

# **Evaluation and Treatment of Tinnitus: A Comparative Effectiveness Review**

## **APPENDICES**



**APPENDIX A.**  
**Search Strategy**

# Search Strategy: Tinnitus

## **Medline-OVID**

1946-June 13 2012

1. Tinnitus/ or tinnitus.ti.
2. animals/ not humans/
3. 1 not 2
4. limit 3 to english language
5. limit 4 to (case reports or comment or editorial or in vitro or interview or letter or newspaper article or webcasts)
7. 4 not 5

## **Embase-OVID**

1980-June 13 2012

1. Tinnitus/ or tinnitus.ti.
2. limit 1 to english language
3. limit 2 to (book or book series or conference abstract or conference paper or editorial or letter or note)
4. 2 not 3
5. limit 4 to human

## **Cochrane Controlled Trials Registry-OVID**

June 13 2012

1. Tinnitus/ or tinnitus.ti.

## **PsycINFO-OVID**

1967-June 13 2012

1. Tinnitus/ or tinnitus.ti.
2. animals/ not humans/
3. 1 not 2
4. limit 3 to english language
5. limit 4 to (abstract collection or chapter or "column/opinion" or "comment/reply" or dissertation or editorial or encyclopedia entry or letter or obituary or poetry or review-book or review-media or review-software & other)
6. 4 not 5

## **AMED-OVID**

1985-June 13 2012

1. Tinnitus/ or tinnitus.ti.
2. animals/ not humans/
3. 1 not 2
4. limit 3 to english language

## **APPENDIX B.**

### **Data Extraction Forms**

## Title & Abstract Screening Form – Level 1

- 1. This article was published prior to 1970.**
  - Yes (submit for now)
  - No/unsure
- 2. Is this an animal research study? (hint)**
  - Yes (stop)
  - No/Unclear
- 3. What is the age group of the research participants? (hint)**
  - Under 18 years (stop)
  - 18 years of age or older/Unclear
- 4. Is the research limited to a focus on pulsatile tinnitus only? (hint)**
  - Yes (stop)
  - No/Unclear
- 5. Does the research address any of the following:**
  - a) Tinnitus symptoms [please see (hint) below]**
  - b) Tinnitus diagnosis; or diagnostic instruments/tests**
  - c) Tinnitus treatments/interventions (hint)**
    - Yes/Unclear
    - No (stop)
- 6. What is the research study design? (hint)**
  - Randomized control trial, clinical control trial, other randomized trial
  - Observational study (cohort, case-control, prospective, retrospective, longitudinal, cross sectional, case series)
  - Systematic review or meta-analysis
  - Narrative or descriptive review or book chapter (stop)
  - Case study (stop)
  - Unclear
- 7. Is the publication in English?**
  - Yes/Unclear
  - No

## Title & Abstract Level 1 Screening Form Help Sheet

<p><b>2. Is this an animal research study?</b></p> <p><b>Yes [stop]</b> -- <i>i.e., the research participants are not human, implication of findings are not sufficient to retain citation in our search. If yes, submit this form now.</i></p> <p><b>No/Unclear</b></p>
<p><b>3. What is the age group of the research participants?</b></p> <p><b>Under 18 years [stop]</b> -- <i>i.e., a teenage or pediatric population. If yes, submit this form now.</i></p> <p><b>18 years of age or older/Unclear</b></p>
<p><b>4. Is the research limited to a focus on pulsatile tinnitus only?</b></p> <p><b>Yes [stop]</b> -- <i>please note: Pulsatile Tinnitus may be referred to as "PT" or "objective tinnitus". Pulsatile tinnitus can be heard by a doctor using a stethoscope (like a pulse), an audible sound emanates from the patient's ears. The sound may have an identified cause.</i></p> <p><b>If yes, submit form now.</b></p> <p><b>No/Unclear</b></p>
<p><b>5. Does the research address any of the following:</b></p> <p><b>a) Tinnitus symptoms</b> <b>b) Tinnitus diagnosis; or diagnostic instruments/tests</b> <b>c) Tinnitus treatments/interventions</b></p> <p><b>Yes/Unclear -- any or all of these subjects themes are considered</b></p> <p><b>a) Symptoms</b> – ringing, buzzing in the ears, qualification of the sound perceived (e.g., pitch, volume) <b>b) Diagnosis, diagnostic instruments/tests</b> – <i>i.e., evaluation of the perception of sound, source of sound, and/or impact on patient's daily life (e.g., physical exam, questionnaires, hearing test, CT scan, MRI)</i> <b>c) Treatments/interventions</b> – <i>i.e., medical/surgical (e.g., Pharmacological, Laser, TMJ and Complementary/Alternative Medicine therapies or treatments), technological (e.g., sound maskers, hearing aids, etc.), psychological (e.g., Tinnitus Retraining therapy, Cognitive Behavioral Therapy, etc.); alternative medicine; or combinations thereof</i></p> <p><b>No [stop]</b> -- <i>None of the above are addressed or Tinnitus is a result of another pathology (e.g., a symptom or outcome of another illness/disease/drug, i.e., brain tumor, hypertension, drug side effect/interaction). If so, submit this form now</i></p>
<p><b>6. What is the research study design?</b></p> <p><b>RCT or CCT (Randomized control trial, clinical control trial, other research that has been randomized)</b>  <u>Randomized Controlled Trial RCT:</u> A controlled clinical trial that randomly (by chance) assigns participants to one of two or more groups. There are various methods to randomize study participants to their groups. Identifying words: – randomization; Open trials; Single blind trials; Double blind trials; Triple and quadruple-blind trials; explanatory trial.  <i>Example:</i> An example is a <i>randomized controlled trial</i> (RCT) to understand whether calcium tablets work to prevent broken bones in women with low bone density. Women with low bone density are randomly assigned to one of two groups. One group receives calcium and the control group receives a placebo (inactive substance). The number of women who suffer fractures in each group are compared to find out whether calcium works. <u>Controlled Clinical Trial CCT:</u> A type of clinical trial comparing the effectiveness of one medication or treatment with the effectiveness of another medication or treatment. In many controlled trials, the other treatment is a placebo (inactive substance) and is considered the "control". <i>Example:</i> An example of a <i>controlled clinical trial</i> is one in which people who took a particular anti-depressive drug were compared with people who did not take the drug to determine its effectiveness in lowering blood pressure.</p> <p><b>Observational study (cohort, case-control, case-series)</b>  <u>Cohort Study:</u> A clinical research study in which people who presently have a certain condition or receive a particular treatment are followed over time and compared with another group of people who are not affected by the condition.  <i>Example:</i> For example, a study that measures effects of tinnitus on quality of life in the same group of men and women with different blood pressure levels over a long period of time.  <u>Case-control study (also called a retrospective study):</u> A study that compares two groups of people: those with the disease or condition under study (tinnitus) and a very similar group of people who <i>do not</i> have the disease or condition. Researchers study the medical and lifestyle histories of the people in each group to learn what factors may be associated with the disease or condition. For example, in the case of tinnitus, they may look at environmental noise influences, current drugs being taken, etc.</p>

<p><b>Case Series</b> (also known as a <i>clinical series</i>): a medical research <a href="#">observational study</a> that tracks patients with a known exposure given similar treatment or examines their medical records for exposure and outcome. (Example: 100 patients with tinnitus using a masking device – impact of tinnitus is measured prior to use of device and after; or 100 active-duty soldiers exposed to noise with outcome of tinnitus treated with....). It can be retrospective or <a href="#">prospective trials</a>. Case series may be <i>consecutive</i> or <i>non-consecutive</i>, depending on whether all cases presenting to the reporting authors over a period of time were included, or only a selection. Case series studies do <b>not</b> make comparisons <i>between</i> groups.</p>
<p><b>Systematic review or meta-analysis</b>  <u>Systematic Review</u>: A summary of the clinical literature. A systematic review is a critical assessment and evaluation of all research studies that address a particular clinical issue. The researchers use an organized method of locating, assembling, and evaluating a body of literature on a particular topic using a set of specific criteria. A systematic review typically includes a description of the findings of the collection of research studies. The systematic review may also include a quantitative pooling of data, called a meta-analysis. <i>Example</i>: Scientists collect all the published studies that compare types of treatment for hypertension. They compile the results of these studies, using in-depth statistical methods (a comparative effectiveness review which is a type of <i>systematic review</i>.)</p>
<p><b>Narrative or descriptive review [stop] Submit form now</b></p>
<p><b>Case study [stop] Submit form now</b>  <b>Case Study</b> Like a case series, but focused only a single case. WE ARE NOT INTERESTED IN SINGLE CASE STUDIES</p>
<p><b>Unclear – another type of design is mentioned or the citation does not discuss research design</b></p>

## Title & Abstract Screening Form – Level 2

**1. Do any of the following apply to this abstract? If you check any, you are finished and can submit.**

- This is not a tinnitus study (stop)
- Publication date is prior to 1970 (stop)
- Language other than English (specify and stop)
- Editorial, comment, conference abstract, letter, opinion piece (stop)
- Animal study (stop)
- Population under 18-years (stop)
- Case study (n=1) (stop)
- Case series (stop)
- Narrative or literature review, dissertations, abstract, or study protocol
- Systematic review
- Meta-analysis (stop)

**2. Please consider the following carefully. If you check any, you are finished and can submit this form now.**

- Tinnitus symptoms are the side-effect of a drug (ototoxicity)
- The research is focused on another problem/pathology. There are no results related to tinnitus
- The Research focuses on the pathophysiology of tinnitus (see help sheet for examples)
- Tinnitus is the symptom of a vestibular schwannoma or acoustic neuroma; and/or is of a pulsatile nature only

**3. The study design includes a comparison/control group (i.e., compares treatment to placebo; treatment to no treatment; a group being treated to a group on a wait list for treatment; one treatment to another treatment, with controls)**

- Yes/Unclear (continue)
- No (stop)

***Note: The following questions will determine the Key Question(s) this study will be assigned consult review sheet and consider carefully. Check 'yes' to all that apply.***

**4. This study addresses one or more clinical evaluation measures/tools used to characterize a subjective diagnosis and/or measure the severity of tinnitus. Consult review sheet for examples.**

- Yes

**5. This study evaluates one or more tinnitus treatments or interventions. Consult review sheet for examples.**

- Yes

6. **This study addresses one or more potential predictors of treatment outcomes. This could be characteristics, symptom characteristics, or prognostic factors. Consult review sheet for examples.**
  - Yes
7. **This study is about adults at risk for tinnitus.**
  - Yes [identify at risk group] \_\_\_\_\_
8. **It is unclear from the abstract if #4, #5, #6, or #7 apply.**
  - Yes
  - No abstract available

## Title & Abstract Level 2 Screening Form Help Sheet

**Question 2: Response 3: Pathophysiology** of tinnitus i.e., brain or neuron activity patterns, brain-based mechanisms, activity in the brain or specific regions in the brain; brain responses, function, process (mechanisms in the central nervous system), plasticity, neuronal firing, varied otoacoustic emissions [OAE], etc. The research does not investigate ways of measuring the subject's perception of tinnitus or treatments for tinnitus

### Question 4: Clinical evaluation measures

Scales/questionnaires used to assess severity of tinnitus: Tinnitus Handicap Inventory, Tinnitus Reaction Questionnaire, Tinnitus Functional Index, Visual Analog Scale, and Tinnitus Severity Index, etc.

**Question 5: Tinnitus Interventions:** Any treatment/therapy (or combination of treatments/therapies) used to reduce or help cope with tinnitus including **but not limited to:**

<b>Medical / Surgical</b>	<ul style="list-style-type: none"> <li>■ Pharmacological treatments               <ul style="list-style-type: none"> <li>□ Tricyclic antidepressants (e.g., amitriptyline, nortriptyline, and trimipramine)</li> <li>□ Selective serotonin-reuptake inhibitors: fluoxetine and paroxetine</li> <li>□ Other: trazodone; anxiolytics (e.g., alprazolam); vasodilators and vasoactive substances (e.g., prostaglandin E1); intravenous lidocaine; gabapentin; Botox (botulinum toxin type A); and pramipexole)</li> </ul> </li> <li>■ Laser treatments</li> <li>■ TMJ treatment: dental orthotics and self-care; surgery</li> <li>■ Transcranial Magnetic Stimulation</li> <li>■ Complementary and alternative medicine therapies: <i>G. biloba</i> extracts; acupuncture; hyperbaric oxygen therapy; diet, lifestyle and sleep modifications (caffeine avoidance, exercise)</li> </ul>
<b>Sound Treatments</b>	Hearing Aids; Sound generators / maskers (both wearable and stationary); Cochlear implants; Neuromonics; Tinnitus Retraining Therapy
<b>Psychological / Behavioral</b>	Cognitive behavioral therapy; Biofeedback; Education; Relaxation therapies; Progressive Tinnitus Management

### Question 6: Predictors of treatment outcomes

<b>Prognostic Factors:</b>	Length of time to treatment after onset, audiological factors (degree and type of hearing loss, hyperacusis, loudness tolerance, masking criteria, etc.), head injury, anxiety, mental health disorders, duration of tinnitus
<b>Patient Characteristics</b>	Age, gender, race, medical or mental health comorbidities, socioeconomic factors, noise exposure (environmental, recreational and work-related, including active military duty personnel or veterans, and occupational hazards), involvement in litigation, third party coverage (health insurance)
<b>Symptom Characteristics</b>	Origin/presumed etiology of tinnitus, tinnitus duration since onset, subcategory of tinnitus, severity of tinnitus

## Full Text Screen

- 1. Do any of the following apply to this paper? If yes, check and submit this form now.**
  - It is not English
  - It does not involve humans
  - Subjects are under 18 years of age
  - The tinnitus being studied is pulsatile
  - Tinnitus is the side-effect of a drug (ototoxicity)
  - This is a case study/report (n=1)
  - This is a case series (specify number of subjects and stop) \_\_\_\_\_
  - Article unavailable to order
- 2. Is this study ONLY to determine the prevalence of tinnitus in a population group at any given time?**
  - Yes (stop)
  - No (continue)
- 3. Is this study ONLY to determine various effects of tinnitus on an individual (e.g., effect on memory, etc)?**
  - Yes (stop)
  - No (continue)
- 4. Is this study ONLY focused on ways of determining whether a patient has 'malingered' tinnitus?**
  - Yes (stop)
  - No (continue)
- 5. Tinnitus is the result of issues in the middle ear (i.e., mechanics, otitis media, otosclerosis, eustachion tube, pressure, etc.) or the intervention is a stapedectomy or tympanoplasty.**
  - Yes (stop)
  - No (continue)
- 6. Is this a primary study (i.e., the original publication of new data and results)?**
  - Yes, e.g. RCT, cohort study, etc. (continue)
  - No, it is a systematic review or meta-analysis (stop)
  - No, it is not primary research (e.g., editorial, comment, conference abstract, letter, opinion piece, protocol, narrative/DESCRIPTIVE study)[Stop]
- 7. Does the study COMPARE:**
  - a) More than one tool/method that RESULT in candidacy for further evaluation or treatment?
  - b) Group treatment outcomes (e.g. treatment to placebo; treatment to no treatment; one treatment to another treatment, with controls)
  - c) Both a and b
  - d) None of the above (comparators do not meet inclusion criteria)
  - e) insufficient detail for aggregation of data/results

## Full Text Screening Form Help Sheet

1. Do any of the following apply to this paper? IF YOU CHECK ANY ANSWERS BELOW YOU ARE FINISHED THIS REVIEW.
  - a. It is not in English (stop)
  - b. It does not involve humans (stop)
  - c. Subjects are under 18 years of age (stop)
  - d. The tinnitus being studied is of a pulsatile nature. NOTE: Pulsatile Tinnitus may be referred to as PT, Objective, OT, or Functional. Pulsatile tinnitus can be heard by a doctor using a stethoscope (like a pulse), an audible sound emanates from the patient's ears. The sound HAS AN IDENTIFIABLE CAUSE (ACOUSTIC NEUROMA, for example). Our interest is in subjective (only the patient can hear it), idiopathic (of unknown origin/cause) tinnitus
  - e. Tinnitus is the side-effect of a drug (ototoxicity). NOTE: if the article is about a drug and mentions tinnitus as a symptom of taking the drug, we are not interested. IN GENERAL, IF A CHANGE IN MEDICATION WOULD LEAD TO TINNITUS DISAPPEARING, the study should be excluded here.
  - f. This is a Case report/study (N=1) Note: a case report is a descriptive study of a single individual in which the possibility of an association between an observed effect and a specific exposure is based on a detailed clinical evaluation and history of the individual.
  - g. This is a case series. [Specify number of subjects and stop] Note: A case series is a descriptive study that follows a group of patients who all have the same diagnosis or who are all undergoing the same procedure/treatment over a certain period of time. Case series do not employ control groups. Results of case series can generate hypotheses that are useful in designing further studies, including randomized controlled trials. However, no causal inferences should be made from case series regarding the efficacy of the investigated treatment.
  
2. Is this study only to determine the prevalence of tinnitus in a population group at any given time? NOTE: A prevalence study could be in a general or a specialized population. The study may look at how many people in Timbuktu have tinnitus or what percentage of the elderly people in Timbuktu over 60 has tinnitus. If this is only a prevalence study we are not interested. HOWEVER, if the study on the elderly with tinnitus in Timbuktu then went on to do further evaluation/treatment research with that population, you would not exclude the study at this point.
  
3. Is this study only to determine various effects of tinnitus on an individual (e.g., effect on sleep or brain wave patterns; effect on memory)? Yes [STOP] NOTE: We are not interested in research on how people with tinnitus have memory problems or what the brain wave patterns of people with tinnitus are, or the fact that people with tinnitus can't sleep. If the study only looks at a way that tinnitus affects an individual but does not look at ways of determining their candidacy for treatment or is not an evaluation of a treatment outcome, it should be excluded.

