years post-treatment Low RoB	Age G1: 8.6 ± 2.97 G2: 9.1 ± 2.58 IQ ≥70 G1: 11 (23.9) G2: 6 (13.3) <70 G1: 35 (76.1) G2: 39 (86.7)	ABC-Irritability G1: 27.22 ± 7.28 G2: 23.44 ± 7.24 ABC-Social Withdrawal G1: 16.05 ± 8.55 G2: 18.52 ± 9.72 ABC-Stereotypic Behavior G1: 10.5 ± 4.43 G2: 8.84 ± 5.22 ABC-Hyperactivity/Noncompliance G1: 34.3 ± 7.95 G2: 28.58 ± 10.4 ABC-Inappropriate Speech G1: 5.71 ± 3.93 G2: 5.59 ± 4.03 CYBOCS G1: 15.29 ± 3.15 G2: 16 ± 3.29 CGI-Severity G1: 5.09 0.7 G2: 5.23 0.65 VABS-Communication G1: 42.81 ± 14.75 G2: 44.21 ± 17.43 VABS-Daily Living Skills G1: 38.56 ± 18.44 G2: 33.25 ± 15.2 VABS-Social Skills	**2 yrs post-treatment** ABC-Irritability G1: 14.82 ± 8.4 G2: 17.78 ± 10.82 G1 vs G2, p=0.0147 ABC-Social Withdrawal G1: 8.43 ± 6.77 G2: 13.33 ± 8.73 G1 vs G2, p=0.0130 ABC-Stereotypic Behavior G1: 6.02 ± 4.4 G2: 6.76 ± 5.37 G1 vs G2, p=0.0866 ABC-Hyperactivity/Noncompliance G1: 17.68 ± 10.16 G2: 23.38 ± 12.06 G1 vs G2, p=0.0020 ABC-Inappropriate Speech G1: 3.86 ± 3.01 G2: 5.15 ± 4.24 G1 vs G2, p=0.0433 CYBOCS G1: 11.67 ± 4.48 G2: 13.08 ± 4.6 G1 vs G2, p=0.3 CGI-Severity G1: 4.4 ± 0.89 G2: 4.65 ± 1.09 G1 vs G2, p=0.3004 **7-38 mos follow-up** VABS-Communication

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
		G1: 47.4 ± 11.71 G2: 48.83 ± 18.19 VABS-Motor Skills G1: 60.34 ± 19.86 G2: 56.88 ± 24.63 VABS-Adaptive Behavior G1: 41.55 ± 15.63 G2: 38.58 ± 15.38 IQ Tests G1: 50.52 ± 23.07 G2: 46.74 ± 30.57 M-RLRS – Sensory Motor G1: 6.95 ± 4.28 G2: 4.76 ± 2.98 M-RLRS – Social Relationships G1: 6.55 ± 4.29 G2: 6.28 ± 4.32 M-RLRS – Affectual Responses G1: 6.13 ± 1.9 G2: 5.2 ± 1.94 M-RLRS – Sensory Responses G1: 20.96 ± 9.06 G2: 19.24 ± 8.8 M-RLRS – Language G1: 2.67 ± 4.31 G2:4.92 ± 4.65	G1: 43.19 ± 18.45 G2: 45.21 ± 21.09 VABS-Daily Living Skills G1: 40.56 ± 20.3 G2: 38.54 ± 21.6 VABS-Social Skills G1: 50.63 ± 15.1 G2: 44.21 ± 18.07 VABS-Motor Skills G1: 61.94 ± 15.72 G2: 63.06 ± 27.17 VABS-Adaptive Behavior G1: 40.25 ± 15.51 G2: 38.96 ± 18.02 IQ Tests G1: 48.73 ± 23.92 G2: 45.85 ± 32.22 M-RLRS – Sensory Motor G1: 4.67 ± 3.06 G2: 4.2 ± 3.42 M-RLRS – Social Relationships G1: 1.02 ± 4.23 G2: 2.4 ± 3.16 M-RLRS – Affectual Responses G1: 3.49 ± 1.88 G2: 4.04 ± 1.88 M-RLRS – Sensory Responses G1: 11.02 ± 7.1 G2: 14.8 ± 7.08 M-RLRS – Language G1: -0.15 ± 3.99 G2:1.96 ± 4.3

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
[a]Scahill et al., 2015[2] RCT G1: Risperidone (up to 2.5 mg/kg), 49/43 G2: Placebo (NA), 52/38 8 weeks/EOT Low RoB	Age G1: 8.6 ± 2.97 G2: 9.1 ± 2.58 IQ ≥70 G1: 11 (23.9) G2: 6 (13.3) <70 G1: 35 (76.1) G2: 39 (86.7)	CYBOCS G1: 15.25 ± 3.25 G2: 14.8 ± 4.27	**EOT** CYBOCS G1: 11.3 ± 3.77 G2: 14.1 ± 4.43 G1 vs G2, p=0.0005; ES=0.74
[a]Scahill et al., 2015[3] RCT G1: Risperidone (up to 2.5 mg/day), 49/49 G2: Placebo (NA), 52/52 8 weeks/EOT Low RoB	Age G1: 7.5 ± 2.80 G2: 9.1 ± 2.58 IQ ≥70 G1: 23 (46.9) G2: 6 (13.3) <70 NR	ABC-Social Withdrawal/Lethargy G1: 16.4 ± 8.2 G2: 16.1 ± 8.7	**EOT** ABC-Social Withdrawal/Lethargy G1 vs G2, p=0.05; ES=0.42
[b]Scahill et al., 2015[2] RCT G1: Risperidone (up to 3.5 mg/day), 49/47 G2: Risperidone + Parent Training (up to 3.5 mg/day + mean of 10.9 sessions), 75/70 8 weeks Low RoB	Age G1: 7.5 ± 2.80 G2: 9.1 ± 2.58 IQ ≥70 G1: 23 (46.9) G2: 6 (13.3) <70 NR	CYBOCS G1: 16.2 ± 2.47 G2: 14.8 ± 4.27	**EOT** CYBOCS G1: 11 ± 3.73 G2: 14.1 ± 4.43 G1 vs G2, p=0.0001; ES=0.88
Wink et al., 2014[4] Retrospective Cohort G1: Risperidone (2.23 mg/day), 72/72 G2: Aripiprazole (11.85 mg/day), 70/70 Varies/EOT Moderate RoB	Age (at initiation) G1: 8.41 ± 3.59 G2: 9.74 ± 3.46 IQ NR	CGI-Severity NR	**EOT** CGI-Improvement G1: 3.2 ± 1.2 G2: 2.9 ± 1.2 G1 vs G2, p=ns

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
[c]Kent et al., 2013[5] RCT G1: Risperidone (0.125-0.175 mg/day; low dose), 30/25 G2: Risperidone (1.25-1.75 mg/day; high dose), 31/25 G3: Placebo (NA), 35/27 6 weeks/EOT Low RoB	Age G1: 10 ± 3.4 G2: 9 ± 3.1 G3: 9 ± 2.6 IQ Mental age G1 + G2 + G3: 5.5 yrs	ABC-Irritability G1: 27.1 ± 6.26 G2: 28.0 ± 7.81 G3: 28.9 ± 6.10 CGI – Severity G1: 5.1 ± 0.92 G2: 5.0 ± 0.78 G3: 4.9 ± 0.67	**EOT** Mean change in: ABC-Irritability G1: -7.4 ± 8.12 G2: -12.4 ± 6.52 G3: -3.5 ± 10.67 G1 vs G3: p=ns G2 vs G3: p<0.001 CGI – Severity G1: -0.4 ± 0.73 G2: -1.0 ± 0.78 G3: -0.3 ± 0.79 G1 vs G3: p=ns G2 vs G3: p<0.001
[c]Kent et al., 2013[6] RCT G1: Risperidone (0.125-0.175 mg/day; low dose)/Risperidone, 30/25 G2: Risperidone (1.25-1.75 mg/day; high dose)/Risperidone, 31/25 G3: Placebo/Risperidone (NA), 35/27 6 weeks/End of open label trial Low RoB	Age G1: 10 ± 3.4 G2: 9 ± 3.1 G3: 9 ± 2.6 IQ Mental age G1 + G2 + G3: 5.5 yrs	ABC-Irritability G1: 13.4 ± 3.99 G2: 14.4 ± 4.64 G3: 13.7 ± 2.66 ABC-Hyperactivity G1: 30.1 ± 11.46 G2: 33.8 ± 9.75 G3: 31.4 ± 8.60 ABC-Stereotypic Behavior G1: 9.3 ± 5.17 G2: 11.5 ± 5.06 G3: 10.5 ± 5.26 ABC-Inappropriate Speech G1: 6.6 ± 3.49 G2: 7.5 ± 2.78 G3: 5.9 ± 3.42 ABC-Social Withdrawal G1: 18.2 ± 9.71 G2: 21.4 ± 9.09 G3: 18.1 ± 10.16 CYBOCS G1: 13.4 ± 3.99 G2: 14.4 ± 4.64 G3: 13.7 ± 2.66 CGI-Severity G1: 5.1 ± 0.93	**At OLE Endpoint** Mean change score ABC-Irritability G1: -13.2 ± 9.29 G2: -13 ± 10.55 G3: -11.8 ± 7.68 ABC-Hyperactivity G1: -10.5 ± 12.42 G2: -12.3 ± 11.78 G3: -11.7 ± 8.54 ABC-Stereotypic Behavior G1: -4.2 ± 6.51 G2: -4.6 ± 5.14 G3: -2.8 ± 4.12 ABC-Inappropriate Speech G1: -1.8 ± 3.93 G2: -2.1 ± 3.07 G3: -1.5 ± 2.69 ABC-Social Withdrawal G1: -8.3 ± 9.03 G2: -10.4 ± 8.57 G3: -6.9 ± 8.08 CYBOCS G1: -4.1 ± 3.01 G2: -5.6 ± 4.66 G3: -5.3 ± 4.99

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
		G2: 5 ± 0.75 G3: 4.9 ± 0.67	CGI-Severity G1: -1 ± 1.02 G2: -1.3 ± 1.17 G3:-0.9 ± 0.88 CGI-Much or Very Much Improved G1: 14 (58) G2: 15 (60) G3: 20 (69) *% of patients with CGI-C ratings of "much" or "very much" improved at OLE endpoint was not significant among the 3 groups (p=0.684) *The percentage of patients with ABC-I response at OLE endpoint (defined as ‡ 25% improvement from DB baseline) was not statistically significantly different among the three groups (p = 0.800). **Mean change scores from baseline** ABC-Irritability G1: -7.4 ± 8.12 G2: -12.4 ± 6.52 G3: -3.5 ± 10.67 G1 Vs G3, p=0.164, ES=0.36 G2 Vs G3, p <0.001, ES=0.94 ABC-Hyperactivity G1: -10.5 ± 12.42 G2: -12.3 ± 11.78 G3: -11.7 ± 8.54 G1 Vs G3, p=0.008 G2 Vs G3, p=0.019 ABC-Stereotypy G1: -4.2 ± 6.51

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
			G2: -4.6 ± 5.14 G3: -2.8 ± 4.12 G1 Vs G3, p=ns G2 Vs G3, p=ns ABC-Inappropriate Speech G1: -1.8 ± 3.93 G2: -2.1 ± 3.07 G3: -1.5 ± 2.69 G1 Vs G3, p=ns G2 Vs G3, p=ns ABC-Social Withdrawal/Lethargy G1: -8.3 ± 9.03 G2: -10.4 ± 8.57 G3: -6.9 ± 8.08 G1 Vs G3, p=0.817 G2 Vs G3, p=0.004 **Change from baseline** CGI-Severity G1: -0.4 ± 0.73 G2: -1 ± 0.78 G3: -0.3 ± 0.79 G1 Vs G3, p=0.769, ES=0.08 G2 Vs G3, p<0.001, ES=1.02 **EOT** CGI-Improvement – much or very much improved G1: 5 (17) G2: 18 (63) G3: 5 (15) G1 Vs G3, p=0.985 G2 Vs G3, p<0.001 CYBOCS NR

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
[b]Scahill et al., [3]2013 RCT G1: Risperidone (up to 3.5 mg/day), 49/47 G2: Risperidone + Parent Training (up to 3.5 mg/day + mean of 10.9 sessions), 75/70 8 weeks/EOT Low RoB	Age G1: 7.5 ± 2.80 G2: 9.1 ± 2.58 IQ ≥70 G1: 23 (46.9) G2: 6 (13.3) <70 NR	ABC-Social Withdrawal/Lethargy G1: 17.1 ± 8.5 G2: 15.2 ± 9	**EOT** ABC-Social Withdrawal/Lethargy NR
[b]Scahill et al., 2009[7] RCT G1: Risperidone (3.5 mg/day), 49/47 G2: Risperidone + Parent Training (up to 3.5 mg/day + mean of 10.9 sessions), 75/70 24 weeks/EOT Low RoB	Age G1: 7.5 ± 2.80 G2: 9.1 ± 2.58 IQ ≥70 G1: 23 (46.9) G2: 6 (13.3) <70 NR	CGI-S – Moderate G1: 14 (28.6) G2: 25 (33.3) CGI-S – Marked G1: 19 (38.8) G2: 33 (44) CGI-S – Severe G1: 15 (30.6) G2: 17 (22.7) CGI-S – Extreme G1: 1 (2) G2: 0 (0) ABC – Irritability G1: 29.7 ± 6.1 G2: 29.3 ± 6.97 ABC – Social Withdrawal G1: 17.1 ± 8.37 G2: 15.2 ± 9.01 ABC – Stereotypic Behavior G1: 10.6 ± 5.46 G2: 7.59 ± 5.2 ABC – Hyperactivity/Noncompliance G1: 36.1 ± 6.86 G2: 35.3 ± 9.3 ABC – Inappropriate Speech	**During Treatment (8 wks)** ABC – Irritability G1: 12.52 ± 8.69 G2: 11.95 ± 8.21 ABC – Social Withdrawal G1: 6.98 ± 7.63 G2: 4.72 ± 6.31 ABC – Stereotypic Behavior G1: 5.23 ± 5.23 G2: 2.89 ± 3.82 ABC – Hyperactivity/Noncompliance G1: 18.8 ± 10.99 G2: 16.5 ± 10.69 ABC – Inappropriate Speech G1: 3.34 ± 3.18 G2: 2.54 ± 2.59 CYBOCS G1: 11.54 ± 3.92 G2: 10.67 ± 3.26 **During Treatment (16 wks)** ABC – Irritability G1: 13.6 ± 9.34 G2: 12.1 ± 8.05 ABC – Social

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
		G1: 6.37 ± 4.03 G2: 5.75 ± 3.43 CYBOCS G1: 16.22 ± 2.47 G2: 14.72 ± 2.85	Withdrawal G1: 6.49 ± 7.56 G2: 4.58 ± 6.07 ABC – Stereotypic Behavior G1: 5.73 ± 5.35 G2: 3.34 ± 4.21 ABC – Hyperactivity/Noncompliance G1: 18.39 ± 10.62 G2: 16.16 ± 10.87 ABC – Inappropriate Speech G1: 3.35 ± 3.34 G2: 2.43 ± 2.73 CYBOCS G1: 11.33 ± 4.48 G2: 9.97 ± 3.98 **EOT** ABC – Irritability G1: 14.53 ± 9.9 G2: 10.96 ± 6.64 ABC – Social Withdrawal G1: 6.44 ± 7.16 G2: 4.26 ± 5.17 ABC – Stereotypic Behavior G1: 6.25 ± 5.68 G2: 3.2 ± 4.09 ABC – Hyperactivity/Noncompliance G1: 20.78 ± 12.38 G2: 15.38 ± 10.23 ABC – Inappropriate Speech G1: 3.3 ± 3.66 G2: 2.56 ± 2.93

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
			CYBOCS G1: 11.86 ± 4.47 G2:10.11 ± 3.83
[d]Shea et al., 2004[8] RCT G1: Risperidone (1 mg/mL), 24 G2: Placebo (NA), 28 8 weeks/EOT Moderate RoB	Age G1: 7.4 ± 2.7 G2: 7.1 ± 2.1 IQ - ≤84 G1: 19 (100) G2: 18 (75) IQ - >84 G1: 0 (0) G2: 6 (25)	ABC-Irritability G1: 20.6 ± 8.1 G2: 21.6 ± 10.2 ABC-Hyperactivity G1: 29.2 ± 9.5 G2: 33.6 ± 6.8 ABC-Social Withdrawal/Lethargy G1: 14 ± 6.8 G2: 13.6 ± 8.6 ABC-Stereotypy G1: 8.4 ± 5.8 G2: 9.4 ± 5.5 ABC-Inappropriate Speech G1: 4.5 ± 3.7 G2: 4.5 ± 3.7 Nisonger-Child Behavior Rating Form – Adaptive/Social G1: 3.8 ± 2.3 G2: 3.9 ± 2 Nisonger-Child Behavior Rating Form – Compliant/Calm G1: 3.8 ± 2.7 G2: 6.2 ± 2.4 Nisonger-Child Behavior Rating Form – Conduct Problem G1: 17.2 ± 8 G2: 21.5 ± 10.7 Nisonger-Child Behavior Rating Form	**During Treatment (1 wk)** ABC-Irritability G1: 13.7 ± 9.1 G2: 16.9 ± 10.7 **During Treatment (2 wks)** ABC-Irritability G1: 10.3 ± 7.6 G2: 15.8 ± 10.8 **During Treatment (3 wks)** ABC-Irritability G1: 8.8 ± 7.3 G2: 14.4 ± 11.7 **During Treatment (5 wks)** ABC-Irritability G1: 8.8 ± 7.2 G2: 13.7 ± 11.1 **During Treatment (8 wks)** ABC-Irritability G1: 7.5 ± 6.4 G2: 13.8 ± 12.2 **EOT** ABC-Irritability G1: 7.2 ± 5.9 G2: 14.1 ± 11.3 G1 vs G2, p=0.002; ES = -0.7 ABC-Hyperactivity G1: 13.3 ± 8.7 G2: 26.4 ± 12.8 G1 vs G2, p=0.001;

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
		– Hyperactive G1: 17.7 ± 5.6 G2: 19.6 ± 5.2 Nisonger-Child Behavior Rating Form – Insecure/Anxious G1: 6.3 ± 6.7 G2: 8.7 ± 6.7 Nisonger-Child Behavior Rating Form – Overly Sensitive G1: 6.7 ± 3.4 G2: 6.6 ± 3.4 Nisonger-Child Behavior Rating Form – Self-Injury/Stereotypic G1: 4.5 ± 4.4 G2: 4.1 ± 4.4 Nisonger-Child Behavior Rating Form – Self-Isolated/Ritualistic G1: 7.3 ± 4 G2: 7.8 ± 4.2 VAS-Aggression G1: 86 ± 14.5 G2: 88.3 ± 9 VAS-Defiance/Disobedience G1: 75 ± 47 G2: 94.8 ± 19.6 VAS-Hyperactivity G1: 68.7 ± 28.6 G2: 96.3 ± 4.2 VAS-Obsessive/Repetitive G1: 86.3 ± 19.4 G2: 98 ± 0 VAS-Tantrums/Negative	ES = -0.8 ABC-Social Withdrawal/Lethargy G1: 4.7 ± 4.4 G2: 8.2 ± 8.9 G1 vs G2, p=0.020; ES = -0.5 ABC-Stereotypy G1: 3.9 ± 4.2 G2: 6.9 ± 6.9 G1 vs G2, p=0.053; ES = -0.4 ABC-Inappropriate Speech G1: 1.9 ± 2.2 G2: 3.1 ± 3.5 G1 vs G2, p=0.058; ES = -0.4 CGI-I - much improved or very much improved G1: 14 (58.3) G2: 6 (21.4) G1 vs G2, p=0.008 Nisonger-Child Behavior Rating Form – Adaptive/Social G1: 5.3 ± 2.4 G2: 4.3 ± 2.4 G1 vs G2, p=0.072 Nisonger-Child Behavior Rating Form – Compliant/Calm G1: 8.7 ± 3.3 G2: 6.9 ± 2.9 G1 vs G2, p=0.072 Nisonger-Child Behavior Rating Form – Conduct Problem G1: 6.5 ± 5.7 G2: 15.5 ± 11.9 G1 vs G2, p=0.005 Nisonger-Child