4. Is this study only focused on ways of determining whether a patient has ‘malingering’ tinnitus? Fabricating or exaggerating the symptoms of tinnitus for a variety of "secondary gain" motives; for example to claim insurance benefits, avoid work, etc.
6. Does this report describe a primary study (i.e., the original publication of new data and results)
7. Does the study design compare:
  - a. More than one method of evaluation to determine candidacy for treatment i.e., the study compares two different scales/questionnaires (tinnitus handicap inventory vs. functional tinnitus index) used to assess severity of tinnitus in order to determine need for further treatment.
  - b. Group treatment outcomes (i.e., one group gets a treatment drug compared to one getting a placebo; one group gets treatment compared to another group getting no treatment; a group being treated compared to a group on a waiting list for treatment; one treatment compared to another treatment; a before/after treatment comparison; within-group comparison; between-group comparison).
  - c. Both a and b
  - d. There is no comparison of methods for evaluating tinnitus or tinnitus treatment outcomes in this study

## Data Extraction

**1. Study design:**

- Randomized clinical trial
- Nonrandomized trial (quasi-experimental, interrupted time series design, etc.)
- Controlled clinical trial (not randomized)
- Cohort, prospective
- Cohort, retrospective
- Case-control
- Cross-sectional
- Before-after
- Other (identify) \_\_\_\_\_

**2. Is there any reason this study should be excluded?**

- Yes (identify) \_\_\_\_\_
- No (continue)

**3. Is this a pilot study?**

- Yes
- No

**4. Country**

\_\_\_\_\_  
**5. Setting (e.g., primary care, ENT, audiology, neurology, mental health service, community, internet, other-identify, etc.)**

\_\_\_\_\_  
**6. Is this the primary diagnosis of subjects in this study subjective (idiopathic, nonpulsatile) tinnitus?**

- Yes
- No, tinnitus is secondary to (a symptom of) another diagnosis [identify primary diagnosis-for example Meniere's disease]\_\_\_\_\_

**7. If tinnitus is secondary to another diagnosis, are there results provided specific to the effect of an intervention on the tinnitus symptoms?**

- Not applicable
- Yes (continue)
- No (submit form now)

**8. Please describe the population included in the study (selection criteria and the number excluded if provided):**

**9. Number of intervention groups** \_\_\_\_\_

**10. Number of control groups** \_\_\_\_\_

**11. Please report the AGE CHARACTERISTICS (if applicable):**

<b>Characteristics</b>	<b>All Patient n=?</b> _____	<b>Intervention Group 1 (I1) n=?</b> _____	<b>Control Group 1 (C1) n=?</b> _____	<b>Identify Group (I# or C#) and n=?</b> _____	<b>Identify Group (I# or C#) and n=?</b> _____	<b>Identify Group (I# or C#) and n=?</b> _____	<b>Identify Group (I# or C#) and n=?</b> _____
<b>Mean</b>							
<b>Standard Dev.</b>							
<b>Standard Error</b>							
<b>Median</b>							
<b>Inter Quartile Range</b>							
<b>Min</b>							
<b>Max</b>							

**12. NOTES for AGE**

**13. Please report GENDER (if applicable):**

<b>Gender</b>	<b>n/% All Patient</b> _____	<b>n/% Intervention 1 (I1)</b> _____	<b>n/% Control 1 (C1)</b> _____	<b>n/% Identify Group (I# or C#)</b> _____	<b>n/% Identify Group (I# or C#)</b> _____
<b>FEMALE</b>					
<b>MALE</b>					

**14. a) NOTES for GENDER**

**15. Please report RACE/ETHNICITY (if applicable):**

<b>Characteristics</b>	<b>n/% All Patient</b>	<b>n/% Intervention 1 (I1)</b>	<b>n/% Control 1 (C1)</b>	<b>n/% Identify Group (I# or C#)</b>	<b>n/% Identify Group (I# or C#)</b>	<b>n/% Identify Group (I# or C#)</b>	<b>n/% Identify Group (I# or C#)</b>
White/Caucasian							
African- American/Black							
Hispanic							
Aboriginal							
Asian							
Other 1							
Other 2							
Other 3							

If other 1, please specify race/ethnicity: \_\_\_\_\_

If other 2, please specify race/ethnicity: \_\_\_\_\_

If other 3, please specify race/ethnicity: \_\_\_\_\_

**16. Identify any medical and/or mental health comorbidities. Record any data and source location if applicable.**

**17. Identify the treatment intervention in this study. (Note: if the study is comparing the effectiveness of two or more interventions, identify all. Use text box to add brief detail- i.e., drug name(s), device name(s), etc.)**

- Pharmacological [identify drug(s) being studied] \_\_\_\_\_
- Laser \_\_\_\_\_
- Temporal Mandibular Joint-TMJ (dental orthotics, self-care, surgery) \_\_\_\_\_
- TMS (transcranial magnetic stimulation) \_\_\_\_\_
- Ginko Biloba extracts \_\_\_\_\_
- Acupuncture \_\_\_\_\_
- Hyperbaric oxygen therapy \_\_\_\_\_
- Electrical Stimulation \_\_\_\_\_
- Diet modification(s) [identify] \_\_\_\_\_
- Sleep therapy/modification \_\_\_\_\_
- Lifestyle changes (not diet or sleep) [identify] \_\_\_\_\_
- Hearing aids \_\_\_\_\_
- Cochlear implants \_\_\_\_\_
- Sound generators/maskers (wearable) [identify make if provided] \_\_\_\_\_
- Sound generators/maskers (stationary) [identify make if provided] \_\_\_\_\_
- Neuromonics \_\_\_\_\_
- Tinnitus Retraining Therapy (TRT) \_\_\_\_\_
- Cognitive Behavioral Therapy (CBT) \_\_\_\_\_
- Patient Education \_\_\_\_\_
- Relaxation therapies \_\_\_\_\_
- Progressive Tinnitus Management (PTM) \_\_\_\_\_
- This study is evaluating a combination of tinnitus interventions [identify the combination] \_\_\_\_\_
- Other [identify] \_\_\_\_\_
- Other [identify] \_\_\_\_\_
- Other[identify] \_\_\_\_\_
- Other[identify] \_\_\_\_\_
- Other[identify] \_\_\_\_\_
- This study ONLY focuses on tools/measures that RESULT in candidacy for treatment.

**18. Interventions: \*Please describe intervention(s) with sufficient detail for replication. Include duration of treatment, intensity of treatment, if feasible. (Length of study; number of follow-ups). Include page number sources of information.**

**19. If the study only discusses one treatment intervention, what is the Intervention compared to?**

- Usual care
- No treatment
- Placebo
- Wait list
- Not-applicable
- Other (identify) \_\_\_\_\_

**20. Number of participants allocated to Intervention Group 1 at baseline** \_\_\_\_\_

**21. Number of participants in Intervention Group 1 at final follow-up** \_\_\_\_\_

**22. Number of participants allocated to Intervention Group 2 at baseline** \_\_\_\_\_

**23. Number of participants in Intervention Group 2 at final follow-up** \_\_\_\_\_

**24. Number of participants allocated to the control group (if not a within-subject study).** \_\_\_\_\_

**25. Number of participants in control group at final follow-up** \_\_\_\_\_

**26. Reasons for withdrawal? (Identify group, # of withdrawals, and any reasons provided-with # per reason if included)**

**27. Identify source of funding (NR if not reported)**

**Additional Notes**

## Modified Jadad

**1. Is this a RCT study?**

- Yes (continue)
- No it is a cross section (stop and use cross-sectional form) \_\_\_\_\_
- No it is a cohort (stop and use NOS cohort form)
- Not it is a case control (stop and use case control form)
- Other (identify and stop) \_\_\_\_\_

**2. Reported as randomized**

- Yes (1 Point)
- No

**3. Randomization is appropriate**

- Yes (1 Point)
- No (-1 Point)
- Not Described

**4. Double blinding is reported**

- Yes (1 Point)
- No

**5. Double blinding is appropriate**

- Yes (1 Point)
- No (-1 Point)
- Not Described

**6. Withdrawals are reported by number and reason per arm**

- Yes (1 Point)
- No

**7. Jadad Score (/5)**

- 0
- 1
- 2
- 3
- 4
- 5

**8. Method(s) used to assess adverse events is described**

- Yes(1 Point)
- No

**9. Method(s) of statistical analysis is described**

- Yes (1 Point)
- No

**10. Inclusion and/or exclusion of the requirements is reported**

- Yes (1 point if at least one of the requirements is reported)
- No

**11. Modified Jadad score (/8)**

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8

**12. Was the allocation adequately concealed? (e.g., pharmacy controlled randomized scheme, sequentially numbered opaque, sealed envelope, sequentially numbered/coded identical containers, central randomization by phone)**

- Yes
- No
- Unclear

**13. Was the analysis based on intention to treat principle?**

- Yes
- No
- Unclear

**14. Was the sample size justified?**

- Yes
- No
- Unclear

## TNT Outcomes Continuous

**1. Identify the outcomes of interest in this study (check all that apply):**

- Sleep
- Discomfort/distress
- Depression
- Self-reported loudness
- Quality of life
- Time to improvement
- Severity
- Worsening of tinnitus
- Sedation
- Surgical complications
- Other (identify) \_\_\_\_\_

**2. Specify the outcome measure(s) for each outcome you identified above (use acronyms where provided)**

- Sleep \_\_\_\_\_
- Discomfort/distress \_\_\_\_\_
- Anxiety \_\_\_\_\_
- Depression \_\_\_\_\_
- Self-reported loudness \_\_\_\_\_
- Quality of life \_\_\_\_\_
- Tinnitus severity \_\_\_\_\_
- Time to improvement \_\_\_\_\_
- Worsening of tinnitus \_\_\_\_\_
- Sedation \_\_\_\_\_
- Surgical Complication \_\_\_\_\_
- Other \_\_\_\_\_

**3. Further definition of outcomes identified above (e.g., units of measurement, full name of tools/measures –Beck Depression Inventory, validated instruments –ref#?). Provide page/paragraph numbers. (i.e., p.12,para3)**

**4. Please identify data type (if continuous AND dichotomous, check both). Use table for continuous and text box below table for dichotomous):**

- Continuous
- Dichotomous

5. **Outline from where you took the data (i.e., variables Sleep and Distress from Table 2, or page and paragraph number).  
USE THIS BOX TO REPORT DICHOTOMOUS DATA if applicable.**

6. **If there is relevant PRE-POST data for the above outcomes that does not fit within the table above, please add here.**

7. **Add all Intention-to-treat analysis information here.**

8. **Very briefly summarize the main conclusion(s) of this article.**

**9. Are there any sub-group analyses provided in the paper? (See example sheet for breakdowns/examples. Only identify groups for which PRE/POST intervention data is provided).**

- Analysis of the effect of patient characteristics on treatment outcomes \_\_\_\_\_
- Analysis of the effect of symptoms characteristics on treatment outcomes \_\_\_\_\_
- Analysis of the effect of prognostic factors on treatment outcomes \_\_\_\_\_
- None of the above

**10. Study design to determine Quality Analysis form:**

- RCT, CCT
- Non randomized trial
- Cohort (prospective; retrospective; before-after; time-series)
- Case control
- Cross section
- Other observational



**APPENDIX C.**  
**Excluded Studies**



## Excluded Studies

Tinnitus. *Lancet*. 1979;1(8126):1124. PMID:86841 OVID-Medline.

Exclude: Article not available

The treatment of tinnitus. *Clin Otolaryngol Allied Sci*. 1980;5(1):1-2. PMID:7363488 OVID-Medline.

Exclude: Not a primary study

Electrical stimulation of the inner ear. *J Laryngol Otol Suppl*. 1984;9:121-44. PMID:6394678 OVID-Medline.

Exclude: Article not available

Objective evaluation: Quantitative assessment and measurement of tinnitus; Clinical experience. *J Laryngol Otol Suppl*. 1984;9:145-92.

PMID:6596357 OVID-Medline.

Exclude: Article not available

Tinnitus. *Lancet*. 1984;1(8376):543-5.

PMID:6142257 OVID-Medline.

Exclude: Article not available

Tinnitus: Treatment methods and results. *J Laryngol Otol Suppl*. 1984;9:247-318. PMID:6440940 OVID-Medline.

Exclude: Article not available

Treatment for tinnitus. *Drug Ther Bull*. 1985;23(11):41-3. PMID:4006746 OVID-Medline.

Exclude: Article not available

Imipramine and tinnitus. *J Clin Psychiatry*. 1987;48(12):496-7. PMID:3693337 OVID-Medline.

Exclude: Not a primary study

Coping with tinnitus. *ASHA*. 1990;32(5):61.

PMID:2337425 OVID-Medline.

Exclude: Not a primary study

Long-standing adverse reactions. *Med J Aust*. 1993;159(9):621. PMID:7901742 OVID-Medline.

Exclude: Not a primary study

Zimbabwean people with head noises are offered help. *Cent Afr J Med*. 1998;44(11):296.

PMID:10189754 OVID-Medline.

Exclude: Not a primary study

Manage tinnitus with techniques used to treat chronic pain. *Geriatrics*. 2000;55(12):16. PMID:11131847 OVID-Medline.

Exclude: Not a primary study

Hearing problems. Tinnitus: When your ears won't stop ringing. *Harv Womens Health Watch*.

2002;10(1):6-7. PMID:12356549 OVID-Medline.

Exclude: Not a primary study

Aazh H, Moore BCJ, Glasberg BR. Simplified form of tinnitus retraining therapy in adults: A retrospective study. *BMC Ear Nose Throat Disord*. 2008;8(1):7. OVID-Embase.

Exclude: Comparators do not meet inclusion criteria

Abbott JA, Kaldo V, Klein B, et al. A cluster randomised trial of an internet-based intervention program for tinnitus distress in an industrial setting. *Cognit Behav Ther*. 2009;38(3):162-73.

PMID:19675959 OVID-Medline.

Exclude: Comparators do not meet inclusion criteria

Abelson TI. Long-term bilateral tinnitus. *JAMA*.

1985;253(19):2830. PMID:3989951 OVID-Medline.

Exclude: Not a primary study

Acrani IO, Pereira LD. Temporal resolution and selective attention of individuals with tinnitus. *Profono*. 2010;22(3):233-8. PMID:21103711 OVID-Medline.

Exclude: Only determined various effects

Adlington P, Warrick J. Stellate ganglion block in the management of tinnitus. *J Laryngol Otol*.

1971;85(2):159-68. PMID:4396190 OVID-Medline.

Exclude: Case Series

Ahmad R, Raichura N, Kilbane V, et al. Vancomycin: A reappraisal. *BMJ Clin Res Ed*.

1982;284(6333):1953-4. PMID:6805786 OVID-Medline.

Exclude: Not a primary study

Ahmad S. Venlafaxine and severe tinnitus. *Am Fam Physician*. 1995;51(8):1830. PMID:7762476 OVID-Medline.

Exclude: Not a primary study

Akkuzu B, Yilmaz I, Cakmak O, et al. Efficacy of misoprostol in the treatment of tinnitus in patients with diabetes and/or hypertension. *Auris Nasus Larynx*. 2004;31(3):226-32. PMID:15364356 OVID-Medline.

Exclude: Insufficient detail for aggregation of data

Al-Jassim AH. The use of Walkman Mini-stereo system as a tinnitus masker. *J Laryngol Otol.* 1988;102(1):27-8. PMID:3343558 OVID-Medline.  
Exclude: Comparators do not meet inclusion criteria

Albrecht III CR, Gambert SR. Botanical and diet-based biological therapies and their use by older persons: Part I. *Clin Geriatr.* 2005;13(1):26-34. OVID-Embase.  
Exclude: Not a primary study

Aleksic M, Schutz G, Gerth S, et al. Surgical approach to kinking and coiling of the internal carotid artery. *J Cardiovasc Surg.* 2004;45(1):43-8. PMID:15041936 OVID-Medline.  
Exclude: Pulsatile Tinnitus

Almeida TA, Samelli AG, Mecca FN, et al. Tinnitus sensation pre and post nutritional intervention in metabolic disorders. *Profono.* 2009;21(4):291-7. PMID:20098946 OVID-Medline.  
Exclude: Insufficient detail for aggregation of data

Andersson G. The role of optimism in patients with tinnitus and in patients with hearing impairment. *Psychol Health.* 1996;11(5):697-707. EBSCO-CINAHL.  
Exclude: Comparators do not meet inclusion criteria

Andersson G. Prior treatments in a group of tinnitus sufferers seeking treatment. *Psychother Psychosom.* 1997;66(2):107-10. PMID:9097339 OVID-Medline.  
Exclude: Insufficient detail for aggregation of data

Andersson G, Ingerholt C, Jansson M. Autobiographical memory in patients with tinnitus. *Psychol Health.* 2003;18(5):667-75. EBSCO-CINAHL.  
Exclude: Only determined various effects

Andersson G, Kaldo V, Stromgren T, et al. Are coping strategies really useful for the tinnitus patient? An investigation conducted via the internet. *Audiol Med.* 2004;2(1):54-9. OVID-Embase.  
Exclude: Only about prevalence

Andersson G, Airikka M-L, Buhrman M, et al. Dimensions of perfectionism and tinnitus distress. *Psychol Health Med.* 2005;10(1):78-87. OVID-Embase.  
Exclude: Only determined various effects

Andersson G, Juris L, Classon E, et al. Consequences of suppressing thoughts about tinnitus and the effects of cognitive distraction on brain activity in tinnitus patients. *Audiol Neuro Otol.* 2006;11(5):301-9. PMID:16837798 OVID-Medline.  
Exclude: Only determined various effects

Andersson G, Kyrre SO, Kaldo V, et al. Future thinking in tinnitus patients. *J Psychosom Res.* 2007;63(2):191-4. PMID:17662756 OVID-Medline.  
Exclude: Only determined various effects

Andersson G, Edsjo L, Kaldo V, et al. Tinnitus and short-term serial recall in stable versus intermittent masking conditions. *Scand J Psychol.* 2009;50(5):517-22. PMID:19778399 OVID-Medline.  
Exclude: Only determined various effects

Andersson G, Keshishi A, Baguley DM. Benefit from hearing aids in users with and without tinnitus. *Audiol Med.* 2011;9(2):73-8. OVID-Embase.  
Exclude: Comparators do not meet inclusion criteria