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
		Mood G1: 80.8 ± 10.1 G2:81.2 ± 13.9	Behavior Rating Form – Hyperactive G1: 9.4 ± 5.4 G2: 14.9 ± 8.4 G1 vs G2, p=0.021 Nisonger-Child Behavior Rating Form – Insecure/Anxious G1: 3.2 ± 4.3 G2: 5.4 ± 4.8 G1 vs G2, p=ns Nisonger-Child Behavior Rating Form – Overly Sensitive G1: 2.8 ± 2.3 G2: 4.3 ± 3.3 G1 vs G2, p=0.029 Nisonger-Child Behavior Rating Form – Self-Injury/Stereotypic G1: 2.2 ± 3.1 G2: 2.8 ± 3.9 G1 vs G2, p=ns Nisonger-Child Behavior Rating Form – Self-Isolated/Ritualistic G1: 2.4 ± 2.5 G2: 4.5 ± 5.5 G1 vs G2, p=0.078 VAS-Aggression G1: 22.3 ± 20 G2: 63.4 ± 37.3 G1 vs G2, p=0.056 VAS-Defiance/Disobedience G1: 60 ± 21.1 G2: 65.2 ± 25 G1 vs G2, p=ns VAS-Hyperactivity G1: 39.7 ± 19.7 G2: 80.5 ± 14.2

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
			G1 vs G2, p=0.040 VAS-Obsessive/Repetitive G1: 70 ± 16.8 G2: 48 ± 63.4 G1 vs G2, p=ns VAS-Tantrums/Negative Mood G1: 28 ± 20.9 G2:43.4 ± 28.8 G1 vs G2, p=0.496
[a]Scahill et al., 2006[9] RCT G1: Risperidone (2.5 mg/day), 48/48 16 weeks/end of 4 months Low RoB	G1: 5-16 yrs	VABS-Communication G1: 43.58 13.48 VABS-Daily Living Skills G1: 39.42 18.06 VABS-Socialization G1: 48.67 9.78 VABS-Composite G1: 42.35 15.79	**End of 4 month open label extension** VABS-Communication G1: 45.21 18.85 d=0.11 VABS-Daily Living Skills G1: 40.38 18.11 d=0.06 VABS-Socialization G1: 5.5 12.94 d=0.14 VABS-Composite G1: 42.06 13.53 d=-0.02
[a]Scahill et al., 2005[10] RCT G1: Risperidone (2.5 mg/day), 49/49 G2: Placebo (NA), 52/42 8 weeks/EOT Low RoB	Age G1 + G2: 8.82 ± 2.69 IQ NR	Ritvo-Freeman Real Life Rating Scales – Overall Score G1: 0.94 ± 0.36 G2: 1.03 ± 0.37 VABS-Total Score G1: 33.26 ± 8.38 G2: 33.51 ± 8.29	**4wks During Treatment** Ritvo-Freeman Real Life Rating Scales – Overall Score G1: 0.54 ± 0.36 G2: 0.84 ± 0.39 **EOT (8 wks)** Ritvo-Freeman Real Life Rating Scales – Overall Score G1: 0.45 ± 0.31 G2: 0.88 ± 0.4 G1 vs G2, ES=1.08 VABS-Total Score G1: 20.34 ± 7.93

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
			G2: 30.27 ± 8.87 G1 vs G2, ES=1.03, Group X time, p<0.001
[a]Scahill et al., 2005[11] RCT G1: Risperidone (2.5 mg/day), 63/63 G2: Placebo-Substitution (NA), NA 4 weeks during open label extension/EOT Low RoB	Age G1 + G2: 8.82 ± 2.69 IQ NR	End of initial 8 wks of med exposure CGI-I – Very much improved G1: 19 (30.2) G2: ND CGI-I – Much Improved G1: 42 (66.7) G2: ND CGI-I Minimally Improved G1: 0 (0) G2: ND CGI-I – No Change G1: 2 (3.2) G2: ND CGI-I – Worse G1: 0 (0) G2: ND CGI-I – Much Worse G1: 0 (0) G2: ND ABC-Irritability G1: 9.5 ± 6.8 G2: ND ABC-Social Withdrawal/Lethargy G1: 7.3 ± 5.4 G2: ND ABC-Stereotypy G1: 4.9 ± 4.3 G2: ND ABC-Hyperactivity G1: 15.1 ± 10 G2: ND	**4 wks During Treatment** CGI-I – Very much improved G1: 13 (20.6) G2: ND CGI-I – Much Improved G1: 38 (60.3) G2: ND CGI-I Minimally Improved G1: 7 (11.1) G2: ND CGI-I – No Change G1: 1 (1.6) G2: ND CGI-I – Worse G1: 20 (33.9) G2: ND CGI-I – Much Worse G1: 1 (1.6) G2: ND **16 wks EOT** CGI-I – Very much improved G1: 20 (33.9) G2: ND CGI-I – Much Improved G1: 31 (5.5) G2: ND CGI-I Minimally Improved G1: 5 (8.5) G2: ND

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
		ABC-Inappropriate Speech G1: 3.4 ± 3.6 G2: ND	CGI-I – No Change G1: 1 (1.7) G2: ND CGI-I – Worse G1: 1 (1.7) G2: ND CGI-I – Much Worse G1: 1 (1.7) G2: ND **EOT (Last Observation)** ABC-Irritability G1: 11.7 ± 8 G2: ND ABC-Social Withdrawal/Lethargy G1: 6.8 ± 5.9 G2: ND ABC-Stereotypy G1: 5.8 ± 4.7 G2: ND ABC-Hyperactivity G1: 15.8 ± 10.2 G2: ND ABC-Inappropriate Speech G1: 3.4 ± 3.2 G2: ND **8 wks During Treatment** Relapse Rate G1: 10 (62.5) G2: 2 (12.5)
[d]Shea et al., 2004[12] RCT G1: Risperidone (0.02 mg/kg/day), 39/39 G2: Placebo (NA), 38/38 8 weeks/EOT	Age G1: 7.6 ± 2.3 G2: 7.3 ± 2.3 IQ – Normal G1: 3 (9.7) G2: 11 (31.4) IQ – Borderline	ABC-Irritability G1: 18.9 ± 8.8 G2: 21.2 ± 9.7 ABC-Hyperactivity G1: 13.7 ± 7 G2: 14.3 ± 8.2 ABC-Social	**Mean Change Score** ABC-Irritability G1: -12.1 ± 5.8 G2: -6.5 ± 8.4 G1 vs G2, p≤0.001 ABC-Hyperactivity G1: -8.6 ± 5.9 G2: -5.7 ± 6.9

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
Moderate RoB	G1: 6 (19.4) G2: 4 (11.4) IQ – Mild G1: 12 (38.7) G2: 8 (22.9) IQ – Moderate G1: 10 (32.3) G2: 12 (34.3)	Withdrawal/Lethargy G1: 27.3 ± 9.7 G2: 30.9 ± 8.8 ABC-Stereotypy G1: 4.6 ± 3.4 G2: 4.8 ± 3.7 ABC-Inappropriate Speech G1: 7.9 ± 5 G2: 8.1 ± 5.6	G1 vs G2, p≤0.01 ABC-Social Withdrawal/Lethargy G1: -14.9 ± 6.7 G2: -7.4 ± 9.7 G1 vs G2, p≤0.001 ABC-Stereotypy G1: -2.6 ± 2.6 G2: -1.6 ± 3 G1 vs G2, p≤0.05 ABC-Inappropriate Speech G1: -4.3 ± 3.8 G2: -2.4 ± 4 G1 vs G2, p≤0.05
[a]Scahill et al., 2002[13] RCT G1: Risperidone (up to 2.5 mg/kg), 49/49 G2: Placebo (NA), 52/52 8 weeks/EOT Low RoB	Age G1 + G2: 8.82 ± 2.69 IQ NR	ABC-Irritability G1: 26.2 ± 7.9 G2: 25.5 ± 6.6 ABC-Lethargy/Social Withdrawal G1: 16.4 ± 8.2 G2: 16.1 ± 8.7 ABC-Stereotypic Behavior G1: 10.6 ± 4.9 G2: 9 ± 4.4 ABC-Hyperactivity G1: 31.8 ± 9.6 G2: 32.3 ± 8.5 ABC-Inappropriate Speech G1: 4.8 ± 4.1 G2: 6.5 ± 3.6 CGI-S – Moderate G1: 9 (18) G2: 9 (18) CGI-S – Marked G1: 27 (55) G2: 28 (57) CGI-S – Severe	**EOT** ABC-Irritability G1: 11.3 ± 7.4 G2: 21.9 ± 9.5 G1 vs G2, p<0.001; ES=1.2 ABC-Lethargy/Social Withdrawal G1: 8.9 ± 6.4 G2: 12 ± 8.3 G1 vs G2, p=0.03, ES=0.4 ABC-Stereotypic Behavior G1: 5.8 ± 4.6 G2: 7.3 ± 4.8 G1 vs G2, p<0.001 ES=0.8 ABC-Hyperactivity G1: 17 ± 9.7 G2: 27.6 ± 10.6 G1 vs G2, p<0.001 ABC-Inappropriate Speech G1: 3 ± 3.1 G2: 5.9 ± 3.8 G1 vs G2, p=0.03. ES=0.3

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
		G1: 12 (24) G2: 12 (24) CGI-S – Extreme G1: 1 (2) G2: 0 (0)	CGI-I – Much Improved or very much improved + 25% reduction on ABI-I G1: 34 (69) G2: 6 (12)
Nagaraj et al., 2006[14] RCT G1: Risperidone (0.5-1.0 mg/day), 19/19 G2: Placebo (NA), 20/20 6 months/EOT Moderate RoB	Age, months G1: 57.95 ± 20.84 G2: 63 ± 20.12 IQ – Borderline IQ G1: 9 (47.7) G2: 8 (40) IQ – Mild Retardation G1: 6 (31.6) G2: 5 (25) IQ – Moderate Retardation G1: 4 (21.1) G2: 7 (35)	CARS, median G1: 39.5 (32.5-46) G2: 38.5 (31.5-43) CGAS G1: 29.79 ± 7.27 G2: 32.65 ± 7.95	**EOT** CARS, median G1: 32 (24.5-40.5) G2: 37.5 (30-42.5) G1 vs G2, p<0.001 CGAS G1: 40.94 ± 7.83 G2: 35.2 ± 9.38 G1 vs G2, p=0.035 CARS (≥25% Improvement from Baseline) G1: 12 (63.2) G2: 0 (0) CGAS (≥25% Improvement from Baseline) G1: 17 (89.5) G2: 2 (10) Global Impression of Parents – Improvement to Some Extent G1: 9 (47.4) G2: 6 (30) Global Impression of Parents – Considerably Improved G1: 9 (47.4) G2: 0 (0) Global Impression of Parents – Worsened G1: 1 (5.3) G2: 4 (20) Global Impression of

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
			Parents – No Change G1: 0 (0) G2: 9 (45)
Aripiprazole			
Findling et al., 2014[15] RCT G1: Aripiprazole (2-15 mg/day), 41/22 G2: Placebo (NA), 44/19 16 weeks/EOT Low RoB	Age G1: 10.1 ± 2.8 G2: 10.8 ± 2.8 IQ G1: NR G2: NR	ABC-I – adjusted mean score NR CGI - improvement scale NR	**EOT** Relapse rate G1: 35% G2: 52% G1 vs G2: p=ns Change scores in: ABC- I G1: 5.2 G2: 9.6 G1 vs G2: p=ns ABC- Hyperactivity G1: 5.0 G2: 10.3 G1 vs G2: p=0.041 ABC- Stereotypy G1: 0.8 G2: 2.8 G1 vs G2: p=0.018 ABC- Inappropriate speech G1: 0.6 G2: 2.1 G1 vs G2: p=0.013 ABC- Social withdrawal G1: 0 G2: 1.5 G1 vs G2: p=ns CGI- I G1: 4.2 G2: 4.8 G1 vs G2: p=ns

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
Ghanizadeh et al., 2014[16] RCT G1: Aripiprazole (1.25-10 mg/day), 29/29 G2: Risperidone (0.25-3 mg/day), 30/30 2 months/EOT Low RoB	Age G1: 9.6 ± 3.3 G2: 9.5 ± 4.6 IQ NR	ABC-Irritability G1: 26.2 ± 4.1 G2: 21.5 ± 7.4 ABC-Hyperactivity G1: 37.1 ± 7 G2: 36 ± 6.2 ABC-Lethargy G1: 27.5 ± 8.4 G2: 25.3 ± 8.9 ABC-Stereotypy G1: 13.6 ± 5.7 G2: 13.2 ± 4.2 ABC-Speech G1: 8.6 ± 3.1 G2: 8.9 ± 3.6	**EOT** ABC-Irritability G1: 14.6 ± 5.5 G2: 12.5 ± 5.4 G1 vs G2, p=ns ABC-Hyperactivity G1: 21.1 ± 9 G2: 19.1 ± 6.1 G1 vs G2, p=ns ABC-Lethargy G1: 17.3 ± 7.4 G2: 16.1 ± 6.9 G1 vs G2, p=ns ABC-Stereotypy G1: 8.2 ± 5 G2: 7.4 ± 3.9 G1 vs G2, p=ns ABC-Speech G1: 4.9 ± 2.3 G2: 5.7 ± 3.1 G1 vs G2, p=ns CGI-Improvement, n Much improved G1: 9 G2: 5 Minimally improved G1: 7 G2: 12 No change G1: 5 G2: 8 Minimally worse G1: 3 G2: 2 G1 vs G2: p=ns

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
[e]Marcus et al., 2012[17] RCT G1: Aripiprazole (2-15 mg/kg; flexibly dosed study), 34/34 G2: Aripiprazole (5 mg/kg), 43/43 G3: Aripiprazole (10 mg/kg), 49/49 G4: Aripiprazole (15 mg/kg), 41/41 G5: Placebo (flexibly dosed study), 39/39 G6: Placebo (fixed-dose study), 37/37 8 weeks/EOT Low RoB	Age G1: 9.5 ± 3.1 G2: 9.4 ± 3 IQ NR	Pediatric QoL-Combined Scales G1: 45 ± 2.9 G2: 41.5 ± 2.3 G3: 43.4 ± 2.1 G4: 38.3 ± 2.3 G5: 38.1 ± 2.7 G6: 42.8 ± 2.5	**EOT** Pediatric QoL-Combined Scales G1: 13.4 ± 1.9 G2: 14 ± 2.4 G3: 10.4 ± 2.2 G4: 18.7 ± 2.4 G5: 2 ± 1.8 G6:10.6 ± 2.6
[e]Marcus et al., 2011[18] RCT G1: De Novo Subjects (2-15 mg/kg), 84/55 G2: Prior Placebo (2-15 mg/kg), 69/37 G3: Prior Aripiprazole (2-15 mg/kg), 169/107 52 weeks Low RoB	Age 9.6 (mean) IQ NR	CGI-Severity G1: 4.8 ± 1 G2: 4.2 ± 1 G3: 3.9 ± 1.1 ABC-Irritability G1: 23.2 ± 8.9 G2: 21.5 ± 9.8 G3: 15 ± 9.2 ABC-Lethargy/Social Withdrawal G1: 14.6 ± 8.6 G2: 11.3 ± 9.2 G3: 10.4 ± 8.9 ABC-Stereotypic Behavior G1: 8.1 ± 5.2 G2: 9.1 ± 5.6 G3: 6.4 ± 5.5 ABC-Hyperactivity G1: 28.4 ± 10.9 G2: 25.8 ± 13.2 G3: 18.4 ± 12 ABC-Inappropriate Speech G1: 5.8 ± 3.2 G2: 5.7 ± 4.2 G3: 4.2 ± 3.6 CYBOCS	**EOT** CGI-Severity G1: -1 ± 0.8 G2: -0.6 ± 1.2 G3: -0.1 ± 1 ABC-Irritability G1: -8 ± 10.1 G2: -6.1 ± 1.9 G3: 0.7 ± 10.2 ABC-Lethargy/Social Withdrawal G1: -6.4 ± 7.9 G2: -4.1 ± 7.2 G3: -2.3 ± 6.4 ABC-Stereotypic Behavior G1: -2.7 ± 3.1 G2: -1.9 ± 4.1 G3: -0.5 ± 4.4 ABC-Hyperactivity G1: -12.3 ± 8.5 G2: -9.1 ± 11.5 G3: 0.6 ± 10.3 ABC-Inappropriate Speech G1: -2 ± 2.5 G2: -1.8 ± 3 G3: -0.3 ± 2.4

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
		G1: 12.6 ± 4.6 G2: 12.1 ± 4 G3: 10.4 ± 3.9	CYBOCS G1: -2.8 ± 3.5 G2: -2.6 ± 5.4 G3: 0.2 ± 4.1
[e]Marcus et al., 2010[19] RCT G1: Aripiprazole (2-15 mg/kg; flexibly dosed study), 46/46 G2: Aripiprazole (5 mg/kg), 52/52 G3: Aripiprazole (10 mg/kg), 59/59 G4: Aripiprazole (15 mg/kg), 53/53 G5: Placebo (flexibly dosed study) 49/49 G6: Placebo (fixed-dose study) 49/49 8 weeks/EOT Low RoB	Age Flexibly dosed study: 9.3 ± 2.9 Fixed dose study: 9.7 ± 3.1 IQ NR	ABC-Irritability G1: 29.6 ± 1 G2: 28.3 ± 1 G3: 27.6 ± 0.9 G4: 28.3 ± 1 G5: 30.8 ± 1 G6: 26.9 ± 1 ABC-Social Withdrawal/Lethargy G1: 19.9 ± 1.6 G2: 17.7 ± 1.4 G3: 16.8 ± 1.3 G4: 18.9 ± 1.4 G5: 18.1 ± 1.6 G6: 18 ± 1.5 ABC-Stereotypic Behavior G1: 11.9 ± 0.9 G2: 11.4 ± 0.8 G3: 11.6 ± 0.8 G4: 10.7 ± 0.9 G5: 10.7 ± 0.8 G6: 10.7 ± 0.8 ABC-Hyperactivity G1: 34.1 ± 1.4 G2: 33.1 ± 1.4 G3: 33.7 ± 1.3 G4: 32.2 ± 1.4 G5: 34.7 ± 1.4 G6: 31 1. ± 4 ABC-Inappropriate Speech G1: 7 ± 0.6 G2: 5.8 ± 0.6 G3: 6.8 ± 0.5 G4: 6.3 ± 0.5 G5: 7 ± 0.6 G6: 5.9 ± 0.6	Change score **EOT** ABC-Irritability G1: -12.9 ± 1.4 G2: -12.4 ± 1.4 G3: -13.2 ± 1.3 G4: -14.4 ± 1 G5: -5 ± 1.4 G6: -8.4 ± 1.4 G1 vs G6, p<0.05 G2 vs G6, p<0.05 G3 vs G6, p<0.05 G4 vs G6, p<0.05 ABC-Social Withdrawal/Lethargy G1: -7.9 ± 1.2 G2: -5.8 ± 1.2 G3: -4.9 ± 1.1 G4: -7.9 ± 1.1 G5: -62 ± 1.1 G6: -5.2 ± 1.2 G5 vs G6, p=ns ABC-Stereotypic Behavior G1: -4.8 ± 0.6 G2: -4.5 ± 0.7 G3: -4.2 ± 0.6 G4: -4.5 ± 0.7 G5: -2 ± 0.6 G6: -1.8 ± 0.7 G1 vs G6, p<0.05 G2 vs G6, p<0.05 G3 vs G6, p<0.05 G4 vs G6, p<0.05 ABC-Hyperactivity G1: 12.7 ± 1.5 G2: -14 ± 1.6 G3: -13.3 ± 1.5 G4: -16.3 ± 1.6 G5: -2.8 ± 1.5 G6: -7.7 ± 1.7 G1 vs G6, p<0.05 G2 vs G6, p<0.05