Ansari H, Patankar T, Jackson A. Whispering enigma. *Br J Radiol.* 2005;78(927):283-4. PMID:15730998 OVID-Medline.  
Exclude: Case Study

Anttonen H, Hassi J, Riihikangas P, et al. Impulse noise exposure during military service. *Scand Audiol Suppl.* 1980;(Suppl 12):17-24. PMID:6939085 OVID-Medline.  
Exclude: Only about prevalence

Aran JM. Electrical stimulation of the auditory system and tinnitus control. *J Laryngol Otol Suppl.* 1981;(4):153-61. PMID:6975341 OVID-Medline.  
Exclude: Case Series

Aran JM, Cazals Y. Electrical suppression of tinnitus. *Ciba Foundation Symposium.* 1981;85:217-31. PMID:6976888 OVID-Medline.  
Exclude: Case Series

Araujo MF, Oliveira CA, Bahmad FM, Jr. Intratympanic dexamethasone injections as a treatment for severe, disabling tinnitus: Does it work? *Arch Otolaryngol Head Neck Surg.* 2005;131(2):113-7. PMID:15723941 OVID-Medline.  
Exclude: Insufficient detail for aggregation of data

Argstatter H, Krick C, Plinkert P, et al. Music therapy for noisiform tinnitus. Concept development and evaluation. *HNO*. 2010;58(11):1085-93. OVID-Embase.  
Exclude: Not in English

Ariizumi Y, Hatanaka A, Kitamura K. Clinical prognostic factors for tinnitus retraining therapy with a sound generator in tinnitus patients. *J Med Dent Sci*. 2010;57(1):45-53. PMID:20437765 OVID-Medline.  
Exclude: Insufficient detail for aggregation of data

Arndt S, Aschendorff A, Laszig R, et al. Comparison of pseudobinaural hearing to real binaural hearing rehabilitation after cochlear implantation in patients with unilateral deafness and tinnitus. *Otol Neurotol*. 2011;32(1):39-47. PMID:21068690 OVID-Medline.  
Exclude: Insufficient detail for aggregation of data

Aschendorff A, Pabst G, Klenzner T, et al. Tinnitus in cochlear implant users: The Freiburg experience. *Int Tinnitus J*. 1998;4(2):162-4. OVID-Embase.  
Exclude: Subjects under 18

Atlas J, Parnes LS. Intratympanic gentamicin for intractable Meniere's disease: 5-year follow-up. *J Otolaryngol*. 2003;32(5):288-93. OVID-Embase.  
Exclude: Insufficient detail for aggregation of data

Atlas JT, Parnes LS. Intratympanic gentamicin titration therapy for intractable Meniere's disease. *Am J Otol*. 1999;20(3):357-63. OVID-Embase.  
Exclude: Tinnitus result of issues in middle ear

Attias J, Shemesh Z, Shoham C, et al. Efficacy of self-hypnosis for tinnitus relief. *Scand Audiol*. 1990;19(4):245-9. PMID:2075417 OVID-Medline.  
Exclude: Insufficient detail for aggregation of data

Attias J, Shemesh Z, Sohmer H, et al. Comparison between self-hypnosis, masking and attentiveness for alleviation of chronic tinnitus. *Audiology*. 1993;32(3):205-12. PMID:8489481 OVID-Medline.  
Exclude: Insufficient detail for aggregation of data

Axelsson A, Andersson S, Gu LD. Acupuncture in the management of tinnitus: A placebo-controlled study. *Audiology*. 1994;33(6):351-60. PMID:7741667 OVID-Medline.  
Exclude: Insufficient detail for aggregation of data

Ayache D, Earally F, Elbaz P. Characteristics and postoperative course of tinnitus in otosclerosis. *Otol Neurotol*. 2003;24(1):48-51. PMID:12544028 OVID-Medline.  
Exclude: Comparators do not meet inclusion criteria

Aydemir G, Tezer MS, Borman P, et al. Treatment of tinnitus with transcutaneous electrical nerve stimulation improves patients' quality of life. *J Laryngol Otol*. 2006;120(6):442-5. PMID:16556347 OVID-Medline.  
Exclude: Comparators do not meet inclusion criteria

Azevedo AA, Figueiredo RR. Tinnitus treatment with acamprosate: Double-blind study. *Revista Brasileira de Otorrinolaringologia*. 2005;71(5):618-23. PMID:16612523 OVID-Medline.  
Exclude: Insufficient detail for aggregation of data

Baguley D. Neurophysiological approach to tinnitus patients. *Am J Otol*. 1997;18(2):265-6. PMID:9093687 OVID-Medline.  
Exclude: Not a primary study

Baguley DM, Humphriss RL, Hodgson CA. Convergent validity of the tinnitus handicap inventory and the tinnitus questionnaire. *J Laryngol Otol*. 2000;114(11):840-3. PMID:11144832 OVID-Medline.  
Exclude: Comparators do not meet inclusion criteria

Baguley DM, McFerran DJ. Current perspectives on tinnitus. *Arch Dis Child*. 2002;86(3):141-3. PMID:11861225 OVID-Medline.  
Exclude: Not a primary study

Bahmad FM, Jr., Venosa AR, Oliveira CA. Benzodiazepines and GABAergics in treating severe disabling tinnitus of predominantly cochlear origin. *Int Tinnitus J*. 2006;12(2):140-4. PMID:17260879 OVID-Medline.  
Exclude: Insufficient detail for aggregation of data

Bakhshae M, Ghasemi M, Azarpazhooh M, et al. Gabapentin effectiveness on the sensation of subjective idiopathic tinnitus: A pilot study. *Eur Arch Otorhinolaryngol*. 2008;265(5):525-30. PMID:17960408 OVID-Medline.  
Exclude: Insufficient detail to aggregate data

Baracca GN, Forti S, Crocetti A, et al. Results of TRT after eighteen months: Our experience. *Int J Audiol*. 2007;46(5):217-22. PMID:17487669 OVID-Medline.  
Exclude: Insufficient detail for aggregation of data

Barber HO. The diagnosis and treatment of auditory and vestibular disorders after head injury. *Clin Neurosurg.* 1972;19:355-70. PMID:4637559 OVID-Medline.

Exclude: Not a primary study

Baribeau J. Reaching out to the youth suffering from idiopathic tinnitus via the Internet. *Ann Rev Cyberther Telemed.* 2006;4:145-52. PsychInfo.

Exclude: Comparators do not meet inclusion criteria

Barrs DM, Brackmann DE. Section 3: Surgical treatment. Translabyrinthine nerve section: Effect on tinnitus. *J Laryngol Otol.* 1983;97(Suppl. 9):287-93. OVID-Embase.

Exclude: Insufficient detail for aggregation of data

Bartels H, Staal MJ, Holm AF, et al. Long-term evaluation of treatment of chronic, therapeutically refractory tinnitus by neurostimulation. *Stereotact Funct Neurosurg.* 2007;85(4):150-7.

PMID:17259751 OVID-Medline.

Exclude: Case Series

Bartels H, Pedersen SS, van der Laan BF, et al. The impact of Type D personality on health-related quality of life in tinnitus patients is mainly mediated by anxiety and depression. *Otol Neurotol.*

2010;31(1):11-8. PMID:19816233 OVID-Medline.

Exclude: Only determined various effects

Bartels H, Middel B, Pedersen SS, et al. The distressed (Type D) personality is independently associated with tinnitus: A case-control study. *Psychosomatics.* 2010;51(1):29-38. PMID:20118438 OVID-Medline.

Exclude: Comparators do not meet inclusion criteria

Bartnik G, Fabijanska A, Rogowski M. Experiences in the treatment of patients with tinnitus and/or hyperacusis using the habituation method. *Scand Audiol Suppl.* 2001;52:187-90. PMID:11318464 OVID-Medline.

Exclude: Insufficient detail for aggregation of data

Bartnik G, Fabijanska A, Rogowski M. Effects of tinnitus retraining therapy (TRT) for patients with tinnitus and subjective hearing loss versus tinnitus only. *Scand Audiol Suppl.* 2001;52:206-8.

PMID:11318470 OVID-Medline.

Exclude: Comparators do not meet inclusion criteria

Bauer CA, Brozoski TJ. Effect of gabapentin on the sensation and impact of tinnitus. *Laryngoscope.* 2006;116(5):675-81. PMID:16652071 OVID-Medline.

Exclude: Insufficient detail for aggregation of data

Bauer CA, Brozoski TJ. Effect of tinnitus retraining therapy on the loudness and annoyance of tinnitus: A controlled trial. *Ear Hear.* 2011;32(2):145-55.

PMID:20890204 OVID-Medline.

Exclude: Insufficient detail for aggregation of data

Bauer W. Transcutaneous electrical stimulation. *Arch Otolaryngol Head Neck Surg.*

1986;112(12):1301-2. PMID:3490266 OVID-Medline.

Exclude: Not a primary study

Bayar N, Boke B, Turan E, et al. Efficacy of amitriptyline in the treatment of subjective tinnitus. *J Otolaryngol.* 2001;30(5):300-3. PMID:11771024 OVID-Medline.

Exclude: Insufficient detail for aggregation of data

Bayazit Y. Neurovascular decompression for tinnitus. *J Neurosurg.* 1998;89(6):1072-3. PMID:9833843 OVID-Medline.

Exclude: Not a primary study

Bayazit YA, Goksu N. Tinnitus and neurovascular compression. *ORL.* 2008;70(3):209.

PMID:18401197 OVID-Medline.

Exclude: Not a primary study

Bayer. Evaluation of vardenafil for the treatment of subjective tinnitus: A controlled pilot study.

ClinicalTrials.gov ID: NCT00666809. 2008; OVID-CCTR.

Exclude: Article not available

Belli S, Belli H, Bahcebasi T, et al. Assessment of psychopathological aspects and psychiatric comorbidities in patients affected by tinnitus. *Eur Arch Otorhinolaryngol.* 2008;265(3):279-85.

PMID:17999075 OVID-Medline.

Exclude: Only determined various effects

Bentler RA, Tyler RS. Tinnitus management.

ASHA. 1987;29(5):27-32. PMID:3593456 OVID-Medline.

Exclude: Article not available

Bentzen O. Treatment of tinnitus with alternative therapy. *Acta Otorhinolaryngol Belgica*. 1986;40(3):487-91. PMID:3788551 OVID-Medline.  
Exclude: Not a primary study

Berninger E, Nordmark J, Alvan G, et al. The effect of intravenously administered mexiletine on tinnitus - A pilot study. *Int J Audiol*. 2006;45(12):689-96. PMID:17132557 OVID-Medline.  
Exclude: Case Series

Berrios GE, Ryley JP, Garvey TPN, et al. Psychiatric morbidity in subjects with inner ear disease. *Clin Otolaryngol Allied Sci*. 1988;13(4):259-66. OVID-Embase.  
Exclude: Only determined various effects

Berry JA, Gold SL, Frederick EA, et al. Patient-based outcomes in patients with primary tinnitus undergoing tinnitus retraining therapy. *Arch Otolaryngol Head Neck Surg*. 2002;128(10):1153-7. PMID:12365886 OVID-Medline.  
Exclude: Case series

Bessman P, Heider T, Watten VP, et al. The tinnitus intensive therapy habituation program: A 2-year follow-up pilot study on subjective tinnitus. *Rehabil Psychol*. 2009;54(2):133-7. PMID:19469602 OVID-Medline.  
Exclude: Insufficient detail for aggregation of data

Bezerra Rocha CA, Sanchez TG, Tesseroli de Siqueira JT. Myofascial trigger point: A possible way of modulating tinnitus. *Audiol Neuro Otol*. 2008;13(3):153-60. PMID:18075244 OVID-Medline.  
Exclude: Insufficient detail for aggregation of data

Bjorne A. Assessment of temporomandibular and cervical spine disorders in tinnitus patients. *Progr Brain Res*. 2007;166:215-9. PMID:17956785 OVID-Medline.  
Exclude: Not a primary study

Blair PA, Reed HT. Amino-oxycetic acid: A new drug for the treatment of tinnitus. *J La State Med Soc*. 1986;138(6):17-9. PMID:3734755 OVID-Medline.  
Exclude: Not a primary study

Blayney AW, Phillips MS, Guy AM, et al. A sequential double blind cross-over trial of tocainide hydrochloride in tinnitus. *Clin Otolaryngol Allied Sci*. 1985;10(2):97-101. PMID:3928215 OVID-Medline.  
Exclude: Insufficient detail for aggregation of data

Boniver R. Forensic aspects of tinnitus in Belgium and France. *Int Tinnitus J*. 1999;5(1):67-70. PMID:10753425 OVID-Medline.  
Exclude: Not a primary study

Borghgi C, Brandolini C, Prandin MG, et al. Prevalence of tinnitus in patients with hypertension and the impact of different antihypertensive drugs on the incidence of tinnitus: A prospective, single-blind, observational study. *Curr Ther Res*. 2005;66(5):420-32. OVID-Embase.  
Exclude: Only about prevalence

Borton TE, Clark SR. Electromyographic biofeedback for treatment of tinnitus. *Am J Otol*. 1988;9(1):23-30. PMID:3364533 OVID-Medline.  
Exclude: Case Series

Bovo R, Ciorba A, Martini A. Tinnitus and cochlear implants. *Auris Nasus Larynx*. 2011;38(1):14-20. PMID:20580171 OVID-Medline.  
Exclude: Case series

Bradley WD. Management of tinnitus. *Cranio*. 1989;7(2):75. OVID-Embase.  
Exclude: Not a primary study

Brattberg G. An alternative method of treating tinnitus: Relaxation-hypnotherapy primarily through the home use of a recorded audio cassette. *Int J Clin Exp Hypn*. 1983;31(2):90-7. PMID:6339424 OVID-Medline.  
Exclude: Subjects under 18

Brewin T. Homoeopathic remedy is ineffective in tinnitus. *Focus Alt Complement Ther*. 1999;4(3):134-5. EBSCO-CINAHL.  
Exclude: Article not available

Briner W, House J, O'Leary M. Synthetic prostaglandin E1 misoprostol as a treatment for tinnitus. *Arch Otolaryngol Head Neck Surg*. 1993;119(6):652-4. PMID:8499097 OVID-Medline.  
Exclude: Insufficient detail for aggregation of data

Brookes GB. Vascular-decompression surgery for severe tinnitus. *Am J Otol*. 1996;17(4):569-76. PMID:8841702 OVID-Medline.  
Exclude: Case Series

Brookler KH, Tanyeri H. Etidronate for the neurotologic symptoms of otosclerosis: Preliminary study. *Ear Nose Throat J*. 1997;76(6):371-81. OVID-Embase.  
Exclude: Tinnitus result of issues in middle ear

Buechner A, Brendel M, Lesinski-Schiedat A, et al. Cochlear implantation in unilateral deaf subjects associated with ipsilateral tinnitus. *Otol Neurotol*. 2010;31(9):1381-5. PMID:20729788 OVID-Medline.

Exclude: Case Series

Bumby AF, Stephens SDG. Clonazepam in the treatment of tinnitus - A pilot study. *J Audiol Med*. 1997;6(2):98-104. OVID-Embase.

Exclude: Insufficient detail for aggregation of data

Burgos I, Feige B, Hornyak M, et al. Chronic tinnitus and associated sleep disturbances. *Somnologie*. 2005;9(3):133-8. OVID-Embase.

Exclude: Only determined various effects

Busis SN. Treatment of tinnitus. *JAMA*. 1992;268(11):1467. PMID:1512918 OVID-Medline.

Exclude: Not a primary study

Cada DJ, Baker DE, Levien T. Gatifloxacin. *Hosp Pharm*. 2000;35(4):405-17. OVID-Embase.

Exclude: Article not available

Caffier PP, Haupt H, Scherer H, et al. Outcomes of long-term outpatient tinnitus-coping therapy: Psychometric changes and value of tinnitus-control instruments. *Ear Hear*. 2006;27(6):619-27. PMID:17086074 OVID-Medline.

Exclude: Insufficient detail for aggregation of data

Caffier PP, Sedlmaier B, Haupt H, et al. Impact of laser eustachian tuboplasty on middle ear ventilation, hearing, and tinnitus in chronic tube dysfunction. *Ear Hear*. 2011;32(1):132-9. PMID:20585250 OVID-Medline.

Exclude: Comparators do not meet inclusion criteria

Campbell K. Tinnitus and vertigo. *Arch Otolaryngol Head Neck Surg*. 1993;119(4):474 PMID:8457316 OVID-Medline.

Exclude: Not a primary study

Canis M, Olzowy B, Welz C, et al. Simvastatin and Ginkgo biloba in the treatment of subacute tinnitus: A retrospective study of 94 patients. *Am J Otolaryngol*. 2011;32(1):19-23. PMID:20015810 OVID-Medline.

Exclude: Comparators do not meet inclusion criteria

Canlon B, Henderson D, Salvi R. Pharmacological strategies for prevention and treatment of hearing loss and tinnitus. *Hear Res*. 2007;226(1-2):1-2. OVID-Embase.

Exclude: Not a primary study

Carbary LJ. Tuning out tinnitus. *J Nurs Care*. 1980;13(8):8-11. PMID:6904524 OVID-Medline.

Exclude: Not a primary study

Carlsson SG, Erlandsson SI. Habituation and tinnitus: An experimental study. *J Psychosom Res*. 1991;35(4-5):509-14. PMID:1920181 OVID-Medline.

Exclude: Only determined various effects

Carmen R, Svihovec D. Relaxation-biofeedback in the treatment of tinnitus. *Am J Otol*. 1984;5(5):376-81. PMID:6383065 OVID-Medline.

Exclude: Case series

Caro AZ. Dimethyl sulfoxide therapy in subjective tinnitus of unknown origin. *Ann New York Acad Sci*. 1975;243:468-74. PMID:1055561 OVID-Medline.

Exclude: Case Series

Carrick DG, Davies WM, Fielder CP, et al. Low-powered ultrasound in the treatment of tinnitus: A pilot study. *Br J Audiol*. 1986;20(2):153-5. PMID:3719163 OVID-Medline.

Exclude: Insufficient detail for aggregation of data

Catalano GB, Di Mauro A., Vancheri M. Tinnitus: Analysis of failures with Vernon treatment. *Rivista Italiana di Otorinolaringologia Audiologia e Foniatria*. 1982;2(1):60-2. OVID-Embase.

Exclude: Article not available

Cathcart JM. Assessment of the value of tocainide hydrochloride in the treatment of tinnitus. *J Laryngol Otol*. 1982;96(11):981-4. PMID:6813410 OVID-Medline.

Exclude: Case Series

Cazals Y, Negrevergne M, Aran JM. Electrical stimulation of the cochlea in man: Hearing induction and tinnitus suppression. *J Am Audiol Soc*. 1978;3(5):209-13. PMID:306987 OVID-Medline.

Exclude: Case Series

Cesarani A, Capobianco S, Soi D, et al. Intratympanic dexamethasone treatment for control of subjective idiopathic tinnitus: Our clinical experience. *Int Tinnitus J.* 2002;8(2):111-4. PMID:14763222 OVID-Medline.  
Exclude: Case Series

Chole RA, Parker WS. Tinnitus and vertigo in patients with temporomandibular disorder. *Arch Otolaryngol Head Neck Surg.* 1992;118(8):817-21. PMID:1642833 OVID-Medline.  
Exclude: Systematic review or meta-analysis

Chopra H, Munjal M, Khurana AS, et al. Comparative study of lignocaine instillation (2% and 4%) and hydrocortisone through ventilation tubes in subjective tinnitus. *Indian J Otol.* 2002;8(2):63-5. OVID-Embase.  
Exclude: Article not available

Chouard CH, Meyer B, Maridat D. Transcutaneous electrotherapy for severe tinnitus. *Acta Otolaryngol.* 1981;91(5-6):415-22. PMID:6973909 OVID-Medline.  
Exclude: Insufficient detail for aggregation of data

Choy DS, Lipman RA, Tassi GP. Worldwide experience with sequential phase-shift sound cancellation treatment of predominant tone tinnitus. *J Laryngol Otol.* 2010;124(4):366-9. PMID:20067647 OVID-Medline.  
Exclude: Insufficient detail for aggregation of data

Christensen RC. Paroxetine in the treatment of tinnitus. *Otolaryngol Head Neck Surg.* 2001;125(4):436-8. PMID:11593197 OVID-Medline.  
Exclude: Not a primary study

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Exclude: Case Series

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Exclude: Case Series

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Exclude: Systematic review or meta-analysis

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Exclude: Subjects under 18

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Exclude: Comparators do not meet inclusion criteria

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## **APPENDIX D.**

### **Characteristics of Included Studies Evidence Tables**



**Appendix D. Table A: Pharmacological or Food Supplement Interventions and Outcomes (n=16)**

Author Year Setting	Population	Interven	Outcome Measures	Results
Aoki, <sup>6</sup> 2012  Japan	<p>Baseline sample: Total n = 60; Interven: n = 30; Cntrl: n = 30 Setting: Department of Otolaryngology Mean age (SD): Interven: 64.9y (11.3); Cntrl: 61.6y (11.1) Gender: 20.7% male</p> <p>Presumed etiology of tinnitus: Idiopathic Duration of tinnitus: &gt; 6 months Severity of tinnitus: unilateral chronic Number of dropouts: 2 Reasons for dropouts: Adverse events Audiological factors: 4-tone average better ear (dB) Interven: 31.8 +/-18.5; Cntrl 31.3 +/-20.4. Four-tone average worse ear (dB): Interven: 60.7+/-23.6; Cntrl: 56.8+/-22.8 Comorbidities: NR</p>	<p>Lyophilized powder of enzymolyzed honeybee larvae (720 mg/4 capsules/day)</p> <p>Comparator: Placebo (hydrogenated dextrin; 720 mg/4 capsules/day) indistinguishable in appearance or odor</p> <p>Duration of treatment: 12 weeks Number of follow ups: 3 (4, 8 and 12 weeks) Duration of study: November 2009 to October 2010</p>	<p>Depression (THI-sub)</p> <p>TS-QOL (THI*, VAS)</p>	<p>The lyophilized powder of enzymolyzed honeybee larvae was not superior to placebo with regard to the total score on the Tinnitus Handicap Inventory and the visual analog scale.</p> <p>Adverse Events: "experienced discomfort after taking the capsules" (1 Interven; 1 Cntrl)</p>
Arda, <sup>7</sup> 2003  Turkey	<p>Baseline sample: Total n = 50; Interven n = 30; Cntrl n = 20 Setting: ENT Clinic Mean age (SD): Total range: 21-74 y; Interven: 55 y (14.3); Cntrl: 51.2 y (12.8) Gender: Interven: 42.8% male; Cntrl: 30.7% male</p> <p>Presumed etiology of tinnitus: Idiopathic Duration of tinnitus: Interven: 39.39 months (<math>\pm</math>34.30); Cntrl: 26.08 months (<math>\pm</math>21.32) Severity of tinnitus: unilateral chronic Number of dropouts: 9 Interven n = 2; Cntrl n = 7 Reasons for dropouts: Non-compliance Interven n = 2; Cntrl n = 7 Audiological factors: Continuous tinnitus Interven 10 (35.7%); Cntrl 6 (46.2%) Comorbidities: Not reported</p>	<p>Zinc</p> <p>Interven: 28 patients in the zinc group were given 50 mg zinc per day for 2 months (Zinco 220, 50 mg).</p> <p>Comparator: Placebo – 1 starch tablet daily for 2 months</p> <p>Duration of treatment: 2 months Number of follow-ups: 1 Duration of study: April 2000 to May 2001</p>	<p>Loudness (Subjective score 0-7)</p>	<p>Clinically favorable progress was detected in 46.4% of patients given zinc. The severity of subjective tinnitus decreased in 82% of the patients receiving zinc (NS). The mean of subjective tinnitus decreased from <math>5.25 \pm 1.08</math> to <math>2.82 \pm 1.81</math> (<math>P &lt; 0.001</math>).</p> <p>Adverse Events: 2 patients in the zinc group had minor gastric disturbances</p>

**Appendix D. Table A: Pharmacological or Food Supplement Interventions and Outcomes (n=16) (cont'd)**

Author Year Setting	Population	Interven	Outcome Measures	Results
Azevedo, <sup>12</sup> 2005  Brazil	<p>Baseline sample: Total n = 50 Interven n = 25; Cntrl n = 25 Setting: Otorhinology Hospital clinic Mean age (SD): 60 y; range 35y to 82y Gender: 58% male</p> <p>Presumed etiology of tinnitus: sensorineural Duration of tinnitus: 9.8% &lt;1y; 53.7% 1 to 7y; 36.6% &gt;7y Severity of tinnitus: NR Number of dropouts: Interven n = 2; Cntrl n = 7 Reasons for dropouts: Side effects: Interven (1); Cntrl (5) Family pressures: Interven (1); Cntrl (2) Audiological factors: conductive and mixed hearing loss were excluded Comorbidities: Hearing loss (59.4%); Dizziness (46.9%); Hyperacusis (9.3%)</p>	<p>Double Blind RCT Acamprosate 333mg, TID</p> <p>Comparator: Placebo, TID</p> <p>Duration of treatment: 90 days Number of followups: 3 at 30 days, 60 days, 90 days Duration of study: October 2003 to October 2004</p>	<p>TS-QOL (subjective)</p>	<p>A high index of success in the relief of tinnitus, about 86.9%.n 47.8% of the cases, more than 50% relief was found.</p> <p>Authors conclude that Acamprosate, a drug used in the treatment of alcoholism, is a safe and successful alternative for sensorineural tinnitus' treatment.</p> <p>Adverse events: The incidence of side effects was low, 12%, all of them mild (epigastralgia, choking).</p>
Dib, <sup>81</sup> 2007  Brazil	<p>Baseline sample: Total n = 85 Interven n = 43; Cntrl n = 42 Setting: NR Age Range: 45 to 80 y Gender: Interven: 41.9% male; Cntrl: 26.2% male</p> <p>Presumed etiology of tinnitus: no defined etiology disease in the middle ear Duration of tinnitus: 1 yr Severity of tinnitus: NR Number of dropouts: 0 Reasons for dropouts: N/A Audiological factors: Normal audiograms, mild/moderate sensorineural hearing loss Comorbidities: NR</p>	<p>Trazodone (antidepressant) 50mg per tablet, single night dose for 60 continuous days. If important side effects were seen, the medication was discontinued.</p> <p>Comparator: Placebo</p> <p>Only the pharmacist knew what drug was being given to which patient.</p> <p>Duration of treatment: 60 days Number of follow ups: 1 Duration of study: February to June (2005)</p>	<p>G-QOL (VAS)  TS-QOL (VAS-s*; VAS-d)</p>	<p>There was a significant improvement in intensity, discomfort and life quality in both groups after treatment; however, there was no significant difference between the drug and placebo groups.</p> <p>Trazodone was not efficient in Cntrlling tinnitus in the patients evaluated under the doses utilized.</p> <p>Adverse Events: No AEs in 83.7% of the Treatment group. AEs included: apathy, hypertensive crisis, epigastralgia, nausea, sleepiness</p> <p>Sleepiness Interven = 3 (7%); Cntrl = 1 (2.4%)</p>

**Appendix D. Table A: Pharmacological or Food Supplement Interventions and Outcomes (n=16)**

Author Year Setting	Population	Interven	Outcome Measures	Results
Drew, <sup>24</sup> 2001  United Kingdom	Baseline sample: Total n = 1,121 Interven n = 559; Cntrl n = 562 Setting: mail and telephone Mean age (SD): Int: 52.9y (9.3); Cntrl: 53.0y (9.3) Gender: Int 69% male; Cntrl 69% male  Presumed etiology of tinnitus: NR Duration of tinnitus: >12 months; ≤5 y Int: 10.0y (8.3); Cntrl: 10.1y (8.3) Severity of tinnitus: NR Number of dropouts: Interven: 99 (17.7%); Cntrl: 87 (15.5%) Reasons for dropouts: didn't return questionnaires Audiological factors: NR Comorbidities: NR	Ginkgo Biloba: 252 tablets containing 50 mg standardized extract LI 1370 (containing 25% flavonoids, 3% ginkgolides, and 5% bilobalides) – instructed to take 3 tablets daily  Comparator: Placebo tablets identical to the active tables in shape, size, color and packaging.  Duration of treatment: 12 weeks Number of followups: 3 (4, 12, 14 weeks) Duration of study: NR	TS-QOL (TSQ- 21)  Loudness (VAS)	50 mg <i>Ginkgo biloba</i> extract LI 1370 given 3 times daily for 12 weeks is no more effective than placebo in treating tinnitus.  Adverse events: The incidence of AEs was similar between the treatment groups. AEs included: gastrointestinal upset, dizziness, headache, mouth ulcer, sleep problems, redness of face, awareness of heartbeat, effects on hearing, hyperacusis. More than 1 AE: Interven: 2.0% Cntrl: 1.6%
Johnson, <sup>24</sup> 1993  United States	Baseline sample: Total n = 40 Interven n = 20; Cntrl n = 20 Setting: University clinic Mean age: NR Gender: NR  Presumed etiology of tinnitus: Idiopathic Duration of tinnitus: >1 year Severity of tinnitus: Constant and not fluctuant in nature, sufficient severity to disrupt daily activities (greater than 600 on the disability sub-scale of the IOWA THQ Number of dropouts: Interven n = 3, Cntrl n = 1 Reasons for dropouts: Excessive drowsiness (2); not attend 2nd appointment (1); noncompliance (1) Audiological factors: NR Comorbidities: NR	Interven: Alprazolam Subjects given a 9-day supply of Alprazolam, 1 per day, return to the clinic for a reevaluation of their tinnitus. Subjects interviewed for adverse reaction to drugs, and loudness of tinnitus evaluated with synthesizer. If no AE for the first week, received an appropriate amount of medication for the next 23 days and asked to return to clinic. Followup at 21 days, if tolerated well, were given a final supply of the drug for 58 days, and scheduled for a return visit in 56 days.  Comparator: Placebo  Duration of treatment: 12 weeks Number of follow-ups: 3 (1, 4, 12 weeks) Duration of study: NR	Loudness (VAS)	Of the 17 patients receiving alprazolam, 13 (76%) had a reduction in the loudness of their tinnitus when measurements were made using a tinnitus synthesizer and a visual analog scale.  Alprazolam is a drug that will provide therapeutic relief for some patients with tinnitus.  Adverse Events: excessive drowsiness (2); mild withdrawal symptoms (1); more dreams (4); unfocused (1)

**Appendix D. Table A: Pharmacological or Food Supplement Interventions and Outcomes (n=16)**

Author Year Setting	Population	Interven	Outcome Measures	Results
Mazurek, <sup>97</sup> 2009  Germany	Baseline sample: Total n=42 Setting: Tinnitus Centre  Mean age (SD): Total=49.0 y (10.2) Gender: 71.4% male  Presumed etiology of tinnitus: Idiopathic Duration of tinnitus: > 3 months Severity of tinnitus: "chronic" (excluded acute or intermittent) Number of dropouts: Interven=5; Cntrl=2 Reasons for dropouts: drug-related adverse events: Interven=4; Cntrl=1; poor compliance: Interven=1; Cntrl=1 Audiological factors: NR Comorbidities: NR	Vardenafil Interven: 10 mg vardenafil administered orally twice a day over a period of 12 week, dosing interval approx.12 hours. Non-medicated follow-up for another 4 weeks.  Comparator: Matching placebo tablets administered orally twice a day over a period of 12 week  Duration of treatment: 12 weeks Number of follow ups: Measured at baseline (V2), 4 weeks into treatment (V3), at the end of treatment (V4), and 4 weeks after treatment (V5).  Duration of study: 16 weeks	G-QOL (SF-36)  TS-QOL (TQ)  Sleep (TQ-subscale)	Vardenafil had no superior efficacy over placebo in the treatment of chronic tinnitus during this study.  Within- and between-groups differences on the TQ were clinically not relevant.  There was a tendency on the TQ subscales for minor deteriorations under Vardenafil medication. All differences in changes from baseline were statistically not significant.  Adverse Events: There were no serious or fatal AEs. 6 subjects (28.5%) in the Vardenafil group reported drug-related AEs of headache, diarrhea, nasal congestion or prolonged penile erection
Meeus, <sup>98</sup> 2011  Belgium	Baseline sample: Total n = 35 Interven n = 13; Cntrl n = 15 Setting: Multidisciplinary Tinnitus Clinic Mean age (SD): 55.4y (9.1) Int: 57.9y ; Cntrl: 53.2y Gender: 89.3% male Int: 76.9%male; Cntrl 100% male  Presumed etiology of tinnitus: unilateral or bilateral tinnitus Duration of tinnitus: > 3m Severity of tinnitus: primary complaint of chronic tinnitus Number of dropouts: 7 Reasons for dropouts: NR Audiological factors: normal MRI pontine angle Comorbidities: none	Double-blind crossover trial – data extracted from end of first period only  Interven: Additional effect of Deanxit (Flupentixol 0.5 mg + melitracen 10 mg) on clonazepam (Rivotril) 1 mg  Comparator: Placebo  Duration of treatment: 3 weeks Number of followups: 1 week washout, switch to treatment Duration of study: NR	Loudness (VAS)  Sleep (TQ-sub)  Depression (BDI)  TS-QOL (TQ*, VAS)	Significant tinnitus reduction was seen after intake of the combination clonazepam-Deanxit, whereas no differences in tinnitus could be demonstrated after the administration of clonazepam-placebo. This was true for all patients according to the following parameters: time patients are annoyed by the tinnitus (p = 0.026) and the VAS for tinnitus annoyance (p = 0.024).  Adverse events: extrapyramidal syndromes and tardive dyskinesia are known side effects of Deanxit – <u>not</u> observed in this study population

**Appendix D. Table A: Pharmacological or Food Supplement Interventions and Outcomes (n=16)**

Author Year Setting	Population	Interven	Outcome Measures	Results
Piccirillo, <sup>101</sup> 2007  United States	Baseline sample: Total n=115 Interven=70; Cntrl=65; Setting: Dept of Otolaryngology Mean age (SD): NR Gender: Interven: 35.6% male; Cntrl: 44.6% males  Presumed etiology of tinnitus: NR Duration of Tinnitus: >6m Severity of tinnitus: Sufficient to disrupt daily activities, THI score ≥38 Number of dropouts: Interven: 11; Cntrl: 9 Reasons for dropouts: Lack of results(9); Nausea(3); Weight gain(2); sleep disturbance(2); Dizziness(1); Other(2) Audiological factors: NR Comorbidities: TMJ Interven: 86%; Cntrl: 77%	Gabapentin (Neurontin) Interven: Patients in gabapentin arm received gradually titrated dosages of gabapentin (week 1, 900 mg/d; week 2, 1800 mg/d; week 3, 2700 mg/d; and week 4, 3600 mg/d). All subjects were provided an equal number of capsules (300 mg each) and instructed to follow a dosing schedule of 3 times per day. If intolerable adverse reactions occurred, the dosage was decreased in 1-dose (300 mg) steps until the drug could be tolerated. The dose established during the titration period was maintained throughout the additional 4 week fixed-dose period afterwards  Comparator: Placebo  Duration of treatment: 8 weeks Number of follow-ups: 2 (4 weeks; 8 weeks) Duration of study: 8 weeks	TS-QOL (THI)	The change among the 59 subjects randomized to the gabapentin arm was 11.3 and the change among the 56 subjects in the placebo arm was 11.0. The difference was 0.03 (95% confidence interval, -5.5 to 6.2; <i>P</i> =.91).  The response to gabapentin, as measured by the THI score, does not reflect a true effect.  Adverse Events: 9/153 (7%) withdrew owing to AEs. Nausea (3); Weight gain (2); Sleep disturbance (2); dizziness (2). All AEs ceased on discontinuation of the study medication.