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
			G3 vs G6, p<0.05 G4 vs G6, p<0.05 ABC-Inappropriate Speech G1: -2.5 ± 0.4 G2: -2 ± 0.5 G3: -1.8 ± 0.4 G4: -2.3 ± 0.4 G5: -0.4 ± 0.4 G6: -1.1 ± 5 G4 vs G6, p<0.05
[e]Marcus et al., 2009[20] RCT G1: Aripiprazole (2-15 mg/kg), 47/39 G2: Placebo (NA), 51/36 8 weeks/EOT Low RoB	Age G1: 9.7 ± 3.2 G2: 8.8 ± 2.6 IQ NR	ABC-Irritability G1: 29.6 ± 6.4 G2: 30.2 ± 6.5 ABC-Hyperactivity/Noncompliance G1: 34.1 G2: 34.7 ABC-Stereotypic Behavior G1: 11.9 G2: 10.7 ABC-Inappropriate Speech G1: 7 G2: 7 CYBOCS G1: 12.8 G2: 13.7	Change Score **EOT** ABC-Irritability G1: -12.9 G2: -5 G1 vs G2, p<0.001 ABC-Hyperactivity/Noncompliance G1: -12.7 G2: -2.8 G1 vs G2, p<0.001 ABC-Stereotypic Behavior G1: -4.8 G2: -2 G1 vs G2, p<0.001 ABC-Inappropriate Speech G1: -2.5 G2: -0.4 G1 vs G2, p<0.001 CYBOCS G1: -3.8 G2: -0.8 G1 vs G2, p<0.001 CGI-Severity G1: -1.2 G2: -0.4 CGI-I – Very much improved or much improved

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
			G1: 31 (67) G2: 8 (16) CGI-I – Minimally improved G1: 7 (15) G2: 10 (20) CGI-I – No change G1: 6 (13) G2: 22 (45) CGI-I – Minimally worse G1: 2 (4) G2: 5 (10) CGI-I – Much or very much worse G1: 0 (0) G2: 4 (8)
[e]Marcus et al., 2009[21] RCT G1: Aripiprazole (5 mg/kg), 53/44 G2: Aripiprazole (10 mg/kg), 59/49 G3: Aripiprazole (15 mg/kg), 54/47 G4: Placebo (NA), 52/38 8 weeks/EOT Low RoB	Age G1: 9 ± 2.8 G2: 10 ± 3.2 G3: 9.5 ± 3.1 G4: 10.2 ± 3.1 IQ NR	ABC-Irritability G1: 28.6 ± 7.6 G2: 28.2 ± 7.4 G3: 28.9 ± 6.4 G4: 28 ± 6.9 ABC-Hyperactivity/Noncompliance G1: 33.1 ± 1.4 G2: 33.7 ± 1.3 G3: 32.2 ± 1.4 G4: 31 ± 1.4 ABC-Stereotypic Behavior G1: 11.4 ± 0.8 G2: 11.6 ± 0.8 G3: 11.6 ± 0.8 G4:10.7 ± 0.8 ABC-Social Withdrawal/Lethargy G1: 17.7 ± 1.4 G2: 16.8 ± 1.3 G3: 18.9 ± 1.4 G4: 18 ± 1.5 ABC-Inappropriate	Change score **EOT** ABC-Irritability G1: -12.4 G2: -13.2 G3: -14.4 G4: -8.4 G1 v G4: p=0.032 G2 v G4: p=0.008 G3 v G4: p=0.001 ABC-Hyperactivity/Noncompliance G1: -14 ± 1.6 G2: -13.3 ± 1.5 G3: -16.3 ± 1.6 G4: -7.7 ± 1.7 G1 v G4: p≤0.005 G2 v G4: p≤0.05 G3 v G4: p≤0.001 ABC-Stereotypic Behavior G1: -4.5 ± 0.68 G2: -4.2 ± 0.63 G3: -4.5 ± 0.66 G4:-1.8 ± 0.69 G1 v G4: p≤0.005

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Time Point Post-Treatment Risk Of Bias	Mean Age, Years ± SD Mean IQ ±SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
		Speech G1: 5.8 ± 0.6 G2: 6.8 ± 0.5 G3: 6.3 ± 0.5 G4: 5.9 ± 0.6 CYBOCS G1: 13.9 ± 0.6 G2: 13.5 ± 0.5 G3: 14.1 ± 05 G4:13.7 ± 0.6 CGI-S G1: 5 ± 0.1 G2: 4.9 ± 0.1 G3: 5.1 ± 0.1 G4: 4.7 ± 0.1	G2 v G4: p≤0.05 G3 v G4: p≤0.005 ABC-Social Withdrawal/Lethargy G1: -5.8 ± 1.2 G2: -4.9 ± 1.1 G3: -7.9 ± 1.1 G4:-5.2 ± 1.2 ABC-Inappropriate Speech G1: -2 ± 0.5 G2: -1.8 ± 0.4 G3: -2.3 ± 0.4 G4: -1.1 ± 0.5 CYBOCS G1: -2.6 ± 0.5 G2: -2.4 ± 0.4 G3: -3.2 ± 0.5 G4: -1.7 ± 0.5 G1 v G4:p=NS G2 v G4:p=NS G3 v G4:p≤ 0.05 CGI-S G1: -0.9 ± 0.2 G2: -1 ± 0.1 G3: -1.1 ± 0.2 G4:-0.6 ± 0.2

[a]Publication in a larger RCT [1-3, 9-11, 13, 22-26]
[b]Publication in a larger RCT [2, 3, 7]
[c]Publication in a larger RCT [5, 6]
[d]Publication in a larger RCT [8, 12]
[e]Publication in a larger RCT [17-21, 27, 28]
ABC-Aberrant Behavior Checklist; CGI-Clinical Global Impression; VABS-Vineland Adaptive Behavior Scale; CYBOCS-Children's Yale-Brown Obsessive Compulsive Scale; M-RLRS-Modified Real Life Rating Scale; EOT-End of Treatment; OLE-Open-label Extension; VAS-Visual Analog Scale; CGAS-Children's Global Assessment Scale

Table F-2. Key Findings in Studies of Methylphenidate (MPH)

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
RUPP 2005[29_4421_4394_380] RCT G1: Methylphenidate - low dose (0.125 mg/kg), 66/45 G2: Methylphenidate - medium dose (0.250 mg/kg), 66/52 G3: Methylphenidate - high dose (0.500 mg/kg), 66/33 G4: Methylphenidate - optimal dose (NA), 66/58 G5: Placebo (NA), 66/46 13 weeks/EOT Low RoB	Age G1+G2+G3+G4+G5: 7.5 IQ NR	**Overall ratings:** CGI severity sub-scale rating, n (%): Moderately ill: 20 (30.3) Markedly ill: 35 (52.0) Severely ill: 11 (16.7) **Educational/cog-nitive/academic attainment:** Slosson IQ, mean ± SD (range): 62.6 ± 32.9 (16-135) **Social skills:** VABS score, mean ± SD (range):† Socialization: 61.7 ± 16.7 (20-109) **Communication/ language:** VABS Communication: 62.8 ± 21.8 (20-126) **Adaptive behavior:** VABS composite: 56.2 ± 21.0 (20-109) VABS Daily living skills: 54.4 ± 19.8 (20-110) **Problem behavior:** ABC score, parent-rated, mean ± SD (range):† Irritability: 16.9 ± 10.1 (0-41) Lethargy/social withdrawal: 12.1 ± 8.9 (0-33)	**Overall ratings:** Responded to treatment, sub-jects completing cross-over phase, n (%): Total: 44 (76) Optimal/best treatment:† Placebo: 9 (20) Low: 11 (25) Medium: 14 (32) High: 10 (23) Response rate, by dose, n (%):† **G1:** 20/61 (33) **G2:** 27/77 (35) **G3:** 18/47 (38) **G5:** 12/61 (20) **G1/G5:** *P* = 0.18 **G2/G5:** *P* = 0.05 (including first medium dose) **G2/G5:** *P* = 0.06 (including first and second medium dose when applicable) **G3/G5:** *P* = 0.07 **Social skills:^** Joint attention (n=33), mean ± SD Initiations: **G1:** 23.29 ± 16.62 **G2:** 20.85 ± 13.01 **G3:** 19.27 ± 14.23 **G4:** 25.09 ± 15.55 **G5:** 18.59 ± 12.03 **G1/G5:** *P* < 0.05 **G2/G5:** *P* = NS **G3/G5:** *P* = NS

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		Stereotypy: 7.6 ± 5.9 (0-21) Hyperactivity: 33.2 ± 8.7 (2-47) Inappropriate speech: 6.0 ± 4.1 (0-12) ABC score, teacher-rated, mean ± SD (range):† Irritability: 16.1 ± 9.4 (0-43) Lethargy/social withdrawal: 15.5 ± 10.9 (0-42) Stereotypy: 7.6 ± 5.1 (0-19) Hyperactivity: 30.9 ± 7.9 (16-45) Inappropriate speech: 5.8 ± 3.6 (0-12) SNAP-IV, parent-rated, mean ± SD:* ADHD: 39.82 ± 8.09 Inattention: 20.21 ± 5.17 Hyperactivity/ impulsivity: 19.61 ± 4.22 Oppositional defiant disorder: 9.61 ± 6.19 SNAP-IV, teacher-rated, mean ± SD:* ADHD: 37.23 ± 7.04 Inattention:	**G4/G5:** *P* < 0.05 Responses: **G1:** 2.48 ± 1.45 **G2:** 1.69 ± 1.42 **G3:** 1.93 ± 1.48 **G4:** 2.24 ± 1.69 **G5:** 1.90 ± 1.71 **G1/G5:** *P* < 0.01 **G2/G5:** *P* = NS **G3/G5:** *P* = NS **G4/G5:** *P* = NS Requesting: G1: 4.04 ± 2.25 G2: 3.81 ± 2.65 G3: 3.69 ± 3.27 G4: 4.13 ± 2.58 G5: 3.67 ± 2.40 G1/G5: P = NS G2/G5: P = NS G3/G5: P = NS G4/G5: P = NS Competing demands task (n=33), mean ± SD: Self-regulating behavior: G1: 19.77 ± 10.89 G2: 16.21 ± 9.03 G3: 15.80 ± 12.65 G4: 16.47 ± 13.91 G5: 12.47 ± 11.29 G1/G5: P = 0.09 G2/G5: P < 0.01 G3/G5: P = NS G4/G5: P = 0.09 Regulated affective state: G1: 12.91 ± 4.98 G2: 12.96 ± 3.85 G3: 11.67 ± 5.53 G4: 12.47 ± 4.99 G5: 9.57 ± 6.72 G1/G5: P = NS G2/G5: P < 0.05

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		19.30 ± 4.32 Hyperactivity/ impulsivity: 17.93 ± 4.81 Oppositional defiant disorder: 8.83 ± 5.19 CYBOCS-PDD, clinician-rated, mean ± SD:* 13.30 ± 3.74 VABS Maladaptive behaviors total: 29.2 ± 9.2 (13-51) Motor skills: 69.2 ± 17.8 (44-113)	G3/G5: P < 0.05 G4/G5: P = 0.09 Clean-up task (n=33), mean ± SD: Compliance behaviors: G1: 3.67 ± 4.87 G2: 3.67 ± 5.64 G3: 4.06 ± 4.55 G4: 3.94 ± 4.88 G5: 3.47 ± 5.41 G1/G5: P = NS G2/G5: P = NS G3/G5: P = NS G4/G5: P = NS Regulated affective state: G1: 8.10 ± 5.18 G2: 6.88 ± 4.86 G3: 6.65 ± 6.03 G4: 7.42 ± 5.05 G5: 7.33 ± 4.86 G1/G5: P = NS G2/G5: P = NS G3/G5: P = NS G4/G5: P = NS Repetitive behavior:† See notes Problem behavior: ABC-hyperactivity subscale score, mean ± SD:† Parent-rated: G1: 23.0 ± 11.29 G2: 20.6 ± 10.27 G3: 22.1 ± 9.67 G4: 17.2 ± 9.87 G5: 26.0 ± 9.90 G1/G5: P = 0.03 (es = 0.29) G2/G5: P < 0.001 (es = 0.54) G3/G5: P = 0.003 (es = 0.40) G4/G5: P <

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			0.001 (es = 0.89) Teacher-rated: G1: 22.9 ± 12.84 G2: 23.6 ± 12.53 G3: 20.3 ± 11.94 G4: 20.1 ± 12.40 G5: 26.0 ± 11.66 G1/G5: P = 0.03 (es = 0.25) G2/G5: P = 0.008 (es = 0.20) G3/G5: P = 0.002 (es = 0.48) G4/G5: P < 0.001 (es = 0.48) SNAP-IV inatten-tion, mean ± SD:* Parent-rated: G1: 14.58 ± 6.56 G2: 13.38 ± 6.48 G3: 14.30 ± 6.35 G4: 11.83 ± 6.02 G5: 15.59 ± 6.51 G1/G5: P = 0.15 (es = 0.15) G2/G5: P < 0.001 (es = 0.34) G3/G5: P = 0.06 (es = 0.20) G4/G5: P < 0.001 (es = 0.60) Teacher-rated: G1: 15.24 ± 6.34 G2: 14.27 ± 6.93 G3: 14.67 ± 6.88 G4: 13.98 ± 6.46 G5: 16.15 ± 6.10 G1/G5: P = 0.21 (es = 0.15) G2/G5: P < 0.001 (es = 0.29) G3/G5: P = 0.02 (es = 0.23) G4/G5: P = 0.003 (es = 0.35) SNAP-IV

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			hyperactivity/ impulsivity, mean ± SD:* Parent-rated: G1: 13.39 ± 5.87 G2: 12.19 ± 6.06 G3: 13.49 ± 6.41 G4: 10.80 ± 5.99 G5: 15.33 ± 5.81 G1/G5: P = 0.02 (es = 0.33) G2/G5: P < 0.001 (es = 0.53) G3/G5: P = 0.01 (es = 0.30) G4/G5: P < 0.001 (es = 0.77) Teacher-rated: G1: 12.76 ± 6.84 G2: 13.00 ± 6.71 G3: 11.45 ± 7.01 G4: 11.26 ± 6.26 G5: 14.41 ± 6.095 G1/G5: P = 0.08 (es = 0.24) G2/G5: P = 0.01 (es = 0.21) G3/G5: P = 0.005 (es = 0.42) G4/G5: P = 0.005 (es = 0.48) SNAP-IV oppositional defiant disorder, mean ± SD:* Parent-rated: G1: 6.77 ± 5.62 G2: 7.02 ± 5.90 G3: 7.53 ± 5.90 G4: 5.86 ± 4.70 G5: 7.69 ± 5.80 G1/G5: P = 0.14 (es = 0.16) G2/G5: P = 0.25 (es = 0.12) G3/G5: P = 0.66 (es = 0.03) G4/G5: P < 0.001 (es = 0.35)

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			Teacher-rated: G1: 5.89 ± 5.43 G2: 6.65 ± 5.10 G3: 6.75 ± 5.63 G4: 5.61 ± 4.85 G5: 7.02 ± 5.80 G1/G5: P = 0.11 (es = 0.20) G2/G5: P = 0.17 (es = 0.07) G3/G5: P = 0.35 (es = 0.05) G4/G5: P = 0.04 (es = 0.26) CYBOCS-PDD, clinician-rated, mean ± SD:* G1: 12.82 ± 4.15 G2: 12.31 ± 4.27 G3: 13.02 ± 4.11 G4: 12.13 ± 4.22 G5: 13.05 ± 3.46 G1/G5: P = 0.90 (es = 0.06) G2/G5: P = 0.21 (es = 0.19) G3/G5: P = 0.80 (es = 0.01) G4/G5: P = 0.08 (es = 0.24) Commonly occurring co-morbidities: SNAP-IV ADHD, mean ± SD:* Parent-rated: G1: 27.97 ± 11.62 G2: 25.57 ± 11.66 G3: 27.79 ± 11.63 G4: 22.63 ± 11.19 G5: 30.92 ± 11.55 G1/G5: P = 0.04 (es = 0.25) G2/G5: P <

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			0.001 (es = 0.46) G3/G5: P = 0.02 (es = 0.27) G4/G5: P < 0.001 (es = 0.73) Teacher-rated: G1: 28.00 ± 12.12 G2: 27.27 ± 12.21 G3: 26.12 ± 12.64 G4: 25.24 ± 11.53 G5: 30.57 ± 11.84 G1/G5: P = 0.10 (es = 0.21) G2/G5: P = 0.001 (es = 0.27) G3/G5: P = 0.005 (es = 0.36) G4/G5: P = 0.003 (es = 0.46)
Pearson et al., 2013[30] RCT G1: Methylphenidate - low dose (0.14-0.21 mg/kg), 24/24 G2: Methylphenidate - medium dose (0.24-0.35 mg/kg), 24/24 G3: Methylphenidate - high dose (0.27-0.48 mg/kg), 24/24 G4: Placebo (NA), 24/24 4 weeks/EOT Low RoB	Age G1+G2+G3+G4: 8.8 ± 1.6 IQ NR	**Parent Ratings** CPRS NR CPRS-ADHD scale G1+G2+G3+G4: 76.4 ± 6.7 SNAP-IV NR ACTeRS NR ABC NR SCQ NR **Teacher Ratings** CTRS NR CTRS-ADHD scale G1+G2+G3+G4: 67.2 ± 8.7 SNAP-IV NR	**EOT** **Parent Ratings** CPRS – CGI Total G1: 61.9 ± 11.7 G2: 59.9 ± 9.8 G3: 55.8 ± 9.3 G4: 66.8 ± 12.7 G4 vs G2, p<0.05 G4 vs G3, p<0.05 G1 vs G3, p<0.05 CPRS – Oppositional G1: 53.1 ± 15.3 G2: 53.8 ± 12.4 G3: 49.8 ± 11.4 G4: 59.2 ± 16 ANOVA p-value for all groups, p<0.05 CPRS – Cognitive

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		ACTeRS NR	Problems/Inattention G1: 67.7 ± 11.6 G2: 63.9 ± 12.5 G3: 60 ± 11.7 G4: 70.3 ± 12.8 G4 vs G2, p<0.05 G4 vs G3, p<0.05 G1 vs G3, p<0.05 CPRS – Hyperactivity G1: 62.6 ± 12.2 G2: 62.1 ± 12 G3: 58.3 ± 10.2 G4: 70.8 ± 15.2 G4 vs G2, p<0.05 G4 vs G3, p<0.05 CPRS – ADHD Index G1: 64.9 ± 9.3 G2: 62.3 ± 10 G3: 59.9 ± 10.5 G4: 70.1 ± 11.9 G4 vs G2, p<0.05 G4 vs G3, p<0.05 SNAP-IV – Inattentive/Hyperactive G1: 26 ± 11.1 G2: 22.8 ± 9.6 G3: 21.6 ± 9.6 G4: 31.6 ± 11 G4 vs G2, p<0.05 G4 vs G3, p<0.05 ACTeRS – Attention G1: 12.4 ± 5.3 G2: 13.4 ± 5

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			G3: 14 ± 4.2 G4:10.9 ± 4.7 G4 vs G3, p=ns ACTeRS – Hyperactivity G1: 13.3 ± 4.5 G2: 12 ± 4 G3: 12 ± 4.3 G4: 15.7 ± 4.5 G4 vs G2, p<0.05 G4 vs G3, p<0.05 ACTeRS – Social Skills G1: 13.3 ± 4.4 G2: 12 ± 3.7 G3: 14 ± 4.3 G4: 12.8 ± 4.5 G2 vs G3, p<0.05 ACTeRS – Oppositional G1: 7.8 ± 5.6 G2: 6.8 ± 4 G3: 6.6 ± 2.6 G4: 8.4± 5.3 G4 vs G2, p<0.05 ABC-Irritability G1: 10 ± 9.2 G2: 8.2 ± 8.1 G3: 7.2 ± 6.9 G4: 12.6 ± 10.4 G4 vs G3, p<0.05 ABC-Social Withdrawal/Lethargy G1: 7.3 ± 5.6 G2: 8.1 ± 5.9 G3: 8.5 ± 6.6 G4: 9.3 ± 8.1 p=ns ABC-Stereotypy G1: 4.3 ± 4.5 G2: 4 ± 3.8 G3: 3.5 ± 3.8

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			G4: 4.9 ± 5.4 p=ns ABC-Hyperactivity G1: 18.1 ± 10.5 G2: 14.5 ± 7.7 G3: 14.5 ± 9.2 G4: 24.1 ± 13 G4 vs G2, p<0.05 G4 vs G3, p<0.05 ABC-Inappropriate Speech G1: 4.3 ± 3.2 G2: 4 ± 3.1 G3: 3.9 ± 3.1 G4: 5.2 ± 3.1 G4 vs G2, p<0.05 G4 vs G3, p<0.05 SCQ – Total G1: 14.2 ± 6.6 G2: 15.2 ± 6.2 G3: 13.4 ± 6.2 G4: 15.5 ± 6.1 ANOVA p-value for all groups, p<0.05 **Teacher Ratings** CTRS – CGI-Total G1: 63.4 ± 12.8 G2: 62.4 ± 12.5 G3: 59.3 ± 12.7 G4: 75.6 ± 11.5 G4 vs G2, p<0.05 G4 vs G3, p<0.05 G1 vs G3, p<0.05 CTRS-Oppositional

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			G1: 56.6 ± 13.2 G2: 58.1 ± 15.4 G3: 55.1 ± 13.5 G4: 65.1 ± 19.5 p=ns CTRS-Cognitive Problems/Inattention G1: 58.3 ± 10.7 G2: 57.8 ± 9.5 G3: 59.3 ± 11.1 G4: 63 ± 11.2 G4 vs G2, p<0.05 G4 vs G3, p<0.05 G1 vs G3, p<0.05 CTRS-Hyperactivity G1: 59.9 ± 13.6 G2: 59.9 ± 11.4 G3: 57.7 ± 11.3 G4: 70.3 ± 13.5 G4 vs G2, p<0.05 G4 vs G3, p<0.05 G1 vs G3, p<0.05 CTRS-ADHD Index G1: 63.1 ± 11.2 G2: 63.6 ± 10.4 G3: 61.5 ± 13 G4: 72.8 ± 12 G4 vs G2, p<0.05 G4 vs G3, p<0.05 G1 vs G3, p<0.05 SNAP-IV – Inattentive/Hyperactive G1: 24.7 ± 10.9

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			G2: 23.7 ± 11.1 G3: 21.8 ± 11.6 G4: 32.7 ± 12.4 G4 vs G2, p<0.05 G4 vs G3, p<0.05 G1 vs G3, p<0.05 ACTeRS – Attention G1: 14.3 ± 6.2 G2: 13.7 ± 5.5 G3: 15.9 ± 8.5 G4: 11.3 ± 4 G4 vs G3, p<0.05 ACTeRS – Hyperactivity G1: 11.8 ± 5.6 G2: 12.8 ± 5.5 G3: 11.2 ± 5 G4: 18.7 ± 5.2 G4 vs G2, p<0.05 G4 vs G3, p<0.05 G1 vs G3, p<0.05 ACTeRS – Social Skills G1: 19.2 ± 4.2 G2: 16.7 ± 4 G3: 18.5 ± 5.8 G4: 15.8 ± 3.6 p=ns ACTeRS – Oppositional G1: 7.6 ± 3.5 G2: 9.2 ± 5.5 G3: 7.1 ± 2.1 G4: 10.6 ± 5.8 G4 vs G3, p<0.05 CGI-Severity (clinician 1) G1: 4 ± 0.81

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			G2: 3.8 ± 0.82 G3: 3.8 ± 0.74 G4: 4.8 ± 0.61 G4 vs G2, p<0.05 G4 vs G3, p<0.05 G1 vs G3, p<0.05 CGI-Improvement (clinician 1) G1: 2.8 ± 1.3 G2: 2.4 ± 1.3 G3: 2.1 ± 1.2 G4: 4 ± 0.81 G4 vs G2, p<0.05 G4 vs G3, p<0.05 G1 vs G3, p<0.05 CGI-Severity (clinician 2) G1: 4 ± 0.72 G2: 4 ± 0.62 G3: 3.9 ± 0.74 G4: 4.7 ± 0.76 G4 vs G2, p<0.05 G4 vs G3, p<0.05 G1 vs G3, p<0.05 CGI-Improvement (clinician 2) G1: 2.8 ± 1.4 G2: 2.6 ± 1.3 G3: 2 ± 1 G4: 4.1 ± 0.95 G4 vs G2, p<0.05 G4 vs G3, p<0.05 G1 vs G3,

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			p<0.05

ABC-Aberrant Behavior Checklist; CGI-Clinical Global Impression; VABS-Vineland Adaptive Behavior Scale; CYBOCS-PDD-Children's Yale-Brown Obsessive Compulsive Scale Modified for Pervasive Developmental Disorder; EOT-End of Treatment; VBS-Visual Analog Scale; CGAS-Children's Global Assessment Scale; SNAP-IV- ; ADHD-Attention Deficit/Hyperactivity Disorder; CPRS-Conners Parent Rating Scale; ACTeRS-ADD-H Comprehensive Teacher Rating Scale; CTRS-Conners Teacher Rating Scale; SCQ-Social Communication Questionnaire

Table F-3. Key Findings in Studies of Nutrition

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
Mankad et al., 2015[31] RCT G1: Omega-3 fatty acid (3.5 mL/day), 19/18 G2: Placebo, 19/19 6 months/EOT Moderate RoB	Age G1: 3.5 ± 1.1 G2: 3.8 ± 1.0 IQ NR	Baseline scores NR	**Change from Baseline** PDDBI – Autism Composite G1: -4.5 G2: -6.4 G1 vs G2: p=ns BASC – Externalizing G1: 3.2 G2: -3.0 G1 vs G2: p=0.02 CGI G1: NR G2: NR G1 vs G2:p=ns VABS G1: 2.8 G2: -0.2 G1 vs G2: p=ns Preschool Language Scale (PLS4) G1: 0.7 G2: -0.6 G1 vs G2: p=ns
Saad et al., 2015[32] RCT G1: Digestive enzymes (15 mL/day), 51/47 G2: Placebo (NA), 50/45 3 months/EOT Moderate RoB	Age G1: 5.94 ± 2.01 G2: 5.87 ± 2.12 IQ NR	CARS G1: 36.1 ± 3.7 G2: 35.3 ± 4.0 GBRS Child's General Behavior G1: 3.01 ± 1.3 G2: 3.50 ± 0.7 Nighttime sleeping G1: 3.89 ± 1.3 G2: 3.84 ± 1.0 Gastrointestinal symptoms G1: 3.79 ± 0.61 G2: 4.02 ± 0.28 Daytime wetting G1: 3.86 ± 0.67 G2: 3.92 ± 0.83	**EOT** CARS G1: 31.2 ± 1.2 G2: 35.5 ± 2.8 G1 vs G2: p=0.034 GBRS Child's General Behavior G1: 5.5 ± 0.75 G2: 3.39 ± 1.01 G1 vs G2:, p<0.001 Nighttime sleeping G1: 4.02 ± 1.20 G2: 3.98 ± 0.89 G1 vs G2: p=ns Gastrointestinal symptoms G1: 6.03 ± 0.56 G2: 4.02 ± 0.23

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		Nighttime wetting G1: 4.60 ± 0.97 G2: 3.92 ± 0.6	G1 vs G2: p<0.001 Daytime wetting G1: 3.97 ± 0.88 G2: 4.03 ± 1.04 G1 vs G2: p=ns Nighttime wetting G1: 4.23 ± 1.25 G2: 4.09 ± 0.64 G1 vs G2: p=ns
Bent et al., 2014[33] RCT G1: Omega-3 fatty acid (1.3g/day), 29/29 G2: Placebo, 28/28 6 weeks/EOT Moderate RoB	Age, months G1: 88.2 ± 12.3 G2: 85 ± 13.2 mos IQ NR	ABC- Hyperactivity Parent Ratings G1: 28.4 ± 8.4 G2: 28.1 ± 7.6 ABC-Hyperactivity Teacher Ratings G1: 18.1 ± 12.0 G2: 14.6 ± .4 ABC-Irritability Parent G1: 20.0 ± 8.9 G2: 16.8 ± 8.3 ABC-Irritability Teacher G1: 14.3 ± 9.8 G2: 9.4 ± 9.3 ABC-Stereotypy Parent G1: 8.0 ± 6.0 G2: 5.4 ± 4.7 ABC-Stereotypy Teacher G1: 5.1 ± 4.8 G2: 3.7 ± 4.1 ABC-Lethargy Parent G1: 12.2 ± 8.8 G2: 8.8 ± 4.2 ABC-Lethargy Teacher G1: 9.9 ± 8.9 G2: 8.3 ± 7.1 ABC-Inappropriate speech Parent G1: 7.0 ± 3.4	**Mean change score** ABC – Hyperactivity Parent G1: -5.3 ± 7.2 G2: -3.4 ± 7.5 G1 vs G2: p=ns ABC- Hyperactivity Teacher G1: -2.6 ± 8.0 G2: -1.0 ± 10.0 G1 vs G2: p=ns ABC-Irritability Parent G1: -2.0 ± 6.9 G2: -2.1 ± 4.4 G1 vs G2: p=ns ABC-Irritability Teacher G1: -1.3 ± 8.6 G2: -0.2 ± 6.8 G1 vs G2: p=ns ABC-Stereotypy Parent G1: -2.0 ± 3.7 G2: -0.5 ± 2.6 G1 vs G2: p=0.05 ABC-Stereotypy Teacher G1: -1.0 ± 4.2 G2: -0.7 ± 3.2 G1 vs G2: p=ns ABC-Lethargy Parent G1: -2.1 ± 4.2 G2: 0.1 ± 2.6 G1 vs G2: p=0.01

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		G2: 5.8 ± 2.8 ABC-Inappropriate speech Teacher G1: 4.2 ± 3.9 G2: 3.1 ± 3.3 SRS-total G1: 89.7 ± 12.7 G2: 88.3 ± .7 CGI-S G1: 3.8 ± 1.0 G2: 4.0 ± 0.79	ABC-Lethargy Teacher G1: -2.5 ± 7.9 G2: -1.6 ± 5.5 G1 vs G2: p=ns ABC-Inappropriate speech Parent G1: -0.6 ± 2.7 G2: -0.9 ± 2.2 G1 vs G2: p=ns ABC-Inappropriate speech Teacher G1: -1.0 ± 2.6 G2: -0.1 ± 5.5 G1 vs G2: p=ns SRS-total G1: -2.6 ± 8.3 G2: -6.1 ± 7.8 G1 vs G2:p=ns CGI-S G1: NR G2: NR
Voigt et al., 2014[34] RCT G1: Docosahex-aenoic acid (DHA) (500 mg/day), 24/19 G2: Placebo, 24/15 6 months/EOT Moderate RoB	Age G1: 5.8 ± 1.8 G2: 6.5 ± 2.2 IQ NR	CGI-I Parent NR BASC – Parent G1: 26.5 ± 7.1 G2: 30.3 ± 9.1 BASC – Teacher G1: 32.2 ± 7.6 G2: 38.5 ± 4.3	CGI-I Parent **3 months** G1: 4/21 (19) G2: 5/16 (31) G1 vs G2: p=ns **6 months** G1: 5/18 (28) G2: 2/13 (15) G1 vs G2: p=ns CGI-I Investigator **3 months** G1: 1/17 (6)) G2: 0/13 (0) G1 vs G2: p=ns **6 months** G1: 0/18 (0) G2: 1/14 (7) G1 vs G2: p=ns **EOT** BASC – Parent G1: 26.3 ± 6.8

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			G2: 33.3 ± 9.7 G1 vs G2: p=0.04 BASC – Teacher G1: 33.6 ± 9.3 G2: 34.0 ± 5.6 G1 vs G2: p=0.02
Fahmy et al. 2013[35] RCT G1: L-carnitine, 16/16 G2: Placebo,14/14 6 months/EOT Moderate RoB	Age (months) G1: 69 (29-103) G2: 68.5 (32-98) IQ NR	CARS – Mild/Moderate Severity G1: 1 (6.3) G2: 9 (64.3) CARS – Severe G1: 15 (93.80) G2: 5 (35.7)	**EOT** Mild/Moderate Severity G1: 9 (56.3) G2: 9 (64.3) G1 vs G2, p=ns CARS – Severe G1: 7 (43.8) G2: 5 (35.7) G1 vs G2, p=ns
Bent et al., 2011[36] RCT G1: Omega-3 fatty acid (1.3 g/day), 14/13 G2: Placebo, 13/12 12 weeks/EOT Low RoB	Age, months G1: 70.2 ± 22 G2: 69.8 ± 17 IQ G1: 77.5 ± 27 G2: 77.5 ± 17	ABC –Hyperactivity G1: 16.8 ± 13 G2: 20.3 ± 8 PPVT G1: 72.2 ± 28 G2: 85.8 ± 12 EVT G1: 70.8 ± 33 G2: 86.4 ± 14 SRS G1: 76.9 ± 11 G2: 79.0 ± BASC-Externalizing G1: 53.8 ± 13 G2: 66.3 ± 25 BASC- Internalizing G1: 43.3 ± 10 G2: 50.1 ± 9 BASC-Behavioral G1: 60.9 ± 14 G2: 65.4 ± 3 BASC- Adaptive skill G1: 29.8 ± 9 G2: 31.9 ± 9	**Mean change score** ABC – Hyperactivity G1: 2.7 ± 4.8 G2: 0.3 ± 7.2 G1 vs G2: p=ns PPVT G1: 2.7 ± 11.6 G2: 1.9 ± 12.4 G1 vs G2: p=ns EVT G1: 2.2 ± 7.6 G2: 5.8 ± 5.7 G1 vs G2: p=ns SRS G1: -0.9 ± .5 G2: 1.7 ± 7.2 G1 vs G2: p=ns BASC-Externalizing G1: 0.1 ± 6.7 G2: 6.6 ± 30.4 G1 vs G2: p=ns BASC-Internalizing G1: 0.3 ± 6.6 G2: -2.9 ± 7.6 G1 vs G2: p=ns

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		BASC-Hyperactivity G1: 61.8 ± 17 G2: 64.6 ± 7	BASC-Behavioral G1: -1.1 ± 6.1 G2: -2.0 ± 4.9 G1 vs G2: p=ns BASC-Adaptive skill G1: 1.8 ± 6.8 G2: 0.8 ± 7.1 G1 vs G2: p=ns BASC-Hyperactivity G1: 2.1 ± 6.3 G2: 1.2 ± 5.8 G1 vs G2: p=ns
Geier, et al., 2011[37] RCT G1: Levocarnitine (50 mg/kg/day), 19/16 G2: Placebo, 11/11 3 months/EOT High RoB	Age: G1: 6.3 ± 2.4 G2: 6.7 ± 1.6 IQ NR	CARS G1: 35.7±5.3 G2: 38.2±6.0 CGI G1: 2.0 G2: 2.0 Hand Muscle Testing G1: 32.7±13.9 G2: 35.3±13.2 ATEC Total G1: 55.1±23.3 G2: 62.8±31.7 ATEC Speech G1: 9.9±6.3 G2: 10.5±6.4 ATEC Sociability G1: 12±7.1 G2: 11.9±7.7 ATEC Cognitive G1: 12.7±6.1 G2: 14.4±7.6 ATEC Health/Behavior G1: 20.5±8.1 G2: 26±14.8	**EOT** CARS G1: 33.8±5.8 G2: 38.4±6.3 p=.02 CGI G1: 1.5±0.63 G2: 2.09±0.7 p= .03 Hand Muscle Testing G1: 34.3±16.7 G2: 35.1±7.5 p= ns ATEC Total G1: 40.1±22.8 G2: 56±27.6 p= ns ATEC Speech G1: 7.8±5.9 G2: 10.9±7.2 p= ns ATEC Sociability G1: 8.3±5.9 G2: 10.8±8.4 p=ns ATEC Cognitive G1: 9.2±5.5 G2: 14.9±7.3 p=.009 ATEC Health/Behavior

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			G1: 14.8±7.9 G2: 19.5±10.9 p=ns
Bertoglio et al., 2010[38] RCT G1: Methyl B12 (64.5 µg/kg) G2: Placebo Crossover design N=30 total 12 weeks/EOT Low RoB	Age G1 + G2: 3-8 IQ NR	CGIS NR	No significant group difference in behavior measures **EOT** CGIS Improvement (≥1 point) n (%) G1+G2: 9 (30) 3 received placebo first and 6 received active treatment CBCL improvement (≥5 points): G1+G2: 3 (10) ABC improvement (≥5 points): G1+G2: 5 (16.7)
Munasinghe et al., 2010[39] RCT G1: Digestive enzyme supplement-Peptizyde (up to 2 capsules/day) G2: Placebo (360 mg/day) Crossover design N=43 total 3 months/EOT Moderate RoB	Age, months G1 + G2: 5.78 ± 1.77 IQ NR	GBRS G1+G2: 4 ARS G1+G2: 4 LDS NR	**EOT** Food variety score G1: 4.42 ± 0.62 G2: 4.06 ± 0.45 p= 0.02 Parent Behavior score G1: 4.29 ± 0.79 G2: 4.11 ± 0.73 p = ns GI symptoms score G1: 4.01 ± 0.68 G2: 3.87 ± 0.36 p = ns Sleep Quality score G1: 3.95 ± 0.75 G2: 3.87 ± 0.56 p = ns Therapist engagement score G1: 4.59 ± 0.96 G2: 4.43 ± 0.55 p = ns LDS Vocabulary

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			percentile score G1: 56.95 ± 28.6 G2: 55.59 ± 28.6 p = ns LDS Sentence length percentile score G1: 62.38 ± 26.2 G2: 63.91 ± 24.9 p = ns

ABC-Aberrant Behavior Checklist; CGI-Clinical Global Impression; VABS-Vineland Adaptive Behavior Scale; EOT-End of Treatment; PDDBI-Pervasive Developmental Disorders Behavior Inventory; BASC-Behavior Assessment System for Children; CARS-Childhood Autism Rating Scale; GBRS-Global Rating Scale; SRS-Social Responsiveness Scale; PPVT-Peabody Picture Vocabulary Test; EVT-Expressive Vocabulary Test; ATEC-Autism Treatment Evaluation Checklist; CGIS-Clinical Global Impressions Scale; CBCL-Child Behavior Checklist; GBRS-Global Rating Scale; ARS-Additional Rating Scale; LDS-Language Development Survey

Table F-4. Key Findings in Studies of Diet

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
Hyman et al., 2016[40] RCT Gluten-free/casein-free diet followed by weekly challenges of gluten, casein, gluten and casein and placebo G1: gluten G2: casein G3: gluten and casein G4: placebo Crossover study n=14 12 weeks/EOT Low RoB	Age 3.78 ± 0.60 IQ NR	LS means **Day before challenge** Conners- research asst rater G1: 6,65 ± 2.38 G2: 5.71 ± 2.18 G3: 5.32 ± 2.13 G4: 6.17 ± 3.01 Conners- teacher G1: 8.50 ± 3.72 G2: 8.29 ± 3.73 G3: 6.89 ± 2.40 G4: 8.84 ± 5.92 Conners- parent G1: 6.10 ± 3.53 G2: 6.48 ± 3.99 G3: 5.79 ± 4.17 G4: 5.71 ± 3.50 Day before challenge:	**EOT** LS means **Day after challenge** Conners- research asst rater G1: 5.57 ± 1.61 G2: 6.19 ± 2.47 G3: 6.73 ± 3.24 G4: 6.55 ± 2.83 p=ns Conners- teacher G1: 7.76 ± 3.08 G2: 7.42 ± 2.79 G3: 7.19 ± 2.81 G4: 7.43 ± 3.88 p=ns Conners- parent G1: 6.75 ± 3.69 G2: 6.31 ± 3.75 G3: 7.15 ± 4.42