**Appendix D. Table A: Pharmacological or Food Supplement Interventions and Outcomes (n=16)**

Author Year Setting	Population	Interven	Outcome Measures	Results
Rejali, <sup>103</sup> 2004  United Kingdom	<p>Baseline sample: Total n = 66 Interven n = 33; Cntrl n = 33 Setting: Otolaryngology clinic Mean age (SD): Interven: 60 y (11.4); Cntrl: 59 y (10.4) Gender: Interven: 55% male; Cntrl: 59% male Presumed etiology: noise exposure (55%); middle ear disease (22%); idiopathic (43%) Duration of tinnitus: Duration of tinnitus: Interven: 4.4 y; Cntrl: 5.9 y</p> <p>Severity of tinnitus: main complaint Number of dropouts: 6 Int n = 2; Cntrl n = 4 Reasons for dropouts: Death from a co- existing condition (Int=1); Loss to follow-up (Int=1; Cntrl=2); co-existing illnesses (Cntrl=2) Audiological factors: active middle or external ear disease excluded Comorbidities: NR</p>	<p>Ginkgo Biloba Interven: Patients received 120 mg once daily sustained release formulation of G. biloba Comparator: Placebo</p> <p>Duration of treatment: 12 weeks Number of follow-ups: 1 Duration of study: NR</p>	<p>TS-QOL (THI)</p> <p>G-QOL (GHSI)</p>	<p>Ginkgo biloba does not benefit patients with tinnitus</p> <p>Adverse Events: diarrhea (6% in placebo and 3% in active group) and headache (3% in each group).</p>

**Appendix D. Table A: Pharmacological or Food Supplement Interventions and Outcomes (n=16)**

Author Year Setting	Population	Interven	Outcome Measures	Results
Robinson, <sup>105</sup> 2005  United States	<p>Baseline sample: Total: n = 115; Interven n = 57; Cntrl n = 58 Setting: Otolaryngology clinic</p> <p>Mean age: 57 y Gender: 58% male Presumed etiology of tinnitus:</p> <p>Duration of tinnitus: &gt;6m Severity of tinnitus: NR Number of dropouts: 26 Interven n = 17; Cntrl n = 5 Reasons for dropouts: adverse events (side effect, perceived increase in tinnitus) Audiological factors: NR Comorbidities: Major depression (n=1) Number of dropouts: 26 (Interven=17; Cntrl=5) Reasons for dropouts: adverse events (side effect, perceived increase in tinnitus)</p>	<p>Paroxetine: Treatment 10 mg of paroxetine (or placebo) per day for the first week. Dose increased to 20 mg per day for 2 weeks. Dose was increased in 10-mg increments every 2 weeks to a maximum of 50 mg per day.</p> <p>Comparator: Placebo</p> <p>Duration of treatment: 100 days Number of follow-ups: 1 (1 month post-treatment) Duration of study: (mean) 100 days</p> <p>NOTE: 21 participants who withdrew from the study had their last observation carried forward, resulting in a total of 115 participants with follow-up data, used in the ITT analysis</p>	<p>Depression (HADS-D, BDI*)</p> <p>Anxiety (HADS-A, BAI*)</p> <p>TS-QOL (THQ*, Likert 0 to 7)</p> <p>Sleep (PSQI)</p> <p>G-QOL (QWB)</p>	<p>Majority of individuals did not benefit from paroxetine in a consistent fashion.</p> <p>Adverse Events: Significantly more participants in the paroxetine group (n=17) dropped out because of adverse events than those in the placebo group (n=5), <i>p</i> &lt;.05). Significantly more participants in the paroxetine group reported moderate or severe sexual dysfunction, drowsiness, and dry mouth than in the placebo group at follow-up.</p>
Sharma, <sup>106</sup> 2012  India	<p>Baseline sample: Total n = 40 Setting: Outpatient Department of ENT Hospital Mean age (SD): 53 years Gender: NR</p> <p>Presumed etiology of tinnitus: Idiopathic Duration of tinnitus: NR Severity of tinnitus: NR Number of dropouts: 5 Reasons for dropouts: worsening of condition (n=2); left treatment at crossover and could not complete the study (n=3) Audiological factors: varying degrees of sensorineural hearing loss; 65% of patients had bilateral hearing loss; 35% had bilateral tinnitus Comorbidities: NR</p>	<p>Acamprosate</p> <p>Interven: tab. acamprosate 333 mg 1 tab TID for 45 days; then washout period of 7 days; crossed over to matched placebo 1 tab orally TID for next 45 days Cntrl: matched placebo 1 tab TID for next 45 days; then washout period of 7 days; crossed over to tab acamprosate 333 mg 1 tab orally TID for 45 days Comparator: Placebo</p> <p>Duration of treatment: 45 days Number of follow-ups: 3 (45 days, 7 day washout, 45 day) Duration of study: NR</p>	<p>G-QOL (Subjective)</p> <p>Loudness (VAS)</p>	<p>The drug had shown a statistically significant improvement in reducing the tinnitus score in 92.5% of the patients and placebo with an improvement in 12.5% of the patients.</p> <p>Adverse Events: The drug was well tolerated without any serious drug reactions</p>

**Appendix D. Table A: Pharmacological or Food Supplement Interventions and Outcomes (n=16)**

Author Year Setting	Population	Interven	Outcome Measures	Results
Sullivan, <sup>107</sup> 1993  United States	<p>Baseline sample: Total n = 117: Interven n = 63, Cntrl n = 54 Setting: University otolaryngology clinic Mean age (SD): 62.1 y (8.0) Gender: 52% male Interven: 61% male; Cntrl: 42% male</p> <p>Presumed etiology of tinnitus: Idiopathic Duration of tinnitus: ≥ 6 months Severity of tinnitus: sufficient severity to disrupt daily activities (score ≥600 THQ disability subscale) Number of drop outs: Interven n = 14; Cntrl n = 11 Reasons for dropouts: Interven: Anticholinergic side effects, sedation; Cntrl: Unsatisfactory therapeutic response and scheduling conflicts Audiological factors: Treatable otologic disorder related to the tinnitus excluded Comorbidities: 28 participants had current major comorbid depression and 54 were depression-NOS subjects</p>	<p>Nortriptyline Intervention: Treatment initiated at 25 mg at bedtime and titrated upward 25 mg per week. When therapeutic or side effects were evident or when 100 mg was reached, blood level was assessed. Dosage adjusted to a therapeutic level between 50 and 150 mg/mL and maintained there for 6 weeks. Comparator: Placebo</p> <p>Nortriptyline and placebo groups received same number of capsules and same titration protocol.</p> <p>Duration of treatment: 12 weeks Number of follow ups: 1 Duration of study: NR</p>	<p>Depression (HDS)  Anxiety (Sheehans' Disability Scale)  TS-QOL (IOWA*, Likert scale)</p>	<p>The antidepressant Nortriptyline decreases depression, functional disability, and tinnitus loudness associated with severe chronic tinnitus.</p> <p>Separate analysis demonstrates that decreases in tinnitus disability closely parallel decreases in depression severity.</p> <p>Adverse Events: anticholinergic side effects and sedation (n=11)</p>

**Appendix D. Table A: Pharmacological or Food Supplement Interventions and Outcomes (n=16)**

Author Year Setting	Population	Interven	Outcome Measures	Results
Topak, <sup>109</sup> 2009  Turkey	<p>Setting and subject recruitment: Hospital Baseline Sample: Total n=69 Mean age (SD): Interven: 49.9 y; Cntrl: 55.3 y Gender: Interven: 66.7% male; Cntrl: 58.6% male</p> <p>Presumed etiology of tinnitus: Subjective tinnitus of cochlear origin Duration of tinnitus: NR Severity of tinnitus: Only subjects for whom drug treatment had failed Number of dropouts: 11 Reasons for dropouts: Failed to return for follow-up Audiological factors: Patients with sudden sensorineural hearing loss excluded Comorbidities: NR</p>	<p>Methylprednisolone (by intratympanic injection). Patients were randomized to receive one of two treatments: 0.3 to 0.4 ml intratympanic injections of either a 6.25mg methylprednisolone solution or placebo (saline solution). The treatment protocol comprised 3 intratympanic injections, 1 per week for 3 weeks.</p> <p>Comparator: Placebo</p> <p>Duration of treatment: 3 weeks Number of follow ups: 1 Duration of study: 30 months</p>	<p>TS-QOL (TSI)</p> <p>Loudness (Self- rated)</p>	<p>No significant post-treatment changes in the tinnitus severity index individual and total scores were observed in either group.</p> <p>The results of this study indicate that intratympanic methylprednisolone has no benefit, compared with placebo, for the treatment of subjective tinnitus of cochlear origin refractory to medical treatment.</p> <p>Adverse Events: pain during injection, vertigo, a burning sensation around the ear and in the throat, and a bitter taste</p>
Westerberg, <sup>11</sup> 1996  United States	<p>Baseline sample: Total n = 63 Interven n = 31; Cntrl n = 32 Setting: ear institute Mean age (SD): Total: 51.2 y Gender: 57% male Interven: 58% male; Cntrl: 56% male</p> <p>Presumed etiology of tinnitus: Idiopathic Duration of tinnitus: NR Severity of tinnitus: NR Number of dropouts: 11 Reasons for dropouts: side effects (n=9); unknown (n=2) Audiological factors: Only constant, non- pulsatile included Comorbidities: NR</p>	<p>Baclofen vs Placebo</p> <p>Baclofen: Three weeks of baclofen (10 mg BID for 1 week, 20 mg BID 2<sup>nd</sup> week and 30 mg BID 3<sup>rd</sup> week) were given to drug group. Drug was tapered before discontinuation</p> <p>Comparator: Placebo designed to mimic baclofen capsules in route, schedule appearance and taste</p> <p>Duration of treatment: 3 weeks Number of follow-ups: 1 (3 weeks) Duration of Study: NR</p>	<p>TS-QOL (THI)</p> <p>Self-reported Loudness (Subjective 0- 10)</p>	<p>Reports of subjective improvement occurred in only 9.7% of the baclofen vs 3.4% of the placebo groups (NS).</p> <p>Adverse Events: 26% withdrawals from the baclofen arm due to AEs. None were severe or life threatening and all resolved with stopping the medication or by study's end.</p>

**Appendix D. Table A: Pharmacological or Food Supplement Interventions and Outcomes (n=16)**

Author Year Setting	Population	Interven	Outcome Measures	Results
Zoger, <sup>114</sup> 2006  Companion: Holgers, <sup>90</sup> 2011  Sweden	<p>Baseline sample: Total n = 76; Interven n = 38; Cntrl n = 38 Setting: Audiology department, university hospital Mean age (SD): Interven: 40 y; Cntrl: 46 y Gender: Interven: 51.7% male; Cntrl: 61.8% male</p> <p>Presumed etiology of tinnitus: Idiopathic Duration of tinnitus: NR Severity of tinnitus: major complaint Number of drop outs: Interven n = 9; Cntrl n = 4 Reasons for drop outs: Interven; A/E (2), moved (1), stress (2), other (4) Cntrl: changed psychiatric condition (2), moved (1); other (1) Audiological factors: Pure-tone averages better than 50dB HL in the worse hearing ear; positive answer on at least one of NHP items Comorbidities: excluded psychiatrically severe condition in need of acute treatment</p>	<p>Sertraline Interven: During the first week, 25mg/d of sertraline; 50 mg/d thereafter. To alleviate an expected initial worsening of psychological distress, all patients offered oxazepam 10mg during first 2 weeks of the study. Limit 3 tablets of oxazepam 10mg daily to maximum of 25 tablets</p> <p>Comparator: Placebo</p> <p>Duration of treatment: 16 weeks Number of follow-ups: 2 (16 weeks and 28 weeks) Duration of study: 28 weeks</p> <p>All patients were offered an open trial of sertraline at week 16 for another 12 weeks (post-data is taken before crossover portion of this study).</p>	<p>TS-QOL (TSQ*, VAS)</p> <p>Loudness (VAS)</p> <p>Anxiety (HAS*, CPRS-S-A, PGWB sub)</p> <p>Depression (HDS*, CPRS-S-A, PGWB sub)</p> <p>G-QOL<sup>90</sup> (PGWB)</p>	<p>Individuals in the Interven condition who completed the post-assessment experienced a significant reduction in tinnitus distress from pre-Interven to post-Interven (p =.0001).</p> <p>The between-groups difference in the rates of reliable change, although in the hypothesized direction, was not statistically significant (p =.15).</p> <p>Adverse Events: Sexual side effects (1 Interven; 2 Cntrl)</p>

\*Indicates the test used to measure outcomes which were selected to represent the domain in the forest plots (and subsequent SOE decisions)

Abbreviations: A/E = Adverse events; AMT = active motor threshold; CBT = cognitive behavioral treatment; ENT = ear, nose and throat; grp = group; G-QOL = global quality of life; HADS = Hospital Anxiety and Depression Scale; HDS = Hamilton Depression Rating Scale; interven = intervention; month = month; N/A = not applicable; NR = not reported; QOL = quality of life; RCT = randomized controlled trial; SD = standard deviation; TCT = Tinnitus Coping Therapy; THI = Tinnitus Handicap Inventory; TMJ = temporal mandibular joint; TS = tinnitus specific; TSQ = Tinnitus Severity Questionnaire; VAS = visual analog scale; week = week; WLC = wait list Cntrl; yr = year

**Appendix D. Table B: Medical Interventions and outcomes (n=11)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Anders, <sup>73</sup> 2010  Czech Republic	<p>Baseline sample: Total n = 52; Interven n = 26; Cntrl n = 26 Setting: Outpatient Otorhinolaryngology clinic Mean age (SD): Interven: 48.1y (14.86); Cntrl: 50.1y (13.97) Gender: 69% male</p> <p>Presumed etiology of tinnitus: Idiopathic Duration of tinnitus: &gt; 6 months Severity of tinnitus: Uni- or bilateral tinnitus according to KD-10, no response to &gt;3 months of pharmacological treatment Number of dropouts: 10 Reasons for dropouts: Treatment n = 4; worsening of tinnitus (2); adverse events(2) Cntrl n = 6; lack of efficacy (3); adverse events (2); unknown (1) Audiological factors: Included age-adjusted normal sensorineural hearing. Excluded profound hearing loss or Meniere's disease Comorbidities: NR</p>	<p>Repetitive Transcranial Magnetic Stimulation (rTMS) Patients were treated with either real or sham low frequency rTMS over a period of 2 weeks. Blinding design applied.</p> <p>Comparator: Placebo</p> <p>Duration of treatment: 2 weeks Number of follow ups: 4 Duration of study: 6 months</p>	<p>TS-QOL (THI*, TQ-mod, VAS)</p>	<p>The ability to reduce the symptoms of the tinnitus appeared in both randomized groups immediately after the 1 Hz rTMS and sham stimulation phase. There was a significant reduction in both groups of the tinnitus total score on the Tinnitus Handicap Inventory (THI) (real rTMS p=0.00t; sham rTMS p=0.049). Reduction of symptoms as evaluated using the TQ was significant compared to baseline in the real rTMS group at week 2, 6 and 14 (p=0.003; p=0.024; p=0.022).</p> <p>Real 1 Hz rTMS treatment was capable of significantly reducing the total baseline score of basic scales that measure tinnitus severity. Important for patients with long-term symptoms resistant to pharmacological treatment.</p> <p>Adverse Events: unacceptable pain in stimulation area, headache, lack of efficacy and subjective worsening of tinnitus</p>

**Appendix D. Table B: Medical Interventions and outcomes (n=11) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Chung, <sup>79</sup> 2012  China	<p>Baseline sample: Total n = 22 Intervention n = 12 Cntrl n = 10 Setting: University medical Hospital Total Mean age: 52.96 (range 20-76 yrs) Gender: Int 91.6% male Cntrl 90.0% male</p> <p>Presumed etiology of tinnitus: Duration of tinnitus: : Int range 0.5 to 20 years Cntrl: 2 to 10 years Severity of tinnitus: Mean score on TQ and THI Number of dropouts: 0 Reasons for dropouts: NA Audiological factors: Most subjects had unilateral problems Comorbidities: Excluded subjects with known history of metal implants, head injury, stroke, epilepsy</p>	<p>Intervention: rTMS coil was placed over the auditory cortex with the intensity setting at 80% of the resting motor threshold. Continuous theta-burst rTMS (cTBS) was delivered at a burst frequency of 5 Hz (the theta rhythm in the EEG); each burst consisted of 3 pulses repeated at 50 Hz. We administered 900 pulses (300 bursts) of stimulation once daily for 10 consecutive business days.</p> <p>Comparator: Sham rTMS</p> <p>Duration of treatment: Once daily for 10 consecutive days Number of followups: 1 week and 1 month post treatment. Duration of study: NR</p>	<p>TS-QOL (THI*, TQ)  Loudness (VAS)</p>	<p>9/12 patients (75%) in the active-stimulation group reported tinnitus suppression following treatment with rTMS. TQ global scores averaged 8.58 points lower 1 week after treatment, a significant decrease compared to the sham-stimulation group (p &lt;0.01). THI scores were, on average, 8.33 points lower after treatment, which were also significantly lower than those of patients in the sham-stimulation group (p &lt;0.01). Tinnitus loudness also decreased significantly after delivering rTMS. (p&lt;0.05)</p> <p>Adverse Events: No patients experienced sustained side effects after the rTMS treatment.</p>
Cuda, <sup>80</sup> 2008  Italy	<p>Baseline sample: Total n = 46 Interven n = 26; Cntrl n = 20 Setting: University Otolaryngolgy clinic Mean age (SD): 56.4y (13.6) Int: 50.3y (9.8); Cntrl: 64.4y (14.1) Gender: 58.7 % male</p> <p>Presumed etiology of tinnitus: non-intermittent subjective tinnitus Duration of tinnitus: mean 6.4 years (8.8) Severity of tinnitus: 'disturbing' &gt; 3 months Number of dropouts: None Reasons for dropouts: NA Audiological factors: 60.9% had no clinically significant hearing impairment Comorbidities: NR</p>	<p>Low Level Laser Stimulation + combined counseling protocol (LLS+). Emission power was 5mW, and the wavelength was 650nm. Patients trained to use the device for 20 minutes per day, each day for 3 months.</p> <p>Comparator: combined counseling protocol with sham LLS (LLS-) Combined Counseling consisted of a combination of hypnotic techniques with relations techniques based on respiration, proprioception and insight</p> <p>Duration of treatment: 3m Number of followups: 10 Duration of study: NR</p>	<p>TS-QOL (THI)</p>	<p>Approximately 61% of irradiated patients had tinnitus severity decreased by one class, in comparison to 35% of the placebo group.</p> <p>This study confirmed a significant difference in the benefit of treatment between the LLS+ and LLS-groups.</p> <p>Adverse events: NR</p>