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		NR **Day of challenge** Sensory motor G1: 0.34 ± 0.27 G2: 0.32 ± 0.28 G3: 0.31 ± 0.37 G4: 0.33 ± 0.30 Social relationships G1: -0.30 ± 0.24 G2: -0.30 ± 0.21 G3: -0.27 ± 0.17 G4: -0.20 ± 0.16 Affectual relationships G1: 0.08 ± 0.12 G2: 0.09 ± 0.13 G3: 0.05 ± 0.11 G4: 0.09 ± 0.11 Sensory responses G1: 0.25 ± 0.14 G2: 0.26 ± 0.19 G3: 0.21 ± 0.14 G4: 0.30 ± 0.19 Language G1: -0.07 ± 0.31 G2: -0.04 ± 0.27 G3: -0.03 ± 0.30 G4: 0.00 ± 0.24 **Day before challenge** Minutes of sleep G1: 631 ± 67.3 G2: 627 ± 76.6 G3: 616.7 ± 48.3 G4: 693 ± 56.4 Number of wakings G1: 0.34 ± 1.53 G2: 0.10 ± 0.30 G3: 0.11 ± 0.40 G4: 0.08 ± 0.27	G4: 7.15 ± 4.25 p=ns **Day after challenge** Sensory motor G1: 0.28 ± 0.29 G2: 0.29 ± 0.22 G3: 0.43 ± 0.42 G4: 0.32 ± 0.21 p=ns Social relationships G1: -0.27 ± 0.21 G2: -0.28 ± 0.18 G3: -0.30 ± 0.19 G4: -0.26 ± 0.16 p=ns Affectual relationships G1: 0.04 ± 0.06 G2: 0.11 ± 0.13 G3: 0.09 ± 0.15 G4: 0.07 ± 0.09 p=ns Sensory responses G1: 0.29 ± 0.17 G2: 0.27 ± 0.16 G3: 0.26 ± 0.17 G4: 0.32 ± 0.18 p=ns Language G1: -0.03 ± 0.25 G2: -0.03 ± 0.25 G3: -0.07 ± 0.32 G4: 0.00 ± 0.25 p=ns **Day after challenge** Minutes of sleep G1: 646 ± 69.1 G2: 641 ± 68.2 G3: 633 ± 70.7 G4: 641 ± 61.3 p=ns Number of wakings G1: 0.20 ± 0.58 G2: 0.03 ± 0.16 G3: 0.17 ± 0.45

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			G4: 0.05 ± 0.22 p=ns
Navarro et al., 2015[41] RCT G1: "gluten-dairy containing (GD(+)) diet", 6/6 G2: gluten-dairy free (GD(−)) diet, 6/6 4 weeks/EOT Low RoB	Age G1: 6 (6-7) G2: 5.5 (4-7) IQ G1: 55 (52-88) G2: 79 (76-97)	ABC-Irritability G1: 19.77 ± 15.15 G2: 10.50 ± 8.55 ABC-Hyperactivity G1: 23.20 ± 11.28 G2: 22.17 ± 7.31 Connors Parent Rating Scale-Revised-Cognitive Problems/Inattention G1: 12.17 ± 7.11 G2: 15.83 ± 3.82	**EOT** ABC-Irritability G1: 16.0 G2: 14.50 G1 vs G2, p= NR ABC-Hyperactivity G1: 26.5 G2: NR Connors Parent Rating Scale-Revised G1: 21 G2: NR
Pusponegoro et al., 2015[42] RCT G1: Gluten-casein, 38/24 G2: Placebo, 36/26 7 days/EOT Moderate RoB	Age, median (range) G1: 5.4 (4.8-6.7) G2: 5.1 (4.3-6.1) IQ NR	Pervasive Developmental Disorder Behavior Inventory – Approach Withdrawal problems composite AWPC G1: 56.96 ± 11.72 G2: 57.08 ± 11.46 Gastrointestinal Symptom Severity Index, median G1: 0 G2: 0	**EOT** Pervasive Developmental Disorder Behavior Inventory - Approach Withdrawal problems composite AWPC G1: 39.38 ± 2.89 G2: 39.63 ± 3.05 G1 vs G2: p=ns Gastrointestinal Symptom Severity Index, median (range) G1: 3 (0-9) G2: 0 (0-7) G1 vs G2: p=ns

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
Whiteley et al., 2010[43_746] RCT G1: Gluten and casein-free diet, 38/26 G2: No diet, 34/29 24 months/EOT Moderate RoB	Age, months G1: 94.2 [IQR 76.6-118.0] G2: 96.4 [IQR 76.3-120.3] IQ NR	ADOS-Communication G1: 1.13 G2: 1.00 ADOS-Social G1: 1.18 G2: 1.22 ADOS-Repetitive G1: 0.46 G2: 0.36 GARS-Social G1: 6.96 G2: 6.41 GARS-Communication G1: 7.23 G2: 7.28 GARS-Stereotyped G1: 6.81 G2: 6.76 VABS-Communication G1: 66.46 G2: 62.45 VABS-Social G1: 64.58 G2: 64.03 VABS-Daily Living G1: 59.88 G2: 55.55 ADHD-IV scale-Inattention G1: 11.96 G2: 11.21 ADHD-IV scale-Hyperactivity G1: 10.31 G2: 10.79	**8 months** ADOS-Communication G1: 0.87 G2: 1.07 G1 vs G2: p=ns ADOS-Social G1: 1.09 G2: 1.30 G1 vs G2: p=ns ADOS-Repetitive G1: 0.35 G2: 0.34 G1 vs G2: p=ns GARS-Social **(8 mos)** G1: 5.88 G2: 6.34 GARS- Social **(12 mos)** G1: 5.38 G2: 6.00 G1 vs G2: p=ns GARS-Communication **(8 mos)** G1: 6.00 G2: 6.76 GARS-Communication **(12 mos)** G1: 5.74 G2: 5.81 G1 vs G2: p=ns GARS-Stereotyped **(8 mos)** G1: 5.85 G2: 5.97 GARS-Stereotyped **(12 mos)** G1: 5.35 G2: 5.37 G1 vs G2: p=ns VABS-Communication **(8 mos)** G1: 66.69 G2: 63.46

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			VABS-Communication **(12 mos)** G1: 67.38 G2: 64.07 G1 vs G2: p=ns VABS-Social **(8 mos)** G1: 66.12 G2: 65.39 VABS-Social (**12 mos)** G1: 60.42 G2: 61.21 G1 vs G2: p=ns VABS-Daily Living **(8 mos)** G1: 62.92 G2: 55.18 VABS-Daily Living **(12 mos)** G1: 63.35 G2: 53.96 G1 vs G2: p=ns ADHD-IV scale-Inattention **(8 mos)** G1: 9.81 G2: 11.52 ADHD-IV scale-Inattention **(12 mos)** G1: 9.77 G2: 11.11 G1 vs G2: p=ns ADHD-IV scale-Hyperactivity **(8 mos)** G1: 8.27 G2:10.62 ADHD-IV scale-Hyperactivity**(12 mos)** G1: 8.62 G2:10.00 G1 vs G2: p=ns

ABC-Aberrant Behavior Checklist; VABS-Vineland Adaptive Behavior Scale; EOT-End of Treatment; AWPC-Approach Withdrawal Problems Composite; ADOS-Autism Diagnostic Observation Schedule; GARS-Gilliam Autism Rating Scale

Table F-5. Key Findings in Studies of Risperidone Adjuncts

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
Ghaleiha et al., 2015[44] RCT G1: Risperidone + pioglitazone (up to 2 mg/day + 30 mg/day), 22/20 G2: Risperidone + placebo (NA), 22/20 10 weeks/EOT Low RoB	Age G1: 6.95 ± 2.40 G2: 6.20 ± 1.32 IQ NR	ABC-Irritability G1: 18.25 ± 4.38 G2: 19.00 ± 5.70 ABC-Lethargy G1: 15.05 ± 7.56 G2: 13.66 ± 7.26 ABC-Stereotypic behavior G1: 7.70 ± 4.61 G2: 9.40 ± 5.28 ABC-Hyperactivity G1: 25.00 ± 10.05 G2: 27.86 ± 9.85 ABC-Inappropriate speech G1: 5.70 ± 3.60 G2: 4.70 ± 3.78	**Change scores from baseline** ABC-Irritability G1: 10.20 ± 5.87 G2: 5.90 ± 5.04 G1 vs G2: p=0.03 ABC-Lethargy G1: 3.75 ± 4.69 G2: 1.05 ± 2.96 G1 vs G2: p=0.04 ABC-Stereotypic behavior G1: 2.10 ± 2.90 G2: 1.40 ± 1.98 G1 vs G2: p=ns ABC-Hyperactivity G1: 10.15 ± 6.42 G2: 5.30 ± 7.76 G1 vs G2: p=0.04 ABC-Inappropriate speech G1: 1.40 ± 3.20 G2: 0.70 ± 1.45 G1 vs G2: p=ns Treatment responses: n (%) Partial response (≥ 25% reduction in irritability score): G1: 9 (45) G2: 3 (15) G1 vs. G2: p=0.04 Complete response (≥ 50% reduction in irritability score): G1: 9 (45) G2: 7 (35) G1 vs. G2: p=ns

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
Ghanizadeh et al., 2015[45] RCT G1: Risperidone + buspirone (up to 3 mg/day + up to 20 mg/kg), 20/16 G2: Risperidone + placebo (NA), 20/18 8 weeks/EOT Low RoB	Age G1: 7.05 ± 2.3 G2: 7.5 ± 2.6 IQ NR	ABC-Irritability G1: 25.7 ± 5.7 G2: 24.7 ± 7.6	**EOT** ABC-Irritability G1: 16.6 ± 7.6 G2: 18.2 ± 7.7 Treatment response, n (%): >25% reduction in irritability score: n (%): G1: 13 (81.2) G2: 8 (44.4) G1 vs. G2: p<0.02, RR=1.82 ≥ 30% reduction in irritability score: G1: 13 (81.2) G2: 7 (38.9) G1 vs. G2: p<0.01, RR=2.1
Nikoo et al., 2015[46] RCT G1: Risperidone + N-acetylcysteine (1-2.0 mg/day + 600-900 mg/day), 25/20 G2: Risperidone + placebo (NA), 25/20 10 weeks/EOT Low RoB	Age G1: 7.50 ± 2.63 G2: 7.60 ± 2.60 IQ G1: NR G2: NR	ABC-Irritability G1: 21.20 ± 5.16 G2: 19.70 ± 7.61 ABC-Lethargy G1: 21.10 ± 6.39 G2: 20.65 ± 9.62 ABC-Stereotypic behavior G1: 10.55 ± 4.22 G2: 10.05 ± 5.35 ABC-Hyperactivity G1: 27.65 ± 6.16 G2: 25.10 ± 9.44 ABC-Inappropriate speech G1: 5.70 ± 2.92 G2: 4.75 ± 3.72	**EOT** ABC-Irritability G1: 11.95 ± 4.87 G2: 14.35 ± 6.27 G1 vs G2: p<0.05 ABC-Lethargy G1: 17.15 ± 5.46 G2: 17.95 ± 8.40 G1 vs G2: p=ns ABC-Stereotypic behavior G1: 7.75 ± 4.90 G2: 8.70 ± 5.44 G1 vs G2: p=ns ABC-Hyperactivity G1: 21.45 ± 8.47 G2: 23.05 ± 9.03 G1 vs G2: p<0.05 ABC-Inappropriate speech G1: 4.95 ± 2.85 G2: 4.80 ± 3.47 G1 vs G2: p=ns

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
Ghanizadeh, et al., 2013[47] RCT G1: Risperidone + N-Acetylcysteine (up to 3 mg/day + 1200 mg/day), 20/17 G2: Risperidone + placebo (NA), 20/14 8 weeks/EOT Low RoB	Age: G1: 8.8 ± 3.1 G2: 7.9 ± 2.4 IQ NR	ABC-Irritability G1: 13.2 ± 5.3 G2: 16.7 ± 7.8 ABC-Hyperactivity G1: 29.3 ± 6.4 G2: 31.9 ± 8.9 ABC-Lethargy G1:11.9 ± 6.5 G2: 12.2 ± 8.3 ABC-Stereotypic behavior G1: 6.6 ± 4.5 G2: 8.5 ± 6.3 ABC-Inappropriate speech G1: 3.9 ± 3.7 G2: 5.7 ± 3.8	**EOT** ABC-Irritability G1: 9.7 ± 4.1 G2: 15.1 ± 7.8 G1 vs G2: p<0.035 ABC-Hyperactivity G1: 18.3 ± 6.9 G2: 24.3 ± 12.1 G1 vs G2: p=ns ABC-Lethargy G1: 8.5 ± 6.5 G2: 10.9 ± 7.6 G1 vs G2: p=ns ABC-Stereotypic behavior G1: 3.9 ± 2.7 G2: 7.8 ± 6.6 G1 vs G2: p=ns ABC-Inappropriate speech G1: 3.2 ± 3.4 G2: 5.2 ± 4.0 G1 vs G2: p=ns
Asadabadi, et al., 2013[48] RCT G1: Risperidone + celecoxib (up to 3 mg/day + up to 300 mg/day), 20/20 G2: Risperidone + placebo (NA), 20/20 10 weeks/EOT Low RoB	Age G1: 7.6 ± 1.7 G2: 7.5 ± 1.5 IQ NR	ABC-Irritability G1: 17.3 ± 1.6 G2: 17.6 ± 2.4 ABC-Lethargy G1: 17.0 ± 3.0 G2: 17.1 ± 3.2 ABC-Stereotypic behavior G1: 9.1 ± 2.2 G2: 9.2 ± 2.3 ABC-Hyperactivity G1: 22.0 ± 2.9 G2: 22.6 ± 3.0 ABC-Inappropriate speech G1: 5.4 ± 1.4 G2: 5.5 ± 0.9	**EOT** ABC-Irritability G1: 8.7 ± 1.6 G2: 12.4 ± 3.0 G1 vs G2: p<0.001 ABC-Lethargy G1: 9.9 ± 3.1 G2: 14.3 ± 2.1 G1 vs G2: p<0.001 ABC-Stereotypic behavior G1: 4.0 ± 1.2 G2: 6.9 ± 2.3 G1 vs G2: p<0.001 ABC-Hyperactivity G1: 11.2 ± 2.1 G2: 12.9 ± 2.6 G1 vs G2: p=ns ABC-Inappropriate speech

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			G1: 4.1 ± 2.0 G2: 4.3 ± 1.2 G1 vs G2: p=ns
Ghaleiha, et al., 2013[49] RCT G1: Risperidone + memantine (up to 3 mg/day + up to 20 mg/day), 20/20 G2: Risperidone + placebo (NA), 20/20 10 weeks/EOT Low RoB	Age G1: 7.42 ± 1.48 G2: 7.97 ± 1.68 IQ NR	ABC-Irritability G1: 18.25 ± 1.55 G2: 17.65 ± 3.74 ABC-Lethargy G1: 16.55 ± 4.26 G2: 16.85 ± 3.48 ABC-Stereotypic behavior G1: 8.83 ± 3.08 G2: 8.26 ± 2.67 ABC-Hyperactivity G1: 23.00 ± 4.69 G2: 22.45 ± 7.91 ABC-Inappropriate speech G1: 6.00 ± 1.36 G2: 5.85 ± 1.46	**EOT** ABC-Irritability G1: 8.90 ± 1.55 G2: 12.75 ± 3.05 G1 vs G2: p<0.01 ABC-Lethargy G1: 11.65 ± 3.39 G2: 13.85 ± 2.10 G1 vs G2: p=ns ABC-Stereotypic behavior G1: 3.30 ± 1.30 G2: 6.99 ± 1.97 G1 vs G2: p<0.01 ABC-Hyperactivity G1: 8.25 ± 2.19 G2: 13.85 ± 3.28 G1 vs G2: p=<0.01 ABC-Inappropriate speech G1: 4.50 ± 1.75 G2: 4.69 ± 1.60 G1 vs G2: p=ns
Ghaleiha, et al., 2013[50] RCT G1: Risperidone + riluzole (up to 3 mg/day + up to 100 mg/day), 25/20 G2: Risperidone + placebo (NA), 24/20 10 weeks/EOT Low RoB	Age G1: 8.4 ± 2.3 G2: 7.6 ± 1.7 IQ NR	ABC-Irritability G1: 21.40 ± 4.18 G2: 22.10 ± 9.98 ABC-Lethargy G1: 23.95 ± 8.04 G2: 24.30 ± 10.98 ABC-Stereotypic behavior G1: 7.80 ± 3.43 G2: 8.25 ± 4.93	**EOT** ABC-Irritability G1: 11.85 ± 5.57 G2: 16.25 ± 7.86 G1 vs G2: p=0.03 Treatment responses: n (%) Partial response (≥ 25% reduction in irritability score): G1: 17 (85)

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		ABC-Hyperactivity G1: 26.35 ± 7.67 G2: 27.95 ± 10.68 ABC-Inappropriate speech G1: 5.85 ± 3.38 G2: 5.80 ± 3.10	G2: 8 (40) G1 vs. G2: p=0.003 Complete response (≥ 50% reduction in irritability score): G1: 7 (35) G2: 3 (15) G1 vs. G2: p=ns ABC-Lethargy G1: 17.10 ± 5.98 G2: 21.45 ± 9.43 G1 vs G2: p=0.02 ABC-Stereotypic behavior G1: 4.90 ± 3.49 G2: 7.75 ± 5.10 G1 vs G2: p=0.03 ABC-Hyperactivity G1: 20.35 ± 9.15 G2: 26.65 ± 9.97 G1 vs G2: p=0.005 ABC-Inappropriate speech G1: 4.95 ± 3.20 G2: 5.70 ± 2.51 G1 vs G2: p=ns CGI – Very Much Improved G1: 3 (15) G2: 1 (5) CGI – Much Improved G1: 8 (40) G2: 4 (20) CGI-responders: G1:11 (55) G2: 5 (25) G1 Vs. G2, p=0.05

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
Ghaleiha 2013[51] RCT G1: Galantamine + Risperidone (2-24 mg/day + 0.5-2 mg/day), 23/20 G2: Risperidone + Placebo (0.5-2mg/day), 23/20 10 weeks/EOT Low RoB	Age G1: 6.85 ± 1.98 G2: 5.90 ± 1.38 IQ NR	ABC-C-Irritability G1: 15.59 ± 5.83 G2: 14.95 ± 4.38 ABC-C-Lethargy/Social withdrawal G1: 11.10 ± 5.34 G2: 10.40 ± 5.27 ABC-C-Stereotypical behavior G1: 6.10 ± 5.93 G2: 5.80 ± 5.08 ABC-C-Hyperactivity/noncompliance G1: 20.85 ± 11.69 G2: 22.30 ± 9.83 ABC-C-Inappropriate Speech G1: 3.50 ± 3.95 G2: 3.25 ± 4.43	**EOT** ABC-C-Irritability G1: 5.30 ± 4.25 G2: 8.80 ± 5.03 G1 vs G2: p=0.017 ABC-C-Lethargy/Social Withdrawal G1: 5.60 ± 4.43 G2: 8.35 ± 5.59 G1 vs G2: p=0.003 ABC-C-Stereotypical Behavior G1: 3.95 ± 5.06 G2: 4.50 ± 4.34 G1 vs G2: p=ns ABC-C-Hyperactivity/noncompliance G1:10.85 ± 9.49 G2:16.05 ± 7.52 G1 vs G2: p=ns ABC-C-Inappropriate Speech G1: 2.15 ± 2.68 G2: 2.80 ± 3.63 G1 vs G2: p=ns
Mohammadi, et al., 2013[52] RCT G1: Risperidone + amantadine (up to 2 mg/day + up to 150 mg/day), 20/20 G2: Risperidone + placebo (NA), 20/19 10 weeks/EOT Low RoB	Age G1: 6.4 ± 2.3 G2: 7.1 ± 2.4 IQ NR	ABC-Irritability G1: 20.00 ± 5.30 G2: 20.90 ± 6.61 ABC-Lethargy G1: 18.55 ± 7.13 G2: 18.15 ± 4.80 ABC-Stereotypic behavior G1: 10.90 ± 4.03 G2: 11.30 ± 5.42 ABC-Hyperactivity G1: 28.15 ± 6.88 G2: 28.55 ± 8.67 ABC-Inappropriate speech G1: 5.70 ± 3.11 G2: 4.55 ± 3.48	**Change (reduction from baseline)** ABC-Irritability G1: 8.60 ± 4.65 G2: 5.35 ± 3.95 p=0.02 ABC-Lethargy G1: 1.35 ± 3.18 G2: 1.30 ± 3.33 p=ns ABC-Stereotypic behavior G1: 1.20 ± 2.33 G2: 1.20 ± 2.09 p=ns ABC-Hyperactivity G1: 6.15 ± 5.11 G2: 2.50 ± 5.00