**Appendix D. Table B: Medical Interventions and outcomes (n=11) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Ghossaini, <sup>85</sup> 2004  United States	Baseline sample Total n = 29 Interven n = 15; Cntrl n =14 Setting: NR  Age: Range 23 to 83 y Gender: NR Etiology of tinnitus: cause/origin of tinnitus in the study sample varied Duration of tinnitus: 7 months to 60 y Severity of tinnitus: Chronic >6 months Number of dropouts: 2 Reasons for dropouts: Failure to return for post-treatment testing (not included in analysis) Comorbidities: NR	High-Frequency Pulsed Electromagnetic Energy (Diapulse) Patients received 30-minute treatments with the Diapulse device (model D103) 3 times per week for 1 month.  Comparator: placebo (deactivated machine)  Duration of treatment: 1 month Number of follow-ups: NA Duration of study: NR	TS-QOL (THI*, TMR)	There was no significant change in the pre-treatment and post-treatment audiometric thresholds in either group.  There were no significant differences between the pretreatment and post-treatment THI scores or the tinnitus rating scores in either subject group  Adverse Events: tingling (Treatment) and worsening of tinnitus (5 Control; 4 Treatment)
Langguth, <sup>94</sup> 2008  Germany	Baseline sample: Total n = 32 Interven n = 16; Cntrl n = 16 Setting: Dept. of Psychiatry Mean age (SD): 51.5y (11.6) Int: 52.6y (12.6); Cntrl: 50.3y (10.8) Gender: 71.8% male Int: 81.3% male; Cntrl: 62.5% male  Presumed etiology of tinnitus: NR Duration of tinnitus: Int: 10.9y (10.1); Cntrl: 11.7y (10.9) Severity of tinnitus: 'disturbing' tinnitus Number of dropouts: None Reasons for dropouts: NA Audiological factors: normal middle-ear status Comorbidities: all had tried several standard treatment modalities	To investigate whether priming stimulation enhances the efficacy of low-frequency rTMS. Medtronic  Interven: Priming protocol (960 stimuli; 6 Hz + 1040 stimuli; 1 Hz)  Comparator: standard protocol (2000 stimuli; 1 Hz)  Duration of treatment: 10 working days Number of followups: 4 over 13 weeks Duration of study: NR	TS-QOL (TQ)	There was no significant difference between the standard protocol and the protocol involving priming stimulation.  Data does not support an enhancing effect of higher frequency priming on low-frequency rTMS in the treatment of tinnitus.  Adverse Events: No serious adverse or side effects were observed

**Appendix D. Table B: Medical Interventions and outcomes (n=11) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Marcondes, <sup>96</sup> 2010  Spain	<p>Baseline sample: Total n=19 Interven=10 Cntrl=9</p> <p>Setting: Otorhinolaryngology clinic Mean Age: NR Gender: NR</p> <p>Presumed etiology of tinnitus: Idiopathic Duration of tinnitus: &gt; 3 months Severity of tinnitus: NR Number of dropouts: 1 Reasons for dropouts: 1 participant withdrew consent before treatment began Audiological factors: Hearing lever in tinnitus ears – data presented by ear Comorbidities: NR</p>	<p>Repetitive Transcranial Magnetic Stimulation: 5 sessions of rTMS performed on 5 consecutive days</p> <p>Comparator: Placebo</p> <p>Duration of treatment: 5 days</p> <p>Number of follow ups: 10</p> <p>Duration of study: 6 months</p>	TS-QOL (THI)	<p>Significant improvement of the tinnitus score in the active rTMS group as compared to sham rTMS for up to 6 months after stimulation. SPECT measurements demonstrated a reduction of metabolic activity in the inferior left temporal lobe after active rTMS.</p> <p>Results demonstrate a significant reduction of tinnitus complaints over a period of at least 6 months and significant reduction of neural activity in the inferior temporal cortex.</p> <p>Adverse Events: no relevant side effects</p>
Mirz, <sup>99</sup> 1999  Denmark	<p>Baseline sample: Total n = 50 Interven n = 25; Cntrl n = 25</p> <p>Setting: otorhinolaryngology clinic Mean age (SD): Interven n = 48.6 y; Cntrl n = 48.7 y Gender: Total: 75.5% male Interven: 64.0% male; Cntrl: 87.5% male</p> <p>Presumed etiology of tinnitus: Idiopathic Duration of tinnitus: Mean 5.5y Severity of tinnitus: Disabling, chronic Number of dropouts: 1 Reasons for dropouts: Unrelated illness Audiological factors: sensorineural hearing loss Comorbidities: NR</p>	<p>Laser Therapy vs Placebo</p> <p>The active laser applied 50mW (cw, 830 nm) over a period of 10 min per session. The laser treatment consisted of three periods of five consecutive days separated by weekends, totaling 15 treatment sessions.</p> <p>Comparator: Placebo – an identical looking laser probe was inactivated by the producer</p> <p>Duration of treatment: 5 week days Number of follow ups: 4 Duration of study:</p>	<p>Anxiety (STAI)</p> <p>Depression (BDI)</p> <p>Loudness (VAS)</p> <p>TS-QOL (THI*, VAS-Ann, VAS-Att)</p>	<p>The results showed only moderate (18%) subjective improvement with no statistically significant differences between the effects of the active laser and placebo treatment.</p> <p>There were no statistically significant differences in pre-post measurements of tinnitus loudness, VAS scores, THI scores, or TCSQ scores for patients treated with active laser compared with those treated with placebo.</p> <p>Adverse Events: No serious untoward adverse or side effects were noticed</p>

**Appendix D. Table B: Medical Interventions and outcomes (n=11) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Plewnia, <sup>102</sup> 2012  Germany	<p>Baseline sample: Total n = 48                      Interven1 (SAC) n = 16                      Interven2 (TAC) n = 16                      Cntrl (PLC) n = 16                      Setting: University Psychiatry and outpatient clinic Department of Otorhinolaryngology                      Mean age (SD):                      SAC: 46.4y (13.0); TAC: 55.8y (9.7);                      PLC: 45.6y (10.3)                      Gender:                      SAC 10.5%male; TAC 43.8%male;                      PLC 50%male</p> <p>Presumed etiology of tinnitus: NR                      Duration of tinnitus: &lt; 5y chronic tinnitus                      Severity of tinnitus: NR                      Number of dropouts: total n = 8;                      SAC n = 4; TAC n = 2; PLC n = 2                      Reasons for dropouts: Tinnitus worsening (4); Patient decision (3); sudden hearing loss (1)                      Audiological factors:                      Comorbidities:</p>	<p>4 weeks of bilateral cTBS to the secondary auditory cortex (SAC) and temporoparietal cortex (TAC)                      Stimulation (cTBS) intensity was standardized at 80% AMT                      Each stimulation train (40 s) consisted of 600 stimuli applied in bursts of 3 pulses at 50 Hz given every 200 msec (i.e., at 5 Hz). Fifteen minutes after the first 2 trains, a second pair of cTBS trains was given (a total of 2,400 stimuli/day). Patients received cTBS treatment each working day for 4 weeks (20 sessions) the 10–20 EEG electrode placement system was used to localize Brodmann area 39 (TAC: halfway between T5/P3 and T6/P4) and Brodmann area 42/22 (SAC: halfway between T3/C3 and T4/C4). For adequate masking of the patients, sham stimulation (PLC) was performed behind the mastoid.                      Comparator: sham stimulation (PLC)</p> <p>Duration of treatment: 4 weeks                      Number of followups: 1 (12 weeks)                      Duration of study: Feb 2008 to May 2010</p>	TS-QOL (TQ)	<p>Tinnitus severity was slightly reduced from baseline by a mean (SD) 2.6 (8.2) after sham, 2.4 (8.0) after temporoparietal, 2.2 (8.3) after temporal treatment of 16 patients each, but there was no significant difference between sham treatments and temporal (confidence interval [CI] -5.4 to +6.7) or temporoparietal cTBS (CI -5.9 to +6.3) or real cTBS (CI -7 to +5.1).</p> <p>Patients' global evaluation of tinnitus change after treatment did not indicate any effects.</p> <p>Adverse events:                      Patients reported the following side effects: headache (SAC: 2, TAC: 2, PLC: 3), worsening of tinnitus (SAC: 1, TAC: 2, PLC: 3), increased sensitivity to noise (TAC: 1, PLC: 1), painful local sensation (SAC: 1), and sleep disturbance (SAC: 1). An acute hearing loss associated with increased tinnitus loudness was observed in 1 patient after session 17 (SAC). In this patient, hearing thresholds and tinnitus returned to baseline after 3 weeks.</p>

**Appendix D. Table B: Medical Interventions and outcomes (n=11) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Tass, <sup>108</sup> 2012  Germany	<p>Baseline sample: Total n=63 Interven (4 groups) G1 n = 22; G2 n = 12; G3 n = 12; G4 n = 12 Cntrl (G5) n = 5 Setting: 2 treatment centers in Germany Mean age (SD): &gt;18 G1: 45.7 (10.8); G2 47.7 (5.6); G3 50.0 (14.7); G4 50.3 (11.8); G5 57.6 (6.3) Gender: G1: 72.7% male; G2: 83.3% male; G3: 50.0% male; G4: 75.0% male; G5: 60.0% male</p> <p>Presumed etiology of tinnitus: chronic tonal tinnitus Duration of tinnitus [years – Mean (SD)]: all &gt;6 months G1: 5.7 (5.1); G2: 6.6 (6.0); G3: 5.4 (3.5); G4: 7.9 (9.8); G5: 11.3 (5.6) Severity of tinnitus: chronic Number of dropouts: 0 Reasons for dropouts: N/A Audiological factors: Morbus Meniere, TMJ, psychiatric disorders and objective tinnitus excluded Comorbidities: NR</p>	<p>Acoustic Coordinated Reset (CR) neuromodulation: 4 stimulation groups. For G1, G3 and G4 four tones (top, f1 to f4) are grouped around the tinnitus frequency (ft). G3 differs only in repetition rate F being adapted to the individual EEG <math>\delta</math>-band peak. For G2 each CR cycle is formed by a varying composition of four tones (dark green: active) chosen out of twelve tones (middle, f1 to f12) surrounding ft.</p> <p>Comparator: Placebo stimulation (G5) is formed similar to G1 using a down-shifted stimulation-frequency fp (<math>fp = 0.7071 \cdot ft / (2n)</math>, fp within [300 Hz, 600 Hz]) outside the synchronized tinnitus focus.</p> <p>Duration of treatment: G1 to G3 received stimulation for 4 to 6 hours every day for 12 weeks applied either continuously or split into several sessions not shorter than 1 hour G4 and G5 all received stimulation for 1 hour max. every day</p> <p>Number of followups: 1,4,8, 12 and 16 weeks after beginning of treatment and every 4 weeks during optional 24 week LTE</p> <p>Duration of study: NR</p>	TS-QOL (TQ*, VAS)  Loudness (VAS)	<p>Strong and significant reduction of VAS loudness in G1 and G3 in the on-stimulation condition (<math>p \leq 0.01</math>) G1 also significant compared to placebo (G5) (<math>p &lt; 0.05</math>)</p> <p>A reduction of at least 6 TQ points was obtained in 75% of patients with a mean TQ reduction of 50% among responders.</p> <p>Adverse events – 15 AEs: 13 AEs during blinded phase, 2 AEs in LTE. 2 SAEs not associated with treatment were reported; All other AEs were of mild to moderate intensity and none was permanent. 8 AEs were judged to be treatment related of which 3 AEs were associated with a transient increase of tinnitus loudness</p>

**Appendix D. Table B: Medical Interventions and outcomes (n=11) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Teggi, <sup>31</sup> 2009  Italy	Baseline sample Total n = 60 Interven: n = 30; Cntrl n = 30 Setting: ENT department Mean age (SD): Interven: 51.6y (11.3); Cntrl: 53.1y (12.9) Gender: Interven: 59.2% male; Cntrl: 51.2% male  Presumed etiology of tinnitus: NR Duration of Tinnitus: NR Severity of tinnitus: NR Number of dropouts: Interven n = 3; Cntrl n = 3 Reasons for dropouts: familial reasons (4), increase in tinnitus loudness (2) Audiological factors: NR Comorbidities: NR	Laser Therapy All patients instructed to perform laser therapy with the TinniTool soft laser at home for 20 min a day for a period of 3 months; patients in the first group (group L) received an active laser  Comparator: Placebo - a dummy laser (group C).  Duration of treatment: 3 months Number of follow ups: 1 Duration of study: NR	TS-QOL (THI)  Loudness (VAS)	No statistical difference was detected between the 2 groups in the THI total score (p = 0.97), and the functional (p = 0.89), emotional (p = 0.89) and catastrophic (p = 0.89) subscales. VAS for self-perceived loudness of the tinnitus showed no difference between the groups (p = 0.69).  Soft laser therapy demonstrated no efficacy as a therapeutic measure for tinnitus in this report.  Adverse Events: subjects with migraine presenting hyperacusis (Treatment = 4; Control = 2). Increase in loudness (Treatment = 1; Control = 1)
Vilholm, <sup>110</sup> 1998  Denmark	Baseline sample Total n = 54 Interven n = 29; Cntrl n = 25 Setting: Department of Audiology Mean Age (SD): 53.1 y Gender: Int: 68.9% male; Cntrl: 60.0% male  Presumed etiology of tinnitus: Idiopathic Duration of tinnitus: ≥ 1 yr Severity of tinnitus: Severe treatment-resistant tinnitus Number of dropouts: 0 Reasons for dropouts: N/A Audiological factors: NR Comorbidities: NR	Acupuncture vs Placebo Acupuncture group treated with traditional Chinese acupuncture of 25 treatment sessions over 2 months. Sessions distributed over 3 treatment periods of 10, 5 and 10 treatments separated first by a pause of one week, and then by a pause of two weeks. Treatment given each day for 30 minutes. Comparator: Placebo group treated with placebo acupuncture.  Duration of treatment: 4 months Number of follow ups: 2 Duration of study: NR	TS-QOL (VAS-Ann*, VAS-Awr)  Loudness (VAS)	No statistically significant differences were found between the acupuncture group and the placebo group.  Adverse Events: NR

\*Indicates the test used to measure outcomes which were selected to represent the domain in the forest plots (and subsequent SOE decisions)

Abbreviations: A/E = Adverse events; AMT = active motor threshold; CBT = cognitive behavioral treatment; ENT = ear, nose and throat; G1 to G5 = group; G-QOL = global quality of life; HADS = Hospital Anxiety and Depression Scale; interven = Intervention; month = month; N/A = not applicable; NR = not reported; QOL = quality of life; RCT = randomized Controlled trial; SD = standard deviation; TCT = Tinnitus Coping Therapy; THI = Tinnitus Handicap Inventory; TMJ = temporal mandibular joint; TS = tinnitus specific; TSQ = Tinnitus Severity Questionnaire; VAS = visual analog scale; week = week; WLC = wait list Cntrl; yr = year

Appendix D. Table C: Sound treatment/technologies intervention and outcomes (n=5)

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Davis, <sup>46</sup> 2007  Australia	<p>Baseline sample: Total n = 35 Stage1 n = 16; Stage2 n = 19 Setting: Clinic Mean age (SD): 58.5y(13.4) Stage1: 61.3y(8.9); Stage2: 56.1y(16.2) Gender: 74%male</p> <p>Presumed etiology of tinnitus: NR Duration of tinnitus: 11.0y (11.3) Severity of tinnitus: moderate to severe Number of dropouts: 1 Reasons for dropouts: NR Audiological factors: decreased sound tolerance Comorbidities: NR</p>	<p>Participants were provided with a high fidelity personal sound player with earphones and an acoustic stimulus that had been spectrally modified according to their individual audiometric profile. They were instructed to use the acoustic stimulus for at least 2 hr per day, particularly at those times when their tinnitus was usually disturbing. Each group had equal amounts of clinician time for education, monitoring, and support. Complete covering of perception initially, then intermittent perception (Stage2)</p> <p>Comparator: intermittent perception throughout (Stage1)</p> <p>Duration of treatment: 12m Number of followups: 2,4,6 and 12 m Duration of study: NR</p>	<p>TS-QOL (TRQ, VAS)</p> <p>Loudness (VAS)</p>	<p>Improvements increased with time over the first 6 months of therapy, at which time 91% of all subjects across the two groups reported an improvement in tinnitus disturbance (as measured by the TRQ) of at least 40%, with a mean improvement of 65%.</p> <p>Inter-group differences were not statistically significant measuring tinnitus disturbance.</p> <p>Adverse events: NR</p>
Dineen, <sup>82,83</sup> 1999, 1997  Australia	<p>Baseline sample: Total n = 96 Group I: n = 28; Group ID: n = 20 Group IR: n = 28; Group IDR: n = 20 Setting: Hearing Clinic, University Mean age (SD): 54.37y (13.86) Gender: 66.1% male</p> <p>Presumed etiology of tinnitus: NR Duration of tinnitus: NR Severity of tinnitus: NR Number of dropouts:25 Group I: 10 (36%); Group ID: 7 (35%) Group IR: 5 (18%); Group IDR: 3 (15%) Reasons for dropouts: 12 returned questionnaires, 2 in hospital; 2 away; 5 couldn't attend clinic; 3 tinnitus not a sufficient problem Audiological factors: NR Comorbidities: NR</p>	<p>Tinnitus management training designed to characterize common components of published tinnitus management programs</p> <p>Group I: Information Only Group ID: Information plus long-term low-level white noise (LTWN) – Starkey TM devices, 2 3- hour sessions Group IR: Information plus relaxation therapy Group IDR: Information plus LTWN plus relaxation</p> <p>Duration of treatment: 2.5 hours per subject Number of followups: 3m, 12m Duration of study: NR</p>	<p>TS-QOL (TRQ, VAS)</p> <p>Loudness (VAS)</p> <p>G-QOL (DSP)</p>	<p>Subjects who initially had low ability to cope with tinnitus and preferred a more active coping style reported significantly greater benefit from LTWN stimulation than subjects whose primary approach to coping was to regulate the emotional impact of tinnitus.</p> <p>Adverse Events: NR</p>