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			P=0.03 ABC-Inappropriate speech G1: 0.40 ± 0.99 G2: 0.05 ± 0.22 p=ns CGI Very much improved, n: G1: 2 G2: 1 Much improved, n: G1: 8 G2: 3 Improvement, n (%): G1: 10 (50) G2: 4 (20) G1 vs. G2: p=0.047
Hasanzadeh, et al., 2012[53] RCT G1: Risperidone + Ginko T.D (up to 3 mg/day + up to 120 mg/day), 23/23 G2: Risperidone + placebo (NA), 24/ 24 10 weeks/EOT Low RoB	Age G1: 6.04 ± 1.61 G2: 6.76 ± 2.60 IQ NR	ABC-Irritability G1: 14.95 ± 7.86 G2: 14.08 ± 7.55 ABC-Lethargy G1: 11.63 ± 7.90 G2: 12.32 ± 9.38 ABC-Stereotypic behavior G1: 6.77 ± 4.42 G2: 6.32 ± 4.11 ABC-Hyperactivity G1: 22.68 ± 9.88 G2: 21.36 ± 6.96 ABC-Inappropriate speech G1: 3.36 ± 1.96 G2: 3.92 ± 2.11	**EOT** ABC-Irritability G1: 10.54 ± 5.75 G2: 9.88 ± 7.35 G1 vs G2: p=ns ABC-Lethargy G1: 6.86 ± 6.08 G2: 7.36 ± 6.14 G1 vs G2: p=ns ABC-Stereotypic behavior G1: 4.7 ± 23.28 G2: 5.00 ± 3.80 G1 vs G2: p=ns ABC-Hyperactivity G1: 16.54 ± 8.51 G2: 14.84 ± 6.25 G1 vs G2: p=ns ABC-Inappropriate speech G1: 2.09 ± 1.63 G2: 2.44 ± 1.58 G1 vs G2: p=ns

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
Akhondzadeh, et al., 2010[54] RCT G1: Risperidone + pentoxifylline (up to 3 mg/day + up to 600 mg/day), 20/20 G2: Risperidone + placebo (NA), 20/20 10 weeks/EOT Moderate RoB	Age: G1: 8.05 ± 2.01 G2: 7.37 ± 2.41 IQ NR	ABC-Irritability G1: 16.67 ± 2.71 G2: 16.06 ± 3.00 ABC-Lethargy G1: 18.27 ± 2.97 G2: 17.29 ± 3.23 ABC-Stereotypic behavior G1: 8.01 ± 1.30 G2: 7.72 ± 1.44 ABC-Hyperactivity G1: 16.03 ± 2.60 G2: 15.44 ± 2.88 ABC-Inappropriate speech G1: 5.13 ± 0.83 G2: 4.94 ± 0.92	**EOT** ABC-Irritability G1: 7.14 ± 3.23 G2: 11.65 ± 1.72 Group X time: p≤0.0001 ABC-Lethargy G1: 8.03 ± 3.64 G2: 13.05 ± 1.93 Group X time: p≤0.0001 ABC-Stereotypic behavior G1: 3.57 ± 1.61 G2: 5.59 ± 0.82 Group X time: p≤0.0001 ABC-Hyperactivity G1: 8.92 ± 4.05 G2: 12.59 ± 1.86 Group X time: p≤0.0001 ABC-Inappropriate speech G1: 2.08 ± 0.94 G2: 3.73 ± 0.55 Group X time: p≤0.0001
Rezaei, et al., 2010[55] RCT G1: Risperidone + topiramate (up to 3 mg/day + up to 200 mg/day), 20/20 G2: Risperidone + placebo (NA), 20/20 8 weeks/EOT Low RoB	Age G1: 8.17 ± 1.85 G2: 7.85 ± 1.82 IQ NR	ABC-Irritability G1: 17.25 ± 3.12 G2: 16.80 ± 4.22 ABC-Lethargy G1: 17.65 ± 6.02 G2: 17.55 ± 4.28 ABC-Stereotypic behavior G1: 8.83 ± 3.89 G2: 8.71 ± 3.21 ABC-Hyperactivity G1: 22.75 ± 4.85 G2: 22.00 ± 9.17 ABC-Inappropriate speech	**EOT** ABC-Irritability G1: 8.20 ± 2.44 G2: 15.30 ± 4.64 G1 vs G2: p=0.04 ABC-Lethargy G1: 14.15 ± 6.67 G2: 15.60 ± 4.28 G1 vs G2: p=ns ABC-Stereotypic behavior G1: 3.40 ± 1.04 G2: 8.09 ± 3.04 G1 vs G2: p=0.04 ABC-Hyperactivity G1: 7.60 ± 2.37

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		G1: 5.25 ± 2.01 G2: 5.10 ± 1.80	G2: 19.25 ± 8.30 G1 vs G2: p=0.04 ABC-Inappropriate speech G1: 3.93 ± 2.17 G2: 4.24 ± 1.59 G1 vs G2: p=ns
Akhondzadeh et al., 2008[56] RCT G1: Risperidone + Piracetam (+ 3 mg/day + 800 mg/day), 20/20 G2: Risperidone + Placebo (NA), 20/20 10 weeks/EOT Moderate RoB	Age G1: 6.90 ± 1.86 G2: 6.75 ± 1.80 IQ NR	ABC-Community Total Score G1: 23.15 ± 5.8 G2: 24 ± 8.25	**Mean change score from baseline** ABC-Community Total Score G1: -11.9 ± 3.79 G2: -5.15 ± 3.04 G1 vs G2, p<0.0001

EOT-End of Treatment; ABC-Aberrant Behavior Checklist; CGI-Clinical Global Impression

Table F-6. Key Findings in Studies of Medical – Other

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
Donepezil			
Handen et al., 2005[57] RCT G1: Donepezil (2.5-10 mg/day), 18/15 G2: Placebo (NA), 16/16 10 weeks/EOT Moderate RoB	Age, mean (range) G1: 11 yrs 6 mos (8 yrs 7 mos – 16 yrs 8 mos) G2: 11 yrs 8 mos (8 yrs 1 mo – 16 yrs 6 mos) IQ G1: 96.8 (73-142) G2: 96.7 (82-146)	Trail Making Test G1: 123.6 56.5 G2: 154.9 77.8 Verbal Fluency-total number of verbal fluency switches G1: 6.83 3.17 G2: 8.31 2.73 Design Fluency-number of design fluency test switches G1: 3.44 2.5 G2: 4.75 2.79 Color-Word Interference-inhibition/switch time G1: 93.3 38.3 G2: 90.5 25.4 Sorting Test (STCC and STFS)-number of confirmed correct sorts G1: 6.72 2.97 G2: 7.19 1.87 Sorting Test (STCC and STFS)-total number of free sorts G1: 25.2 11.1 G2: 26.6 7.6 Twenty Questions Test-total number of questions asked G1: 24.7 13.7 G2: 18.9 8.9 Tower of California test-total number of moves G1: 12.1 4.1 G2: 12.3 4.9 Word Context Test-total number of points	**EOT** Trail Making Test G1: 118.3 79.1 G2: 104.7 53.4 G1 Vs G2, p= 0.72 Verbal Fluency-total number of verbal fluency switches G1: 6.17 5.12 G2: 6.94 4.97 G1 Vs G2, p=0.372 Design Fluency-number of design fluency test switches G1: 5.22 2.69 G2: 4.31 4.25 G1 Vs G2, p=0.57 Color-Word Interference-inhibition/switch time G1: 81.3 28.9 G2: 79.7 34.2 G1 Vs G2, p=0.74 Sorting Test (STCC and STFS)-number of confirmed correct sorts G1: 5.89 3.1 G2: 5.69 4.36 G1 Vs G2, p=0.89 Sorting Test (STCC and STFS)-total number of free sorts G1: 19.4 11.6 G2: 21.7 10.9 G1 Vs G2, p=0.57 Twenty Questions Test-total number of questions asked G1: 22.2 10.8 G2: 15.1 8.5 G1 Vs G2, p=0.06

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		earned G1: 4.9 4.9 G2: 6.1 3.3 EOWPVT-Expressive Language Scaled Score G1: 104.6 22.4 G2: 108.7 17 Memory Test-Percent Correct G1: 40.7 14.1 G2: 47.1 10.3	Tower of California test-total number of moves G1: 15.2 4.7 G2: 14.9 7.7 G1 Vs G2, p=0.94 Word Context Test-total number of points earned G1: 3 3.2 G2: 3.8 4.9 G1 Vs G2, p=0.43 EOWPVT-Expressive Language Scaled Score G1: 3.8 4.9 G2: 109.7 21 G1 Vs G2, p=0.5 Memory Test-Percent Correct G1: 114.5 16.1 G2: 50.2 11 G1 Vs G2, p=0.28
Anti-epileptics			
Hollander 2010[58] RCT G1: Divalproex sodium (125mg qhs - 500mg bid), 16/16 G2: Placebo (NA), 11/11 12 weeks/EOT Low RoB	Age G1: 9.66 ± 2.64 G2: 8.97 ± 2.8 IQ G1: 52.92 ± 18.5 G2: 76.1 ± 26.45	ABC – Irritability G1: 22 ± 7.81 G2: 20.30 ± 7.36 CGI – Irritability G1: 5.13 ± 0.72 G2: 4.73 ± 0.47 The Overt Aggression Scale-Modified (OAS-M) G1: 6.43 ± 1.41 G2: 5.36 ± 2.2 CYBOCS G1: NR G2: NR VABS G1: 37.13 ± 15.9 G2: 42.4 ± 17.21	**EOT** ABC – Irritability G1: 14.5 ± 6.67 G2: 17.70 ± 7.94 G1 vs G2: p= NR CGI – Irritability Response, n (%) G1: 10 (62,5) G2: 1 (9.1) G1 vs G2, p=0.008 The Overt Aggression Scale-Modified (OAS-M) G1: 5.42 ± 2.17 G2: 6.25 ± 1.28 G1 vs G2: p=ns CYBOCS G1: NR G2: NR G1 vs G2:p=ns

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			VABS G1: NR G2: NR G1 vs G2: p=ns
Bumetanide			
Du et al., 2012[59] RCT G1: Bumetanide + ABA (0.5mg/bid), 32/29 G2: ABA only (30-40mins/day), 28/26 3 months/EOT High RoB	Age G1: 4.60 ± 1.90 G2: 4.50 ± 1.67 IQ NR	Autism Behavior Checklist G2: 74.68 ± 4.47 G1: 75.61 ± 11.38 G1 vs G2, p=0.700 CARS G2: 37.28 ± 3.53 G1: 36.39 ± 3.85 G1 vs G2, p=0.362 Clinical Global Impressions (CGI) - Improvement and severity G2: 4.48 ± 0.82 G1: 4.47 ± 1.05 G1 vs G2, p=0.975	**EOT** Autism Behavior Checklist G2: 62.88 ± 4.96 G1: 57.47 ± 7.19 G1 vs G2, p< 0.01 CARS G2: 31.64 ± 1.72 G1: 30.79 ± 2.45 G1 vs G2, p=ns Clinical Global Impressions (CGI) - Improvement and severity G1: G1: 3.17 ± 0.38 G2: 3.40 ± 0.50 G1 vs G2, p< 0.05
Lemonnier et al., 2012[60] RCT G1: Bumetanide (0.5mg/bid), 30/27 G2: Placebo (NA), 30/27 3 months/EOT Moderate RoB	Age, months G1: 82.5 ± 23.2 G2: 85.3 ± 21.3 mos IQ NR	CARS G1: 41.6 ± 3.6 G2: 41.1 ± 4.1 CGI NR ADOS-G NR	CARS **(day 90)** G1: 36 ± 5.7 G2: 39.3 ± 4.9G1 vs G2: p= 0.004 CARS **(day 120)** G1: 38.8 ± 4.7 G2: 40.5 ± 3.8 **EOT** CGI G1: 2.04 ± 0.87 G2: 1.56 ± 0.85 G1 vs G2: p=0.017 Significant amelioration G1: 14 (51.8% G2: 6 (22.2) Small amelioration G1: 7 (25.9) G2: 3 (11.1)

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			No amelioration G1: 6 (22.2) G2: 18 (66.6) ADOS-G, mean change scores G1: +7.8 ± 7.4 G2: +5.3 ± 6.6 G1 vs G2: p=ns
HBOT			
Sampanthavivat et al., 2012[61] RCT G1: HBOT (20, 1 hr sessions/day at 153kPa), 29/29 G2: Sham air (20, 1 hr sessions/day at 116kPa), 29/29 20 days/EOT Moderate RoB	Age G1: 6.10 ± 1.17 G2: 5.67 ± 1.01 IQ NR	ATEC-Parent G1: 68.07 ± 25.43 G2: 64.86 ± 22.80 ATEC-Clinician G1: 60.21 ± 19.92 G2: 60.55 ± 21.36 CGIS-Parent G1: 4.03 ± 1.05 G2: 3.79 ± 0.98 CGIS-Clinician G1: 3.62 ± 0.78 G2: 3.83 ± 0.93	**EOT** ATEC-Parent G1: 58.31 ± 21.94 G2: 55.86 ± 24.93 G1 vs G2: p=ns ATEC-Clinician G1: 52.38 ± 19.11 G2: 52.93 ± 18.93 G1 vs G2: p=ns CGIS-Parent G1: 3.69 ± 0.93 G2: 3.66 ± 0.86 G1, p=0.005 G2, p=NS CGIS-Clinician G1: 3.48 ± 0.78 G2: 3.76 ± 0.83 G1 vs G2: p=ns Change scores CGIC-Parent G1: 2.34 ± 0.61 G2: 2.55 ± 0.83 G1 vs. G2:p=ns CGIC-Clinician G1: 2.31 ± 0.6 G2: 2.72 ± 0.8 G1 vs G2:, p=0.03
Granpeesheh et al., 2010[62] RCT G1: HBOT (24% oxygen at 1.3 atm pressure), 18/17 G2: Placebo (NA), 16/16 15 weeks/EOT	Age G1: 6.11 G2: 6.25 IQ NR	SRS NR ADOS NR	**Mean change score:** SRS- Social Awareness G1: -3.14 ± 14.21 G2: -1.33 ± 16.62 G1 vs G2: p=ns SRS-Social Cognition

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
Low RoB			G1: 1.79 ± 8.82 G2: -5.33 ± 16.01 G1 vs G2: p=ns SRS-Social Communication G1: -1.00 ± 13.06 G2: 3.13 ± 12.02 G1 vs G2:p=ns SRS-Social Motivation G1: -5.50 ± 12.45 G2: -6.33 ± 13.12 G1 vs G2:p=ns SRS-Autistic Mannerisms G1: 1.64 ± 14.58 G2: -3.33 ± 12.49 G1 vs G2, p=0.33 Number (%) improving ADOS-Total G1: 5/18 (27.8) G2: 4/16 (25) G1 vs G2: p=ns ADOS-Communication G1: 3/18 (16.7) G2: 2/16 (12.5) G1 vs G2: p=ns ADOS-Socialization G1: 3/18 (16.7) G2: 2/16 (12.5) G1 vs G2: p=ns
Melatonin			
Cortesi et al., 2012[63] RCT G1: Controlled-release melatonin + CBT (3mg/day), 40/35 G2: Controlled-release melatonin (3mg/day), 40/34 G3: CBT (4 sessions/week), 40/33 G4: Placebo (NA), 40/32 12 weeks/EOT Low	Age G1: 6.4 ± 1.1 G2: 6.8 ± 0.9 G3: 7.1 ± 0.7 G4: 6.3 ± 1.2 IQ NR	CSHQ CSHQ-Total score G1: 66.11 ± 5.47 G2: 66.67 ± 8.55 G3: 64.48 ± 5.48 G4: 64.20 ± 4.85 Bed resistance G1: 14.53 ± 1.82 G2: 13.85 ± 2.23 G3: 13.44 ± 2.08 G4: 13.63 ± 1.82	**EOT** CSHQ CSHQ-Total score G1: 47.84 ± 2.94 G2: 54.78 ± 6.22 G3: 60.06 ± 4.71 G4: 64.80 ± 4.52 Time x group p<0.001 Bed resistance G1: 8.46 ± 1.39 G2: 10.50 ± 2.20 G3: 11.62 ± 2.22

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		SOD G1: 2.88 ± 0.32 G2: 2.85 ± 0.35 G3: 2.89 ± 0.30 G4: 2.90 ± 0.31 Sleep anxiety G1: 7.95 ± 1.83 G2: 8.35 ± 2.19 G3: 8.62 ± 1.98 G4: 7.66 ± 1.73 Night-wakings G1: 7.61 ± 0.89 G2: 7.67 ± 0.94 G3: 7.62 ± 0.94 G4: 7.76 ± 0.93 Sleep duration G1: 7.34 ± 1.35 G2: 7.17 ± 1.51 G3: 7.01 ± 1.48 G4: 6.46 ± 1.25 Parasomnias G1: 9.15 ± 1.68 G2: 9.10 ± 2.42 G3: 9.75 ± 2.11 G4: 8.96 ± 1.80 SDB G1: 3.18 ± 0.40 G2: 3.20 ± 0.44 G3: 3.10 ± 0.30 G4: 3.15 ± 0.40 DS G1: 13.92 ± 2.86 G2: 13.35 ± 3.84 G3: 13.31 ± 2.67 G4: 13.13 ± 3.11 Sleep Diary TST G1: 414.03 ± 45.34 G2: 410.28 ± 45.07 G3: 408.08 ± 49.03 G4: 413.00 ± 45.13 SOL G1: 85.84 ± 20.02	G4: 14.10 ± 1.93 Time x group p<0.001 SOD G1: 1.69 ± 0.73 G2: 2.10 ± 0.68 G3: 2.51 ± 0.57 G4: 2.93 ± 0.25 Time x group p<0.001 Sleep anxiety G1: 5.23 ± 0.95 G2: 7.21 ± 1.87 G3: 7.17 ± 1.48 G4: 7.93 ± 1.99 Time x group p<0.001 Night-wakings G1: 4.42 ± 0.90 G2: 5.03 ± 1.10 G3: 7.06 ± 1.06 G4: 7.86 ± 0.81 Time x group p<0.001 Sleep duration G1: 4.38 ± 1.02 G2: 4.82 ± 0.94 G3: 6.68 ± 1.16 G4: 6.40 ± 1.29 Time x group p<0.001 Parasomnias G1: 8.92 ± 1.38 G2: 9.35 ± 1.78 G3: 9.82 ± 2.25 G4: 9.16 ± 1.53 Time x group p=ns SDB G1: 3.22 ± 0.35 G2: 3.15 ± 0.48 G3: 3.20 ± 0.41 G4: 3.20 ± 0.44 Time x group p=ns DS G1: 10.84 ± 1.68 G2: 11.39 ± 2.34 G3: 11.96 ± 1.97 G4: 12.96 ± 1.97 Time x group p<0.001

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		G2: 81.21 ± 32.35 G3: 76.34 ± 31.70 G4: 78.20 ± 33.83 WASO G1: 69.50 ± 23.35 G2: 73.71 ± 45.00 G3: 68.72 ± 31.77 G4: 69.75 ± 45.21 NAPTIME G1: 28.26 ± 49.13 G2: 33.57 ± 56.63 G3: 35.31 ± 60.17 G4: 37.33 ± 56.19 SE G1: 70.26 ± 4.83 G2: 71.10 ± 4.91 G3: 71.37 ± 4.77 G4: 71.13 ± 4.99 BEDTIME G1: 23.33 ± 1.35 G2: 23.45 ± 1.15 G3: 23.39 ± 1.03 G4: 23.41 ± 1.19	Sleep Diary TST G1: 505.01 ± 31.18 G2: 481.10 ± 33.15 G3: 445.13 ± 48.37 G4: 416.23 ± 43.60 Time x group p<0.001 SOL G1: 33.69 ± 14.40 G2: 45.21 ± 23.21 G3: 59.13 ± 27.60 G4: 79.60 ± 31.85 Time x group p<0.001 WASO G1: 29.69 ± 12.97 G2: 42.21 ± 22.35 G3: 61.17 ± 28.93 G4: 70.15 ± 42.76 Time x group p<0.001 NAPTIME G1: 9.20 ± 22.48 G2: 17.00 ± 33.11 G3: 12.29 ± 24.24 G4: 36.10 ± 33.28 Time x group p=ns SE G1: 84.46 ± 4.23 G2: 82.71 ± 4.00 G3: 79.58 ± 2.82 G4: 71.93 ± 4.62 Time x group p<0.001 BEDTIME G1: 22.06 ± 1.05 G2: 22.30 ± 1.10 G3: 22.55 ± 1.01 G4: 23.51 ± 1.12 Time x group p<0.001
Wright et al., 2011[64] RCT G1: Melatonin (2-10mg/day), 9/6 G2: Placebo (NA), 11/10 Crossover 9 months/EOT	Age G1: 8.9 ± 3.0 G2: 8.5 ± 2.3 IQ NR	Dysomnias, n=12 G1+G2: 34.0 ± 9.4 Parasomnias, n=14 G1+G2: 18.7 ± 7.7 Sleep apneas, n=13 G1+G2: 13.0 ± 9.4	**EOT** Dysomnias, n=12 G1: 22.2 ± 6.6 G2: 27.8 ± 6.3 p=0.04 Parasomnias, n=14

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
Moderate RoB		Other sleep disorders, n=10 G1+G2: 25.1 ± 5.6 DBC-Total, n=17 G1+G2: 90.1 ± 18.7 DBC-Disruptive, n=17 G1+G2: 26.2 ± 13.0 DBC- Self-absorption, n=17 G1+G2: 33.0 ± 11.0 DBC-Communication, n=17 G1+G2: 11.4 ± 3.6 DBC-Anxiety, n=17 G1+G2: 8.8 ± 2.8 DBC-Social relating, n=17 G1+G2: 9.4 ± 3.1 GHQ total n=17 G1+G2: 3.7 ± 7.1 No. of wakenings n=17 G1+G2: 0.5 ± 0.5 Total sleep minutes, n=17 G1+G2: 499.9 ± 66.4 Sleep latency, n=17 G1+G2: 135.0 ± 63.0	G1: 17.3 ± 4.5 G2: 20.1 ± 8.1 p=ns Sleep apneas, n=13 G1: 11.4 ± 4.2 G2: 12.7 ± 3.4 p=ns Other sleep disorders, n=10 G1: 23.8 ± 3.4 G2: 25.9 ± 6.2 p=ns DBC-Total G1: 75.12 ± 23.29 G2: 82.25 ± 25.79 p=0.05 DBC-Disruptive G1: 21.82 ± 11.97 G2: 23.88 ± 11.12 p=ns DBC- Self-absorption G1: 28.94 ± 13.41 G2: 30.06 ± 14.05 p=ns DBC-Communication G1: 8.24 ± 3.29 G2: 9.75 ± 5.04 p=0.045 DBC-Anxiety G1: 7.53 ± 3.39 G2: 7.56 ± 3.86 p=ns DBC-Social relating G1: 7.82 ± 3.11 G2: 9.06 ± 4.27 p=ns GHQ total G1: 1.4 ± 2.7 G2: 3.2 ± 4.6 p=ns

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			No. of wakenings G1: 0.43 ± 0.64 G2: 0.58 ± 0.74 p=ns Total sleep minutes G1: 556.11 ± 53.59 G2: 507.66 ± 70.67 p=0.002 Sleep latency G1: 82.84 ± 50.61 G2: 124.79 ± NR p=0.004
Other			
Amatachaya et al., 2014[65, 66] RCT G1: Transcranial direct current stimulation (1mA), 10/10 G2: Sham (NA), 10/10 8 weeks/EOT Moderate RoB	Age G1 + G2: 5-8 IQ NR	CARS G1: 34.95 ± 4.73 G2: 34.6 ± 4.41 ATEC-Total G1: 67.25 ± 9.88 G2: 69.15 ± 8.98 ATEC-Language G1: 10.6 ± 5.59 G2: 10.75 ± 4.72 ATEC- Social G1: 16.4 ± 4.5 G2: 17.45 ± 2.67 ATEC-Sensory and cognitive awareness G1: 20.1 ± 3.91 G2: 20.5 ± 3.4 ATEC-Health and behavioral problem G1: 20.15 ± 8.34 G2: 20.45 ± 7.21 CGAS G1: 54.35 ± 11.07 G2: 53.35 ± 10.31 CGI-Severity G1: 4.05 ± 0.94 G2: 4.15 ± 0.99	**EOT** CARS G1: 32.2 ± 3.98 G2: 35 ± 4.3 p < 0.05 ATEC-Total G1: 58 ± 5.28 G2: 69.65 ± 9.13 p ≤ 0.001 ATEC-Language G1: 10.5 ± 5.39 G2: 10.55 ± 5.2 ATEC- Social G1: 14.45 ± 4.85 G2: 17.7 ± 2.98 p < 0.05 ATEC-Sensory and cognitive awareness G1: 18.35 ± 5.35 G2: 22.3 ± 4.47 p < 0.05 ATEC-Health and behavioral problem G1: 14.7 ± 6.21 G2: 19.1 ± 6.47 p < 0.05 CGAS G1: 60 ± 10.57

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			G2: 53.1 ± 10.14 p < 0.05 CGI-Improvement, n (%) Very much improved G1: 0 G2: 0 p=ns Much improved G1: 9 (45) G2: 3 (15) p≤ 0.05 Minimally improved G1: 8 (40) p=ns No change G1: 1 (5) G2: 6 (30) p=ns Minimally worse G1: 2 (10) G2: 2 (10) p=ns Much worse G1: 0 G2: 5 (25) p < 0.05 Very much worse G1: 0 G2: 0 p=ns
Dadds, et al., 2014[67] RCT G1: Intranasal oxytocin (12 or 24 IU), 19/19 G2: Placebo (NA), 19/189 4 days/EOT Moderate RoB	Age G1: 11.79 ± 2.82 G2: 10.74 ± 2.38 IQ G1: 90.47 ± 11.70 G2: 88.64 ± 7.98	SRS G1: 17.13 ± 5.57 G2: 20.56 ± 6.70 Video Observation Repetitive Behaviors G1: 0.24 ± 0.26 G2: 0.20 ± 0.25 Video Observation Social Interaction Skills G1: 1.63 ± 0.50 G2: 1.69 ± 0.38	**3 mos follow-up** SRS G1:16.47 ± 5.94 G2: 15.78 ± 7.85 G1 vs G2: p=ns Video Observation Repetitive Behaviors G1: 0.27 ± 0.24 G2: 0.25 ± 0.24 G1 vs G2: p=ns Video Observation

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		Facial Emotion Recognition G1: 0.79 ± 0.11 G2: 0.77 ± 0.14 OSU G1: 3.76 ± 0.70 G2: 4.17 ± 0.79 CARS G1: 32.26 ± 3.25 G2: 33.84 ± 3.70	Social Interaction Skills G1: 1.92 ± 0.51 G2: 1.96 ± 0.49 G1 vs G2: p=ns Facial Emotion Recognition G1: 0.87 ± 0.08 G2: 0.86 ± 0.07 G1 vs G2: p=ns OSU G1: 3.60 ± 0.63 G2: 3.78 ± 0.94 G1 vs G2: p=ns CARS G1: 30.07 ± 2.78 G2: 31.06 ± 5.20 G1 vs G2: p=ns
Klaiman, et al., 2013[68] RCT G1: Tetrahydrobiopterin (20mg/kg/day), 23/23 G2: Placebo (NA), 23/23 16 weeks/EOT Low RoB	Age, months G1: 60.1 ± 12.0 G2: 60.2 ± 12.6 IQ NR	CGI-Severity [N (%)] Frequency of markedly, severely, or extremely ill G1: 10 (48) G2: 15 (68) ABC-Irritability G1: 11.1 ± 7.7 G2: 11.9 ± 7.8 ABC-Social withdrawal/lethargy G1: 9.5 ± 7.5 G2: 16.2 ± 10.0 ABC-Stereotypy G1: 6.1 ± 3.9 G2: 6.1 ± 3.6 ABC-Hyperactivity G1: 21.5 ± 10.3 G2: 22.9 ± 11.6 ABC-Inappropriate speech G1: 3.7 ± 2.4 G2: 3.4 ± 4.1 SRS G1: 81.4 ± 10.3	**16 wks follow-up** CGI-Severity [N (%)} Frequency of markedly, severely, or extremely ill G1: 7 (35) G2: 14 (64) G1 vs G2: p=ns Improvement, frequency of very much or much improved G1: 5 (25) G2: 3 (14) G1 vs G2: p=ns ABC-Irritability G1: 10.0 ± 7.8 G2: 10.8 ± 7.8 G1 vs G2: p=ns ABC-Social withdrawal/lethargy G1: 5.2 ± 4.4 G2: 13.6 ± 7.5 G1 vs G2: p<0.01 ABC-Stereotypy G1: 5.4 ± 3.8 G2: 6.7 ± 4.5

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		G2: 83.6 ± 9.2 PLS G1: 77.8 ± 29.2 G2: 57.1 ± 25.7 Vineland G1: 320.5 ± 47.9 G2: 274.4 ± 51.4	G1 vs G2: p=ns ABC-Hyperactivity G1: 18.2 ± 8.5 G2: 22.8 ± 10.3 G1 vs G2: p=ns ABC-Inappropriate speech G1: 2.6 ± 1.9 G2: 3.9 ± 3.6 G1 vs G2: p=ns SRS G1: 76.7 ± 10.9 G2: 83.2 ± 10.4 G1 vs G2: p=ns PLS G1: 84.0 ± 28.8 G2: 60.4 ± 25.4 G1 vs G2: p=0.01 Vineland G1: 344.76 ± 50.0 G2: 294.9 ± 70.1 G1 vs G2: p=0.02
Lv, et al., 2013[69] NRCT G1: Human cord blood mononuclear cells (CBMNCs) (2 × 10^6/kg) + rehabilitation therapy, 14/14 G2: CBMNCs + umbilical cord-derived mesenchymal stem cells (UCMSCs) (2 x 10^6/kg and 1 × 10^6/kg) + rehabilitation, 9/9 G3: Rehabilitation therapy, 14/13 5-7 days (4 transplants)/EOT High RoB	Age G1: 7.41 ± 2.63 G2: 6.20 ± 2.12 G3: 5.60 ± 2.01 IQ G1: NR G2: NR G3: NR	CARS G1: 46.43 ± 8.65 G2: 45.11 ± 4.31 G3: 43.15 ± 4.38 CGI NR ABC-Total G1: 94.07 ± 21.98 G2: 91.78 ± 25.92 G3: 75.46 ± 12.05 ABC-Irritability G1: 16.36 ± 9.61 G2: 15.00 ± 7.81 G3: 9.15 ± 5.58 ABC-Lethargy/Social withdrawal G1: 30.71 ± 6.08 G2: 31.00 ± 6.98 G3: 35.08 ± 4.96	**EOT** CARS G1: 37.14 ± 10.15 G2: 28.00 ± 6.18 G3: 37.23 ± 3.42 CGI-GI [N (%)] Very much improved G1: 1 (7.14) G2: 3 (33.33) G3: 0 (0) Much improved G1: 6 (42.86) G2: 5 (55.56) G3: 1 (7.69) Minimally improved G1: 2 (14.29) G2: 1 (11.11) G3: 11 (84.62) No change G1: 5 (35.71)

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		ABC-Stereotypic behavior G1: 29.43 ± 9.77 G2: 28.33 ± 8.47 G3: 22.77 ± 6.86 ABC-Hyperactivity G1: 11.86 ± 4.55 G2: 11.89 ± 6.88 G3: 6.08 ± 3.15 ABC-Inappropriate speech G1: 5.71 ± 4.30 G2: 5.56 ± 2.83 G3: 2.38 ± 2.10	G2: 0 (0.00) G3: 1 (7.69) Minimally worse G1: 0 (0.00) G2: 0 (0.00) G3: 0 (0.00) Much worse G1: 0 (0.00) G2: 0 (0.00) G3: 0 (0.00) Very much worse G1: 0 (0.00) G2: 0 (0.00) G3: 0 (0.00) CGI-EI [N (%)] Unchanged or worse G1: 5 (35.71) G2: 0 (0.00) G3: 1 (7.69) Minimal G1: 2 (14.29) G2: 1 (11.11) G3: 11 (84.62) Moderate G1: 7 (50.00) G2: 6 (66.67) G3: 1 (7.69) Marked G1: 0 (0.00) G2: 2 (22.22) G3: 0 (0.00) ABC-Total G1: 58.36 ± 31.73 G2: 36.78 ± 16.95 G3: 62.31 ± 11.3 G1 vs G3+ p<0.05 G2 vs G3: p< 0.05 ABC-Irritability G1: 8.14 ± 8.37 G2: 4.22 ± 3.19 G3: 6.92 ± 4.96 p=ns

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			ABC-Lethargy/Social withdrawal G1: 24.14 ± 9.65 G2: 16.00 ± 7.92 G3: 30.54 ± 5.03 G1 vs G3: p<0.05 G2 vs G3: p<0.05 ABC-Stereotypic behavior G1: 17.07 ± 9.93 G2: 9.33 ± 5.81 G3: 17.31 ± 4.05 G2 vs G3: p,0.05 ABC-Hyperactivity G1: 6.86 ± 5.26 G2: 4.67 ± 3.74 G3: 5.08 ± 2.40 p=ns ABC-Inappropriate speech G1: 2.14 ± 2.32 G2: 2.56 ± 2.19 G3: 2.46 ± 2.63 p=ns
Arnold, et al., 2012[70] RCT G1: Mecamylamine (0.5-5 mg/kg/day), 12/10 G2: Placebo (NA), 8/8 14 weeks/EOT Low RoB	Age G1: 6.76 ± 2.24 G2: 8.36 ± 2.83 IQ G1: 77.58 ± 21.12 G2: 62.62 ± 32.53	OACIS-S G1: 5.25 ± 0.75 G2: 5.63 ± 0.74 OARS G1: 1.83 ± 0.42 G2: 2.06 ± 0.45 ABC-Irritability G1: 12.75 ± 9.42 G2: 12.88 ± 9.60 ABC-Lethargy G1: 10.42 ± 6.61 G2: 17.00 ± 9.37 ABC-Stereotype G1: 4.17 ± 3.54 G2: 9.75 ± 6.25 ABC-Hyperactivity G1: 21.08 ± 11.74 G2: 19.13 ± 13.02	**Mean change score** OACIS-S G1: -0.58 ± 0.79 G2: -0.63 ± 0.74 OARS G1: -0.30 ± 0.33 G2: -0.32 ± 0.34 ABC-Irritability G1: -3.17 ± 8.76 G2: -5.00 ± 10.78 ABC-Lethargy G1: -4.25 ± 6.97 G2: -7.50 ± 9.56 ABC-Stereotype G1: -1.42 ± 2.64 G2: -1.63 ± 7.11 ABC-Hyperactivity G1: -6.92 ± 11.25

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		ABC-Inappropriate Speech G1: 4.50 ± 3.73 G2: 4.38 ± 3.16 RBS-Stereotypy G1: 4.58 ± 2.87 G2: 7.38 ± 3.16 RBS-Self Injury G1: 1.75 ± 2.01 G2: 4.50 ± 3.82 RBS-Compulsive G1: 5.50 ± 3.90 G2: 7.25 ± 4.53 RBS-Ritualistic G1: 6.00 ± 4.63 G2: 5.88 ± 4.91 RBS-Sameness G1: 8.08 ± 5.62 G2: 9.38 ± 6.14 RBS-Restricted G1: 3.92 ± 3.23 G2: 4.13 ± 2.75 SRS-Receptive G1: 11.92 ± 2.64 G2: 16.38 ± 2.62 SRS-Cognitive G1: 19.50 ± 2.88 G2: 22.75 ± 6.04 SRS-Expressive G1: 34.33 ± 8.14 G2: 39.88 ± 11.68 SRS-Motivation G1: 13.00 ± 4.69 G2: 19.13 ± 4.26 SRS-Preoccupations G1: 16.33 ± 6.88 G2: 22.50 ± 7.67 EVT	G2: -5.50 ± 12.06 ABC-Inappropriate speech G1: -1.50 ± 3.90 G2: -1.75 ± 2.38 RBS-Stereotypy G1: -1.92 ± 2.94 G2: -0.63 ± 6.21 RBS-Self injury G1: -0.83 ± 1.53 G2: -2.88 ± 4.39 RBS-Compulsive G1: -2.42 ± 3.55 G2: -3.50 ± 3.38 RBS-Ritualistic G1: -1.75 ± 4.58 G2: -2.00 ± 3.02 RBS-Sameness G1: -4.67 ± 6.05 G2: -2.50 ± 3.21 RBS-Restricted G1: -1.58 ± 2.50 G2: -1.13 ± 2.64 SRS-Receptive G1: 0.33 ± 1.78 G2: -2.25 ± 3.06 SRS-Cognitive G1: -2.50 ± 5.39 G2: -2.13 ± 5.74 SRS-Expressive G1: -4.17 ± 7.31 G2: -7.25 ± 8.55 SRS-Motivation G1: -3.83 ± 4.55 G2: -5.75 ± 4.89 SRS-Preoccupations G1: -3.33 ± 7.43 G2: -5.75 ± 4.89

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		G1: 74.0 ± 16.34 G2: 47.5 ± 24.74	EVT G1: -2.14 ± 10.12 G2: 0 ± 6.42
Hardan, et al., 2012[71] RCT G1: N-acetylcysteine (NAC) (900 mg up to 3 times/day), 15/134 G2: Placebo, 18/15 12 weeks/EOT Low RoB	Age G1: 7.0 ± 2.1 G2: 7.2 ± 2.2 IQ NR	ABC Irritability G1: 16.9±7.9 G2: 14.8±9.6 ABC Lethargy G1: 15.2±9.5 G2: 12.1±7.8 ABC Stereotypy G1: 9.1±5.5 G2: 8.9±6.5 ABC Hyperactivity G1: 23.4±9.0 G2: 23.8±9.3 ABC Inappropriate Speech G1: 4.9±3.2 G2: 4.1±3.7 RBS-R Stereotypies G1: 6.7±3.8 G2: 8.1±5.3 RBS Self-Injurious Behavior G1: 3.9±4.4 G2: 3.4±3.8 RBS Compulsions G1: 4.7±3.7 G2: 5.8±4.8 RBS Rituals G1: 5.3±3.7 G2: 6.6±4.5 RBS Sameness G1: 7.8±7.2 G2: 9.2±8.1 RBS Restricted G1: 4.7±3.4 G2: 5.2±3.7 SRS Total G1: 111.9±28.3	**EOT** ABC Irritability G1: 7.2±5.7 G2: 13.1±9.9 p<.001 ABC Lethargy G1: 11±9.4 G2: 8.3±7.7 p=.ns ABC Stereotypy G1: 5.6±5.7 G2: 8.0±7.0 p=ns ABC Hyperactivity G1: 12.4±11.4 G2: 21.0±11.5 p=ns ABC Inappropriate Speech G1: 2.5±2.6 G2: 3.6±3.6 p=ns RBS Stereotypies G1: 4.6±3.4 G2: 6.9±5.2 p= .014 RBS Self Injurious Behavior G1: 2.2±2.3 G2: 3.0±3.6 p=ns RBS Compulsions G1: 2.5±2.1 G2: 5.2±5.0 p=ns RBS Rituals G1: 4.3±3.4 G2: 5.6±4.9 p=ns