**Appendix D. Table C: Sound treatment/technologies intervention and outcomes (n=5) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Hiller, <sup>89</sup> 2005  Germany  Study 1	Baseline sample: Total n = 136 Int1 (CBT+NG) n = 33 Cntrl1 (CBT only) n = 33 Setting: Outpatient Department, University Mean age (SD): Int1 (CBT+NG): 51.0y (13.2); Cntrl1 (CBT only): 51.4y (10.9) Gender: Int1 (CBT+NG): 68% male Cntrl1 (CBT only): 41% male  Presumed etiology of tinnitus: > 25% had sudden hearing loss Duration of tinnitus: at least 6 months Severity of tinnitus: chronic Number of dropouts: Int1 (CBT+NG)= 2; Cntrl1 (CBT only)= 4 Reasons for dropouts: external reasons; insufficient motivation; unknown Audiological factors: NR Comorbidities: NR	CBT: subjects score 40 or more on TQ (severe), training consists of 10 120- minute sessions. Treatment was strictly manualized.  All therapies conducted by two clinical psychologists  Comparator: CBT + Noise generator CBT only  Duration of treatment: up to 10 weeks Number of followups: 6, 18m Duration of study: NR	TS-QOL (TQ, T-Cog)  Loudness (VAS)  Anxiety (WI)	No additive effects due to the NGs could be demonstrated.  Adverse Events: NR

**Appendix D. Table C: Sound treatment/technologies intervention and outcomes (n=5) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Hiller, <sup>89</sup> 2005  Germany  Study 2	Baseline sample: Total n=136 Int2 (TE + NG)= 34 Cntrl2 (TE only) = 36 Setting: Outpatient Department, University Mean age (SD): Int2 (TE + NG)= 52.5y (15.3) Cntrl2 (TE only) = 45.2y (14.1) Gender: Int2 (TE + NG)= 52% male Cntrl2 (TE only) = 61% male  Presumed etiology of tinnitus: > 25% had sudden hearing loss Duration of tinnitus: at least 6 months Severity of tinnitus: chronic, Number of dropouts: Int2 (TE + NG)= 3; Cntrl2 (TE only) = 3 Reasons for dropouts: external reasons; insufficient motivation; unknown Audiological factors: NR Comorbidities: NR	Tinnitus Education (TE): patients with mild to moderate distress as scored by the TQ – abridged version of CBT 4 90-minute weekly sessions  All therapies conducted by two clinical psychologists  TE + Noise generator TE only  Duration of treatment: up to 4 weeks Number of followups: 6, 18m Duration of study: NR	TS-QOL (TQ, T-Cog, VAS, Diary)  Loudness (VAS)  Anxiety (WI)  G-QOL (SCL-90R, PSDI)	No additive effects due to the NGs could be demonstrated.  Adverse Events; NR

**Appendix D. Table C: Sound treatment/technologies intervention and outcomes (n=5) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Parazzini, <sup>100</sup> 2011  Italy, United States	Baseline sample: Total n=91 Interven (OE-HA) n=49; Cntrl (SG) n=42 Setting: Tinnitus clinics in Milan, Baltimore Mean age (SD): 38.8y (1.9) Gender: 51/91 (56%) male Int: 57.1%male; Cntrl: 54.7% male  Presumed etiology of tinnitus: bilateral symmetrical hearing loss Duration of tinnitus: 69.5m (9.4) Severity of tinnitus: NR Number of dropouts: 10 Reasons for dropouts: NR Audiological factors: borderline between category 1 and category 2 (according to the Jastreboff classification) with HL ≤25 dB at 2kHz and HL ≥25 dB at frequencies >2kHz Comorbidities: No participant treated with TRT before; No previous use of hearing aids	TRT with open hearing aids (OE-HA)  Comparator: TRT with sound generator (SG)  Duration of treatment: 1 year Number of followups: 3 (3m, 6m, 12m) Duration of study: NR	G-QOL (VAS) TS-QOL (THI)  Loudness (subjective)	TRT was equally effective with sound generator or open ear hearing aids: they gave basically identical, statistically indistinguishable results  Adverse Events: NR

\*Indicates the test used to measure outcomes which were selected to represent the domain in the forest plots (and subsequent SOE decisions)

Abbreviations: A/E = Adverse events; AMT = active motor threshold; CBT = cognitive behavioral treatment; DSP = Derogatis Stress Profile; ENT = ear, nose and throat; grp = group; G-QOL = global quality of life; HADS = Hospital Anxiety and Depression Scale; intervention = Interven; month = month; N/A = not applicable; NR = not reported; QOL = quality of life; RCT = randomized Controlled trial; SD = standard deviation; TCT = Tinnitus Coping Therapy; THI = Tinnitus Handicap Inventory; TMJ = temporal mandibular joint; TRQ = Tinnitus Reaction Questionnaire; TS = tinnitus specific; TSQ = Tinnitus Severity Questionnaire; VAS = visual analog scale; week = week; WI = Whiteley Index; WLC = wait list Cntrl; yr = year

**Appendix D. Table D: Psychological/Behavioral intervention and outcomes (n=19)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Abbott, <sup>1</sup> 2009  Australia	<p>Baseline Sample: Total n = 56; Interven n = 32; Cntrl n = 24 Setting: Internet in 23 industrial settings, Mean Age (SD): Interven: 50.5 y (9.5); Cntrl: 48.7 y (8.6) Gender: Interven: 96% male Cntrl: 83% male</p> <p>Presumed etiology of tinnitus: idiopathic Duration of tinnitus: &gt; 3 months Severity of tinnitus: NR Number of dropouts: Interven N=4; Cntrl=1 Reasons for dropouts: most indicated withdrawal by no response when contacted Audiological factors: NR Comorbidities: NR</p>	<p>Internet-based education Interven: 10 components, presented in six modules, and completed at the rate of one module per week. Modules included homework assignments and weekly diaries submitted electronically. Participants completed daily online registrations 1 week before Interven (pre-assessment) and 1 week immediately after Interven (post-assessment) on VAS (range 0 to 10)</p> <p>Comparator: Information only</p> <p>Duration of treatment: 6 weeks Number of follow ups: 1 Duration of study: June 2006 to March 2007</p>	<p>Depression (DASS-D)</p> <p>Anxiety (DASS-A)</p> <p>Loudness (VAS)</p> <p>Sleep (VAS)</p> <p>G-QOL (WHO-Social)</p> <p>TS-QOL (TRQ*, VAS, OSI-R)</p>	<p>The CBT program was not found to be superior to the information program for treating tinnitus distress.</p> <p>Participants who completed the program generally reported finding most aspects of it useful, but found the sound enrichment, sound sensitivity, and cognitive restructuring tools less useful.</p> <p>Adverse Events: None</p>
Andersson, <sup>6</sup> 2005  Sweden	<p>Baseline sample Total n = 23; Interven n = 12; Cntrl n = 11 Setting: web pages and newspaper articles Mean age (SD): 70.1y (3.90) Gender: 52% male</p> <p>Presumed etiology of tinnitus: NR Duration of tinnitus: Mean 13y (12.5) Severity of tinnitus: "problem with tinnitus" as inclusion criteria Number of dropouts: None Reasons for dropouts: N/A Audiological factors: 22% previously fitted with hearing aids Comorbidities: NR</p>	<p>CBT Interven: Sessions covered information about tinnitus, applied relaxation, cognitive restructuring, behavioral activation, positive imagery, sound enrichment, exposure to tinnitus, advice regarding hyperacusis, hearing tactics, and relapse prevention.</p> <p>Comparator: Wait list</p> <p>Duration of treatment: 6 weeks of 2 hour sessions Number of follow-ups: 2 (immediately post-treatment and 3 months post-treatment taken after crossover) Duration of study: 19 weeks</p>	<p>TS-QOL (TRQ)</p> <p>Depression (HADS-D)</p> <p>Anxiety (HADS-A*, ASI)</p>	<p>Results showed statistically significant reductions of tinnitus-related distress.</p> <p>CBT was better than no treatment, but the particular aspects of CBT that contributed to the effects can not be established.</p> <p>The findings give some support for the use of group CBT for elderly people with tinnitus.</p> <p>Adverse Events: NR</p>

**Appendix D. Table D: Psychological/Behavioral intervention and outcomes (n=19) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Andersson, <sup>74</sup> 2002  Sweden	<p>Baseline sample Total n = 117; Interven n = 53; Cntrl n = 64 Setting: web pages and newspaper articles Mean age (SD): Interven: 48.5y (12.3); Cntrl: 47.2y (15) Gender: Interven: 54% male; Cntrl: 52% male</p> <p>Presumed etiology of tinnitus: NR Severity of tinnitus: "severe problem" for which patient has seen GP or ENT Number of dropouts: Interven n = 29; Cntrl n = 16 Reasons for dropouts: Interven: 26 did not finish treatment; 4 incomplete questionnaire; Cntrl: 16 incomplete questionnaire Audiological factors: problems in 68% Comorbidities: sleep problems, anxiety, depression</p>	<p>CBT Interven: Self-help manual constructed following cognitive behavioral principles, consisting of 6 modules (1 module performed per week). Daily diary ratings were included for 1 week before and 1 week following the treatment period.</p> <p>Comparator: Wait list</p> <p>Duration of treatment: 6 weeks Number of follow-ups:1 Duration of study: 1 yr</p>	<p>TS-QOL (TRQ*, VAS-Ann, VAS-Ctrl)</p> <p>Anxiety (HADS-A*, ASI)</p> <p>Depression (HADS-D)</p> <p>Sleep (VAS)</p> <p>Loudness (VAS)</p>	<p>No significant differences between the groups were found at either post-treatment (p = 0.29) or at the 1-year follow-up (p= 0 .16).</p> <p>CBT via the Internet can help individuals decrease annoyance associated with tinnitus.</p> <p>Adverse Events: NR</p>
Biesinger, <sup>78</sup> 2010  Germany	<p>Baseline sample Total: n = 40 Interven: n = 20; Cntrl: n = 20 Mean age(SD): Interven: 44.7y (10.9); Cntrl: 39.9y (11.3) Gender: 47.1% male</p> <p>Presumed etiology of tinnitus: Nonsomaterenic tinnitus Duration of tinnitus: &gt;3 months Severity of tinnitus: Main complaint Number of dropouts: Interven: 5; Cntrl: 1 Reasons for dropouts: Missed sessions- job-related, personal, organizational reasons, incomplete data Audiological factors: Normal audiogram (LE 10dB or any frequency) as inclusion criteria Comorbidities: NR</p>	<p>Qigong Therapy is a set of breathing and movement exercises with possible benefits to health through stress reduction and body activity. Qigong contains important principles of modern tinnitus therapy, such as relaxation, reduction of muscle tension, attention distraction, stress reduction, activation, and communication, especially when exercising in groups. Qigong training program for 5 weeks, 2 hrs twice a week under professional Qigong instructor.</p> <p>Comparator: Wait list</p> <p>Duration of treatment: 10 sessions, 5 weeks Number of follow ups: 3 Duration of study: NR</p>	<p>TS-QOL (TBF-12*, VAS)</p>	<p>Qigong was completed by 80% of the assigned patients. Compared with the Cntrl group, Qigong participants experienced improvement in tinnitus severity, as reflected by a significant reduction in both the VAS and the TBF-12. In the subgroup of patients with somatosensory tinnitus, Qigong effects were more pronounced, resulting in a highly significant improvement in both scales compared to the waiting-list group.</p> <p>Adverse events: No Qigong related reasons affected participation in the study. No relevant side effects were reported.</p>

**Appendix D. Table D: Psychological/Behavioral intervention and outcomes (n=19) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Cima, <sup>54</sup> 2012  Netherlands	<p>Baseline sample Total: n = 492 Interven n = 245; Cntrl n = 247 Setting: Tinnitus Centre Mean age (SD): Int: 53.74y (11.05); Cntrl: 54.63y (12.02) Gender: Int: 65% male; Cntrl: 61% male</p> <p>Presumed etiology of tinnitus: Idiopathic Duration of tinnitus: &gt;1 year 70% Severity of tinnitus: primary complaint, 84% with continuous tinnitus Number of dropouts: Interven n=74 (30%); Cntrl n=86 (35%) Reasons for dropouts: NR Audiological factors: 19% with hearing aid; 19% with sound generator Comorbidities: NR</p>	<p>Specialized care of CBT with sound-focused tinnitus retraining therapy. Comparator: Usual Care</p> <p>Duration of treatment: 8 months Number of follow ups: 2 Duration of study: September 2007 and January 2011</p>	<p>G-QOL (HUI)  TS-QOL (TQ*, THI)  Depression (HADS)</p>	<p>Patients assigned to specialized care improved in health-related QOL during a period of 12 months (between-group difference 0.059, 95% CI 0.025 to 0.094; p=0.0009); Decreased tinnitus severity (between group difference -8.062, 95% CI -10.829 to -5.295; p&lt;0.0001) and tinnitus impairment (between group difference -7.506, 95% CI -10.661 to -4.352; p&lt;0.0001). Specialized treatment of tinnitus based on CBT could be suitable for widespread implementation for patients with tinnitus of varying severity.</p> <p>Adverse Events: Adverse results as a result of treatment or measurements did not occur</p>

**Appendix D. Table D: Psychological/Behavioral intervention and outcomes (n=19) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Henry, <sup>87</sup> 1998  Australia	<p>Baseline sample Total n = 54                      Int Grp1: n = 12; Int Grp2: n = 14                      Int Grp3: n = 12; Cntrl: n = 14                      Setting: response to radio or newspaper announcements                      Mean age: 56.3 y (range 35 to 83)                      Gender: 62% male</p> <p>Presumed etiology of tinnitus: idiopathic                      Duration of tinnitus: &gt;6 months                      Severity of tinnitus: primary complaint                      Number of dropouts: 4                      Reason for dropouts: NR                      Audiological factors: score 17+ on the TRQ                      Comorbidities: treatment resistant, 72% had subjective hearing loss</p>	<p>ACI - Attention Cntrl and Imagery Training: cognitive coping strategies to help subject learn to shift attention to and from tinnitus and focus on pleasant stimuli – all subjects provided with a written educational manual                      CR – Cognitive Restructuring – techniques drawn from the literature on cognitive therapy - all subjects provided with a written educational manual based on case examples and educational materials                      ACI+CR – Combined Treatment – condensed version of 2 treatments – subjects provided with treatment manuals and education manual                      3 treatment programs consisted of 8 weekly group sessions lasting 90 minutes</p> <p>Comparator: Wait list Cntrl – treatment provided after 8 weeks</p> <p>Duration of treatment: 8 weeks                      Number of follow-ups: post-treatment, 6 m                      Duration of study: NR</p>	<p>Depression (BDI)</p> <p>TS-QOL (TRQ*, THQ handicap, TCSQ coping, TEQ)</p>	<p>The analyses revealed that the combined treatment condition (ACI +CR) showed significantly greater improvement on a measure of psychological distress and achieved a higher clinical response rate compared to the two single treatments.</p> <p>Subjects in the CR condition improved significantly more than the ACI condition on the TRQ (<math>F(1,46) = 4.47, p &lt; 0.05</math>)</p> <p>Subjects in the combined ACI + CR condition improved significantly more than those subjects in the ACI condition and CR condition on the TRQ (<math>F(1,46) = 4.38, p &lt; 0.05</math>).</p> <p>There were no significant group by time effects for any of the dependent variables at the six-month follow-up.</p> <p>Results were interpreted as supporting the practice of combining the two cognitive approaches.</p> <p>Adverse Events: NR</p>

**Appendix D. Table D: Psychological/Behavioral intervention and outcomes (n=19) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Henry, <sup>86</sup> 1996  Australia	<p>Baseline sample: Total n = 60, Int Grp1: n = 20, Int Grp2: n = 20, Cntrl: n = 20 Setting: Hospital Mean age: 64.6 y Gender: 86.6% male</p> <p>Presumed etiology of tinnitus: idiopathic Duration of tinnitus: &gt;6 months Severity of tinnitus: score <math>\geq</math>17 points on the TRQ; unsuccessful previous treatments Number of dropouts: 0 Reasons for dropouts: NA Audiological factors: no hearing aid, masker or tinnitus suppressive medication previous 6 months Comorbidities: NR</p>	<p>ACI - Attention Cntrl and Imagery Training &amp; CBT vs wait list Treatment groups involved 1 90- minute session per week for six weeks. Treatment conducted in groups of 5 to 7 participants. All psychological treatment was delivered by a clinical psychologist. Int Grp1: Cognitive coping skills training plus education; Int Grp2: Education,  Comparator: Wait List Cntrl</p> <p>Duration of treatment: 6 weeks Number of follow ups: 2 Duration of study: 12 months</p>	<p>Depression (BDI)</p> <p>TS-QOL (TRQ*, TEQ, THQ-handicap, TCSQ coping, TCQ awareness)</p> <p>Loudness (Self reported)</p>	<p>Subjects who received the combined cognitive/education intervention demonstrated significantly greater reductions in distress and handicaps associated with tinnitus and engagement in dysfunctional cognitions, than the subjects who received education alone. No significant effects were obtained on measures of depression or loudness.</p> <p>Adverse Events: NR</p>
Henry, <sup>88</sup> 2007  United States	<p>Baseline sample Total n = 268 Int Grp1 n = 94, Int Grp2 n = 84, Cntrl n = 90 Setting: Hospital Mean age(SD): IntGrp1: 62.1y (8.9); IntGrp2: 60.8y (9.5); Cntrl: 62.0y (11.3) Gender: IntGrp1: 96.8% male; IntGrp2: 96.4% male Cntrl: 96.7% male</p> <p>Presumed etiology: NR Duration of tinnitus: 87.7% GE 3 y Severity of tinnitus: Sufficiently bothersome to warrant Intervent Number of dropouts: IntGrp1 n = 26, IntGrp2 n = 23, Cntrl n = 15 Reasons for dropouts: NR Audiological factors: 93% difficulty hearing at least 'sometimes' Comorbidities: NR</p>	<p>Group Education Counseling (TRT principles) Interven group attended four 1.5 hour group sessions each week conducted by audiologists. Assessed at baseline, and at 1, 6, and 12 months after their last group session. Comparison group (traditional-support) subjects attended four weekly 1.5-hour discussion-type group sessions. Sessions were moderated by the project coordinator. No education was provided in the support group.</p> <p>Comparator: no treatment and traditional support</p> <p>Duration of treatment: 4 weeks Number of follow ups: 3 Duration of study: 12 months</p>	<p>TS-QOL (TSI)</p>	<p>The educational counseling group showed a significant reduction in mean TSI score from baseline to 6 months (<math>p &lt; 0.001</math>) and baseline to 12 months (<math>p &lt; 0.001</math>).</p> <p>The effect sizes for the educational counseling group were 0.59 at 6 months and 0.45 at 12 months, while the effect sizes for the traditional support and no treatment groups were 0.11 or less at 6 and 12 months.</p> <p>Adverse Events: None</p>