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		G2: 104.7±28.1 SRS Social Awareness G1: 12.7±3.4 G2: 13.5±3.7 SRS Social Cognition G1: 21.9±6.3 G2: 21.2±5.8 SRS Social Communication G1: 39.6±11.3 G2: 39.3±8.6 SRS Social Motivation G1: 16.6±6.3 G2: 16.9±6.5 SRS Autism Mannerisms G1: 21.7±5.6 G2: 21.4±7.3 CGI Severity G1: 5.1±0.7 G2: 5.3±0.8	RBS Sameness G1: 5.3±4.7 G2: 7.9±6.2 p=ns RBS Restricted G1: 3.5±2.3 G2: 4.8±3.6 p=ns SRS Total G1: 93.8±26.7 G2: 98.5±37.8 p=ns SRS Social Awareness G1:11.5±3.3 G2: 13.4±4.7 p=ns SRS social Cognition G1: 18.8±7.0 G2: 18.9±5.6 p=.037 SRS Social Communication G1: 33.3±10.9 G2: 34.5±14.5 p=.ns SRS Social Motivation G1: 13.0±4.7 G2: 14.5±7.0 p=ns SRS Autism Mannerisms G1: 16.0±6.1 G2: 20.3±6.9 p=.045 CGI Severity G1: 4.5±0.8 G2: 4.9±0.9 p=ns CGI Improvement G1: 2.9±1.1 G2: 3.2±.09 p=ns

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
Chez, et al., 2003[72] RCT G1: Donepezil hydrochloride only, / G2: Placebo/ Donepezil hydrochloride, / 12 wks/EOT Moderate RoB	Age G1: 6.8 (2.1-9.9) G2: 6.9 (4.1-10.3) IQ NR	CARS G1: 34.7 ± 7.7 G2: 35.1 ± 7.9 Expressive One-Word Picture Vocabulary Test (speech age in months) G1: 35.7 ± 27.8 G2: 31.9 ± 31.1 Receptive One-Word Picture Vocabulary Test (speech age in months) G1: 38.8 ± 23.5 G2: 33.5 ± 27.9	**End of 6 wks** CARS G1: 33.3 ± 8 G2: 32.9 ± 7.7 Expressive One-Word Picture Vocabulary Test (speech age in months) G1: 43.3 ± 27.2 G2: 33.8 ± 32.9 Receptive One-Word Picture Vocabulary Test (speech age in months) G1: 50.3 ± 27 G2: 39.83 ± 27 **EOT** CARS G1: 30.8 ± 7.9 G2: 30.9 ± 9.1 G1 vs G2, p<0.05 Expressive One-Word Picture Vocabulary Test (speech age in months) G1: 42.5 ± 28.5 G2: 40.9 ± 38.8 G1 vs G2, p<0.05 Receptive One-Word Picture Vocabulary Test (speech age in months) G1: 49.7 ± 34.2 G2: 87.37 ± 14.2 G1 vs G2, p<0.05
King, et al., 2001[73] RCT G1: Amantadine, 19/17 G2: Placebo, 20/17 4 wks/EOT Moderate RoB	Age 5-19 IQ >35	ABC – Irritability G1: 19.1 (3-38) G2: 18.7 (3-33) ABC – Hyperactivity G1: 29.4 (16-42) G2: 32.7 (17-46) CGI – Severity (Mild) G1: 0 (0) G2: 1 (5)	**EOT** ABC – Response rate (Reduction of at least 25% for irritability and/or hyperactivity) G1: 7 (37) G2: 9 (47) G1 vs G2, p=ns CGI – Improvement (Marked Improvement)

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
		CGI – Severity (Moderate) G1: 11 (57.8) G2: 11 (55) CGI – Severity (Severe) G1: 8 (42.1) G2: 7 (35)	G1: 5 (26) G2: 1 (5)
Duffy, et al., 2014[74] Retrospective Cohort G1: Steroid (2 mg/kg/day), 20/20 G2: Control (non- steroid treated) (NA), 24/24 4-14 months/EOT High RoB	Age G1: 3.909 ± 1.248 G2: 4.522 ± 1.800 IQ G1: NR G2: NR	EEG NR FMAER NR	**Mean change score** EEG change, n Improved G1: 3 G2: 8 No change G1: 10 G2: 12 Worse G1: 7 G2: 4 G1 vs G2: p=ns CLSQ mean change in scores Receptive G1: 4.80 G2: 0.167 Expressive G1: 4.10 G2: 0.542 Change in language scores, n Receptive Better G1: 17 G2: 6 No difference G1: 3 G2: 16 Worse G1: 0 G2: 2 G1 vs G2: p≤0.0002

Author, Year Study Design Groups (dose), N enrollment / N final Treatment duration/Follow-up timepoint post-treatment Risk of Bias	Mean age, years ± SD Mean IQ ±SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post-treatment scores, mean ± SD
			Expressive Better G1: 17 G2: 10 No difference G1: 2 G2: 13 Worse G1: 1 G2: 1 G1 vs G2: p≤0.0031

ABC-Aberrant Behavior Checklist; CGI-Clinical Global Impression; VABS-Vineland Adaptive Behavior Scale; CYBOCS-Children's Yale-Brown Obsessive Compulsive Scale; EOT-End of Treatment; SRS-Social Responsiveness Scale ; SDB-sleep-disordered breathing ; PLS-Preschool Language Scale ; EOWPVT-Expressive One Word Vocabulary Test ; CSHQ- ; DS-duration of sleep ; TST-Total Sleep Time ; CARS-Childhood Autism Rating Scale ; ADOS-Autism Diagnostic Observation Schedule ; ATEC-Autism Treatment Evaluation Checklist ; CGIS-Clinical Global Impression-Severity ; SOD-sleep onset delay; CGAS- Children's Global Assessment Scale; SOL-sleep onset latency ; WASO-wake after sleep onset ; SE-sleep efficiency; DBC-Developmental Behavior Checklist ; GHQ-General Health Questionnaire ; OSU- ; OACIS- ; OARS- ; RBS- ; EVT- ; EEG-electroencephalogram ; FMAER- frequency modulated auditory evoked response

Harms

Table F-7. Harms/adverse effects in studies of risperidone adjuncts

Harm/Adverse Event*	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
Risperidone + piracetam		
Appetite increase [56]	1 (7/20)	35%
Dry mouth [56]	1 (4/20)	20%
EPS/impaired movement [56]	1 (6/20)	30%
Gastrointestinal problems [56]	1 (4/20)	20%
Somnolence [56]	1 (23/20)	%
Risperidone + amantadine		
Appetite increase [52]	1(6/20)	30%
Risperidone + buspirone		
Appetite Increase [45]	1 (10/16)	61.1%
Somnolence [45]	1 (3/16)	18.75%
Risperidone + celecoxib		
Appetite Increase [48]	1 (3/20)	15%
Dizziness [48]	1 (2/20)	10%
GI [48]	1 (5/20)	25%
Insomnia [48]	1 (2/20)	10%
Somnolence [48]	1 (3/20)	15%
EPS/impaired movement [48]	1 (10/20)	50%
Risperidone + Galantamine		
Agitation/nervousness/restlessness [51]	1 (4/20)	20%
Appetite Increase [51]	1 (8/20)	40%
Somnolence [51]	1 (2/20)	10%

Harm/Adverse Event*	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
Risperidone + Ginkgo biloba		
Agitation/nervousness/restlessness [53]	1 (8/23)	
Appetite decrease [53]	1 (3/23)	13%
Appetite Increase [53]	1 (6/23)	26.1%
EPS/impaired movement [53]	1 (5/23)	21.7%
GI symptoms[53]	1 (8/23)	34.8%
Somnolence [53]	1 (13/23)	56.5%
Risperidone + memantine		
Appetite increase [49]	1 (2/20)	10%
Dizziness [49]	1 (3/20)	15%
GI [49]	1 (5/20)	25%
Skin Changes [49]	1 (2/20)	10%
Somnolence [49]	1 (4/20)	20%
EPS/impaired movement [49]	1 (6/20)	30%
Risperidone + N-Acetylcysteine		
Agitation/nervousness/restlessness [47]	1 (6/17)	35.3%
Appetite decrease [47]	1 (3/17)	17.6%
Appetite Increase [47]	1 (5/17)	29.4%
Dry mouth [46]	1 (2/20)	10%
EPS/impaired movement [47]	1 (7/20)	35%
Gastrointestinal problems[46, 47]	2 (23/37)	5.9%-30%
Headache [46]	1 (4/20)	20%
Somnolence [47]	1 (9/20)	45%
Risperidone + Pentoxifylline		
Agitation/nervousness/restlessness [54]	1 (2/20)	10%
Appetite increase [54]	1 (8/20)	40%
Dry mouth [54]	1 (2/20)	10%
Gastrointestinal problems[54]	1 (6/20)	30%
Somnolence [54]	1 (9/20)	45%
Weight gain [54]	1 (8/20)	40%
EPS/impaired movement [54]	1 (7/20)	25%
Risperidone + Pioglitazone		
Dizziness [44]	1 (2/20)	20%
Gastrointestinal problems[44]	1 (10/20)	50%
Headache [44]	1 (3/20)	15%
Risperidone + placebo		
Agitation/nervousness/restlessness [47, 50-54, 56]	7 (18/138)	4.2%-20.8%
Appetite decrease [45, 47-49, 51-56]	10 (19/196)	5%-20%
Appetite increase [45, 47-54, 56]	10 (43/196)	10%-41.7%
Dizziness [44, 48, 49, 53, 55]	5 (14/104)	5%-20%
Drooling/increased saliva [50, 52, 53]	3 (10/64)	5%-30%
Dry mouth [44-46, 53, 54, 56]	6 (11/122)	4.2%-15%
EPS/impaired movement [48-50, 53-56]	7 (45/144)	4.2%-45%
Gastrointestinal problems [44, 46-56]	12 (55/238)	5%-30%
Headache [44, 46]	2 (5/40)	10%-15%
Infection/fever/cold/congestion symptoms [53]	1 (5/24)	20.8%
Insomnia [48, 49, 55]	3 (8/60)	5%-25%
Paresthesia [55]	1 (5/20)	25%
Skin Changes [47, 49]	2 (2/34)	5%-7.1%
Somnolence [47-51, 53-56]	9 (59/178)	5%-45%
Weight Gain [54]	1 (7/20)	35%
Risperidone + Riluzole		
Agitation/nervousness/restlessness [50]	1 (7/20)	35%
Appetite decrease [50]	1 (2/20)	10%

Harm/Adverse Event*	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
Appetite Increase [50]	1 (12/20)	60%
Drooling/Increased Saliva [50]	1 (6/20)	60%
EPS/Impaired movement [50]	1 (4/20)	10%
Gastrointestinal problems [50]	1 (10/20)	50%
Somnolence [50]	1 (10/20)	50%
Risperidone + Topiramate		
Appetite decrease [55]	1 (7/20)	35%
Dizziness [55]	1 (4/20)	20%
Gastrointestinal problems [55]	1 (6/20)	30%
Insomnia [55]	1 (5/20)	25%
Paresthesia [55]	1 (5/20)	25%
Somnolence [55]	1 (8/20)	40%
EPS/impaired movement [55]	1 (9/20)	45%

*Harms reported by more than one participant. EPS=extrapyramidal symptoms; GI=gastrointestinal

Table F-8. Harms/adverse effects in studies of citalopram

Harm/Adverse Event*	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
Citalopram hydrobromide		
Agitation/Nervousness/Restlessness [75, 76]	1 (13/73)	17.8%
Anxiety [75, 76]	1 (8/73)	11%
Appetite increase [75, 76]	1 (7/73)	9.6%
Appetite decrease [75, 76]	1 (11/73)	15.1%
Attention [75, 76]	1 (9/73)	12.3%
Challenging behavior [75, 76]	1 (64/73)	87.7%
Energy level changes [75, 76]	1 (28/73)	38.4%
GI symptoms [75, 76]	1 (46/73)	63%
Headache [75, 76]	1 (15/73)	20.5%
Hyperactivity [75, 76]	1 (9/73)	12.3%
Infection/Fever/Cold/Congestion symptoms [75, 76]	1 (56/73)	76.7%
Insomnia [75, 76]	1 (28/73)	38.4%
Nightmares [75, 76]	1 (5/73)	6.8%
Repetitive behavior or language [75, 76]	1 (8/73)	11%
Seizure [75, 76]	1 (2/73)	2.7%
Silliness [75, 76]	1 (9/73)	12.3%
Skin changes [75, 76]	1 (21/73)	28.8%
Placebo		
Agitation/Nervousness/Restlessness [75, 76]	1 (7/76)	9.2%
Anxiety [75, 76]	1 (9/76)	11.8%
Appetite increase [75, 76]	1 (8/76)	10.5%
Appetite decrease [75, 76]	1 (10/76)	13.2%
Attention[75, 76]	1 (2/76)	2.6%
Challenging behavior [75, 76]	1 (44/76)	57.9%
Energy level changes [75, 76]	1 (15/76)	19.7%
GI [75, 76]	1 (24/76)	31.5%
Headache [75, 76]	1 (10/76)	13.2%
Hyperactivity [75, 76]	1 (2/76)	2.6%
Infection/Fever/Cold/Congestion symptoms [75, 76]	1 (42/76)	55.3%
Insomnia [75, 76]	1 (17/76)	22.4%
Silliness [75, 76]	1 (10/76)	13.2%
Skin changes [75, 76]	1 (9/76)	11.8%
Somnolence [75, 76]	1 (10/76)	13.2%

*Harms reported by more than one participant. GI=gastrointestinal; EPS-extrapyramidal

Table F-8. Harms/adverse effects in studies of diet and nutritional supplements

Harm/Adverse Event*	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
Omega 3 fatty acids		
Appetite decrease [31]	1 (7/18)	38.9%
Bruising [31]	1 (4/18)	22.2%
Challenging behaviors [31]	1 (11/18)	61.1%
Epistaxis [33, 36]	2 (2/43)	3.4%-7.1%
Eye/Vision changes [31]	1 (3/18)	16.7%
GI symptoms [31, 33, 36]	3 (28/61)	3.4%-50%
Hyperactivity [31]	1 (3/18)	16.7%
Infection/Fever/Cold/Congestion symptoms [31, 33, 36]	3 (39/61)	3.4%-22.2%
Insomnia [31]	1 (13/18)	72.2%
Lethargy [31]	1 (4/18)	22.2%
Right leg internal rotation [31]	1 (2/18)	11.1%
Self-stimulation [33]	1 (2/29)	6.9%
Skin changes [31, 33, 36]	3 (17/61)	3.4%-55.6%
DHA		
Agitation/Nervousness/Restlessness [34]	1 (2/24)	8.3%
Gluten-Dairy Free Diet		
GI symptoms [41]	1 (3/6)	50%
Gluten-Dairy Containing Diet		
GI [41]	1 (3/6)	50%
Peptizyde		
Challenging behavior [39]	1 (5/21)	23.8%
Placebo		
Appetite decrease [31]	1 (3/19)	15.8%
Bruising [31]	1 (2/19)	10.5%
Challenging behavior [31, 39]	2 (10/41)	4.5%-21.1%
Epistaxis [31]	1 (3/19)	15.8%
Eye/Vision changes [31, 33]	2 (2/47)	3.6%-5.3%
Hyperactivity [36]	1 (3/13)	23.1%
Infection/Fever/Cold/Congestion symptoms[a] [31, 33]	2 (24/47)	3.6%-26.3%
Insomnia [31]	1 (7/19)	36.8%
Lethargy [31]	1 (2/19)	10.5%
Skin changes [31]	1 (17/19)	89.5%
Urinary changes [31]	1 (2/19)	10.5%

*Harms reported by more than one participant

[a]One study[31] incorrectly reports number of patients in each group that reported upper respiratory infections. This harm was not included in the "Infection/fever/cold/congestive symptoms" count in this table.

GI=gastrointestinal; EPS=extrapyramidal

Table F-9. Harms/adverse effects in studies of other medical interventions

Harm/Adverse Event*	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
Active tDCS stimulation		
Skin changes [65_63]	1 (3/10)	30%
Amantadine		
Challenging behavior [73]	1 (2/19)	10%
Insomnia [73]	1 (4/19)	21%
Somnolence [73]	1 (2/19)	10%
Bumetanide		
Hyperactivity [60]	1 (2/27)	7.4%
Divalproex sodium		
Agitation/nervousness/restlessness [58]	1 (2/16)	12.5%
Infection/fever/cold/congestion symptoms [58]	1 (2/16)	12.5%
Insomnia [58]	1 (2/16)	12.5%
Skin changes [58]	1 (2/16)	12.5%
Urinary changes [58]	1 (2/16)	12.5%
Donepezil hydrochloride		
Challenging behavior [72]	1 (5/17)	29.4
Mecamylamine		
Appetite decrease [70]	1 (4/12)	33.3%
EPS/impaired movement [70]	1 (2/12)	16.7%
GI symptoms [70]	1 (9/12)	75%
Infection/fever/cold/congestion symptoms [70]	1 (9/12)	75%
Mental symptoms [70]	1 (6/12)	50%
Somnolence [70]	1 (5/12)	41.7%
Melatonin		
Appetite decrease [64]	1 (2/6)	35.3%
GI symptoms [64]	1 (4/6)	70.6%
Somnolence [64]	1 (4/6)	70.6%
N-acetylcysteine		
Agitation/nervousness/restlessness [71]	1 (3/14)	21.4%
Appetite decrease [71]	1 (2/14)	14.3%
Appetite increase [71]	1 (2/14)	14.3%
EPS/impaired movement [71]	1 (3/14)	21.4%
GI symptoms [71]	1 (14/14)	100%
Infection/fever/cold/congestion symptoms [71]	1 (4/14)	28.6%
Tetrahydrobiopterin		
Challenging behavior [68]	1 (4/20)	22%
Hyperactivity [68]	1 (2/20)	9%
Insomnia [68]	1 (2/20)	9%
Skin changes [68]	1 (2/20)	9%
Steroid		
Challenging behavior [74]	1 (10/20)	50%
Cushingoid appearance [74]	1 (18/20)	90%
Hypertension [74]	1 (2/20)	10%
Regression [74]	1 (2/20)	10%
Sleep changes [74]	1 (2/20)	10%
Weight gain [74]	1 (19/20)	95%
HBOT		
Barotrauma [61]	1 (11/29)	37.9%
Placebo		
Agitation/nervousness/restlessness [58, 71]	2 (4/26)	6.7%-13.3%
Appetite decrease [64, 70, 71]	2 (13/33)	20%-62.5%
Barotrauma [61]	1 (3/29)	10.3%

Harm/Adverse Event*	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
Challenging behavior [68, 73]	2 (8/41)	17%-21%
Drooling/increased saliva [71]	1 (2/15)	13.3%
EPS/impaired movement [70, 71]	2 (5/23)	6.7%-25%
GI symptoms [64, 68, 70, 71, 74, 77]	6 (28/81)	6.7%-87.5%
Infection/fever/cold/congestion symptoms [58, 70, 71]	3 (15/34)	27.3%-75%
Insomnia [58, 70, 71]	3 (8/52)	9.1%-17%
Mental symptoms [70]	1 (4/8)	50%
Repetitive behavior or language [68]	1 (2/22)	9%
Seizure [62, 68]	2 (2/37)	4.5%-6.7%
Skin changes [60, 77]	2 (2/53)	3.7%-3.85%
Somnolence [58, 64, 70]	3 (23/29)	25%-81.3%

*Harms reported by more than one participant. GI=gastrointestinal; EPS=extrapyramidal

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