**Appendix D. Table D: Psychological/Behavioral intervention and outcomes (n=19) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Ireland, <sup>52</sup> 1985  Australia	<p>Baseline sample: Total n =33 Setting: University clinic Mean Age: 55.9 y Gender: 46.6% males Int Grp1: 54.5% males Int Grp2: 44.4% males Cntrl:40.0% males</p> <p>Presumed etiology of tinnitus: Idiopathic Duration of tinnitus: NR Severity of tinnitus: Other traditional treatments not recommended or had failed Number of drop outs: 3 Reasons for drop outs: discontinued treatment Audiological factors: NR Comorbidities: NR</p>	<p>Relaxation Therapy vs wait list Int Grp1: Relaxation training; Int Grp2: Counterdemand, Neutral Demand Cntrl: Wait List Cntrl</p> <p>Duration of treatment: 6 weeks Number of follow ups: 2 Duration of study: NR</p>	<p>Anxiety (STAI)</p> <p>Depression (BDI)</p> <p>Loudness (Self-reported)</p> <p>TS-QOL (Tinnitus interference self-report)</p>	<p>No significant effects for relaxation training were found on any measure. The BDI improved significantly from pretreatment to post-treatment, but the degree of change was equivalent for both treated and untreated groups</p> <p>Adverse Events: NR</p>
Kaldo, <sup>91</sup> 2007  Sweden	<p>Baseline sample: Total n=72 Interven=34; Cntrl=38 Setting: phone calls and mailouts Mean age (SD): Interven=45.9 y(13.0); Cntrl=48.5 y (15.7) Gender: Interven: 50% male; Cntrl: 47.3% male</p> <p>Presumed etiology of tinnitus: NR Duration of tinnitus: &gt;6 months Severity of tinnitus: Score of 10 or above on TRQ Number of dropouts: 12 Reasons for dropouts: 4 ended treatment prematurely; 3 general reasons. 5 unclear Audiological factors: NR Comorbidities: NR</p>	<p>Self-help book and brief telephone therapy Treatment group: read the self-help book and had 7 weekly phone calls from one of two therapists over a period of 6 weeks (HIGH therapist contact group) Cntrl group: Wait-list; received self-help book and had one initial phone call after treatment group finished (LOW therapist contact group) Measured pre-treatment, post-treatment, extra 6 week post-treatment for LOW group, and follow-up 1 yr after LOW group's post-treatment measurement.</p> <p>Comparator: Wait list</p> <p>Duration of treatment: 6 weeks Number of follow ups: 3 Duration of study: 1 yr</p>	<p>TS-QOL (THI, TRQ*, VAS)</p> <p>Loudness (VAS)</p> <p>Depression (HADS-D)</p> <p>Anxiety (HADS-A)</p> <p>Sleep (ISI)</p>	<p>On the TRQ, in the treatment group, 32% reached the criteria for clinical significance (at least 50% reduction of the TRQ) compared to 5% in the wait-list group.</p> <p>In the treatment group, 32% reached the criteria for clinical significance (at least 50% reduction of the TRQ) compared to 5% in the wait-list group.</p> <p>Adverse Events: NR</p>

**Appendix D. Table D: Psychological/Behavioral intervention and outcomes (n=19) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Kaldo, <sup>92</sup> 2008  Sweden	Baseline sample: Total n = 51 Interven n = 26; Cntrl n = 25 Setting: Audiology clinic, Internet Mean age (SD): Int: 47.4 (12.9); Cntrl: 45.0 (12.8) Gender: Int 58% male; Cntrl 56% male  Presumed etiology of tinnitus: Idiopathic Duration of tinnitus: Int: 9.9y(13.5); Cntrl: 5.6y (6.1) Severity of tinnitus: primary problem; ≥10 TRQ (Wilson et al., 1991) Number of dropouts: 7 Int n=4; Cntrl n=3 Reasons for dropouts: NR Audiological factors: 33% "Much" or "very much: distressed by hearing deficit Comorbidities: NR	Recruited by advertisements in newspapers, Wait List Cntrl for psychological treatment at the local Dept. of Audiology  Internet-administered CBT self-help  Comparator: traditional CBT group treatment  Both groups used the same treatment manual  Duration of treatment: 7 weeks Number of followups: 1 Duration of study: 14 months	TS-QOL (THI, TRQ, VAS)  Depression (HADS-D)  Anxiety (HADS- A)  Sleep (ISI)  Loudness (VAS)	Both groups had improved, and there were few differences between them.  The effect size for the Internet treatment was d = 0.73 (95% CI = 0.16 to 1.30) and for the group treatment was d = 0.64 (95% CI = 0.07 to 1.21).  The Internet treatment consumed less therapist time and was 1.7 times as cost-effective as the group treatment.  Adverse Events: NR

**Appendix D. Table D: Psychological/Behavioral intervention and outcomes (n=19) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Kröner-Herwig, <sup>93</sup> 1995  Germany	<p>Baseline sample: Total n = 95; TCT1 n = 7; TCT2 n = 8; Yoga n = 9; WLC n = 19 Setting: Dept. of Audiology Mean age (SD): Total: 46.8y (11.5); TCT1: 44.7 y(12.7); TCT2: 48.5 y(10.6); Yoga: 50.0 y (12.6); WLC: 47.3 y (7.9) Gender: TCT1: 57% male; TCT2: 50% male; Yoga: 67% male; WLC: 63% male</p> <p>Presumed etiology of tinnitus: idiopathic Duration of tinnitus: Mean 4.5 y (range 6m to 20y) Severity of tinnitus: &gt;4 on a 10 point scale Number of dropouts: TCT1 n=3; TCT2 n=2; Yoga n=1; WLC n=3 Reasons for dropouts: NR Audiological factors: hearing ability enough to allow communication in a group setting Comorbidities: hearing deficits with 56%</p>	<p>Tinnitus Coping Training: TCT1 and TCT2 to Cntrl for therapist effect – training consisted of Patient Education (1 session); CBT (sessions 2 to 10) Yoga (Hathayoga) – special yogic exercises to foster relaxation and adequate body perception Comparator: Wait List Cntrl (WLC)</p> <p>Duration of treatment: 10- 2 hour sessions Number of followups: end of treatment, 3 month followup Duration of study: 22 weeks</p>	<p>Loudness (Diary)  Sleep (Diary, TQ subscale*)  G-QOL (TQ, Bef-Skala, Bes-Liste*)  Depression (Dep-Skala)  TS-QOL (Diary, TQ*)</p>	<p>Statistical analyses showed effects favoring the TCT treatment in comparison to the Cntrl and yoga treatment. The TCT-treated patients reported more satisfaction with the training than the yoga group.</p> <p>Adverse Events: NR</p>

**Appendix D. Table D: Psychological/Behavioral intervention and outcomes (n=19) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Kröner-Herwig, <sup>13</sup> 2003  Germany	<p>Baseline sample: Total n = 95; Int Grp1 n = 43; Int Grp2 n = 16; Int Grp3 n = 16; Cntrl n = 20 Setting: varied by treatment arm Mean age (SD): Total: 46.8y (11.5); IntGrp1: 44.7 y(12.7); IntGrp2: 48.5 y(10.6); IntGrp3: 50.0 y (12.6); Cntrl: 47.3 y (7.9) Gender: Total: 48.4% male; IntGrp1: 44.2% male; IntGrp2: 58.8% male; IntGrp3: 46.7% male; Cntrl: 50% male</p> <p>Presumed etiology: Idiopathic, exclude Moribus Meniere Duration of tinnitus: NR Severity: Subjective annoyance &gt;40 on 9 scales assessing disruptiveness of tinnitus Number of dropouts: Int Grp1 n = 13; Int Grp2 n = 4; Int Grp3 n = 4; Cntrl n = 0 Reasons for dropouts: NR Comorbidities: NR</p>	<p>Tinnitus Coping Therapy (TCT); Education; Relaxation Therapy Int Grp1: TCT= detailed training manual provided guidelines for 11 sessions Int Grp2: Minimal Contact-Education (MC-E) comprised 2 education sessions regarding tinnitus etiology, 4 weeks self-help exercise Int Grp3: Minimal Contact-Relaxation (MC-R) 4 sessions; educational, verbal relaxation; discussions</p> <p>Comparator: Wait-list Cntrl Duration of treatment: Int Grp1: 11 sessions 90-120 minutes; Int Grp2: 2 sessions (4 weeks); Int Grp3: 4 sessions</p> <p>Number of followups: Int Grp1: 3 followups (immediately post-treatment 6 and 12 months after treatment); Int Grp2 and Int Grp3: 1 followup (immediately post-treatment)</p> <p>Duration of study: NR</p>	<p>Depression (ADS)</p> <p>G-QOL (SCL-90R)</p> <p>TS-QOL (TDI, TQ*, TC cope subscales)</p> <p>Loudness (Diary)</p>	<p>There is no significant superiority of TCT relative to the combined MC treatments in subjective change.</p> <p>Concluded that the cognitive-behavioral outpatient group training of tinnitus shows good efficacy in reducing the negative impact of tinnitus on the person's life by improving coping and reducing the threatening character of tinnitus.</p> <p>Adverse Events: NR</p>

**Appendix D. Table D: Psychological/Behavioral intervention and outcomes (n=19) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Malouff, <sup>9b</sup> 2010  Australia	<p>Baseline sample: Total n = 162 Interven n = 84; Cntrl n = 78 Setting: Internet online participation Mean age (SD): Interven 1: 57.3y (13.7); Cntrl: 57.8y (13.3) Gender: Interven: 51% male; Cntrl: 60.3% male</p> <p>Presumed etiology of tinnitus: Idiopathic Duration of tinnitus: NR Severity of tinnitus: NR Number of dropouts n = 35; Interven: n = 29 (35%); Cntrl n = 8 (10%) Reasons for dropouts: NR Audiological factors: NR Comorbidities: NR</p>	<p>Participants received a book based on cognitive-behavioral principles, including educational information on tinnitus, cognitive reappraisal and restructuring, relaxation and stress management techniques, attention Cntrl techniques, use of self-instruction, making lifestyle changes, and maintaining gains. A brief letter asking participants to read the book and to follow the suggestions it contained in the subsequent 6 weeks.</p> <p>Comparator: WLC</p> <p>Duration of Treatment: 2 months Number of followups: 2m, 4m, 12m Duration of study: NR</p>	<p>G-QOL (GPQ-12)  TS-QOL (TRQ)</p>	<p>Individuals in the Interven condition who completed the post-assessment experienced a significant reduction in tinnitus distress from pre-Interven to post-Interven (p =.0001]. The between-groups difference in the rates of reliable change, although in the hypothesized direction, was not statistically significant (p =.15).</p> <p>Intention-to-treat analyses showed no significant effect for between-groups analyses, but did show a significant effect for the 1-year follow-up pre-post analysis.</p> <p>Adverse Events: None</p>

**Appendix D. Table D: Psychological/Behavioral intervention and outcomes (n=19) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Rief, <sup>104</sup> 2005  Germany	<p>Baseline sample: Total n= 42 Int n = 22; Cntrl n = 20 Setting: University psychotherapy outpatient clinic Mean age (SD): Int: 45.5y (12.8); Cntrl: 48.0y (15.3) Gender: Int 59.1% male; Cntrl 40.0% male</p> <p>Presumed etiology of tinnitus: NR Duration of tinnitus: Int: 4.5 y (5.3); Cntrl: 8.3 y (7.7) Severity of tinnitus: VAS out of 10: Int: 6.5 (1.7); Cntrl: 5.9 (1.6) Number of dropouts: 1 Int n = 0; Cntrl n = 1 Reasons for dropouts: discontinued Interven Audiological factors: hearing problems (57%) Comorbidities: depressive disorder: 36.4% 1st Interven group; 35.0% wait list group</p>	<p>Training consisted of 1 pre-assessment session, 7 treatment sessions, and a final session summarizing Interven strategies and conducting post-assessment. All sessions lasted approximately 1 hour. Training was manual-guided, included handouts (basic information on ear and the hearing system; information processes involved in tinnitus; the vicious circle of tinnitus annoyance, muscular reactivity, and selective attention; and aspects of tinnitus maintenance, modulating factors, coping strategies, etc.).</p> <p>Comparator: Waiting-list Cntrl Setting: outpatient clinic Duration of Treatment: 8 weeks Number of followups: 1 (6 months) Duration of study: October 2002 to November 2003</p>	<p>TS-QOL (TQ)</p> <p>G-QOL (HRLS*, GSI, SCL-90R)</p> <p>Loudness (diary)</p>	<p>On most tinnitus specific variables, patients in the treatment group improved significantly more than patients on the Wait List Cntrl.</p> <p>Main effect sizes for tinnitus-specific variables were up to 0.89.</p> <p>Adverse events: Participants did not report any adverse events</p>
Scott, <sup>1</sup> 1985  Sweden	<p>Baseline sample: Total n=24; Interven=12; Cntrl=12 Setting: Department of Audiology, Hospital Mean age: 52.6 Interven: 50.9 y; Cntrl: 54.3 y Gender: Total: 43.4% male Interven: 41.6% male; Cntrl: 45.5% male</p> <p>Presumed etiology of tinnitus: Idiopathic Duration of tinnitus: mean 9.4y (1-23 years) Severity of tinnitus: grade 2 or 3 (Klockhoff &amp; Lindblom) Number of dropouts: 2 Cntrl group, women Reasons for dropouts: NR Audiological factors: All had some form of hearing impairment Comorbidities: no retrocochlear lesions suspected</p>	<p>Relaxation Therapy vs wait list The treatment comprised 10 one-hour sessions over 3 weeks: relaxation training, training of self-control by distraction exercises with the aim of reducing the discomfort from tinnitus, and application of the method in situations associated with tinnitus.</p> <p>Comparator: WLC</p> <p>Duration of treatment; 10 to 11 weeks Number of follow ups: 1 Duration of study: NR</p>	<p>Depression (Self-report R)</p> <p>TS-QOL (Self-report D)</p> <p>Loudness (Self-report D)</p>	<p>Tinnitus annoyance can be treated by psychological methods.</p> <p>Adverse Events: 8 (38%) reported an increase of negative effects of the intensive self-monitoring on the loudness of and discomfort from their tinnitus. 14/15 patients reported a general reduction of dizziness, headache and troublesome muscle tension.</p>

**Appendix D. Table D: Psychological/Behavioral intervention and outcomes (n=19) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Weise, <sup>14</sup> 2008  Germany	<p>Baseline sample: Total n = 111                      Setting: Outpatient treatment center for psychological Intervens                      Mean age (SD):                      Interven: 49.5 y (11.83);                      Cntrl: 52.9 y (11.92)                      Gender:                      Interven: 55.8% male                      Cntrl: 55.9% male</p> <p>Presumed etiology: Idiopathic                      Duration of tinnitus: &gt;6 months                      Severity of tinnitus: High tinnitus annoyance                      Number of dropouts:                      Interven n = 15; Cntrl n= 20                      Reasons for dropouts:                      Interven: incomplete (4), discontinued Interven (7), refused follow-up assessment (4);                      Cntrl=1 incomplete (1), discontinued waiting period (7), discontinued Interven (7), refused follow-up assessment (5)                      Comorbidities: Depression</p>	<p>Biofeedback-based CBT</p> <p>Interven: 12 sessions of 20 mins. of biofeedback training combined with 20 mins of CBT. Treatment over 3 months.</p> <p>Comparator: Waitlist group measured at initiation, 3 months later, then had the Interven and measured again after Interven (6 months).</p> <p>Duration of treatment: 3 months                      Number of follow ups: 1 (6 months)                      Duration of study: 9 months</p>	<p>Loudness (VAS)</p> <p>Sleep (VAS*, TQ-sub)</p> <p>G-QOL (GSI SCL-90-R)</p> <p>Depression (BDI)</p> <p>TS-QOL (TQ*, VAS, TRSS catastrophizing, TRCS helplessness)</p>	<p>For the TQ and the tinnitus diary, the MANOVA showed a statistically significant group effect, <math>F(13, 97) = 2.84, p &lt; .01</math>; a significant time effect, <math>F(13, 97) = 14.75, p &lt; .001</math>; and a significant interaction for Time x Group, <math>F(13, 97) = 5.16, p &lt; .001</math> for the completer analysis.</p> <p>Improvements were maintained over a 6-month follow-up period in which medium-to-large effect sizes were observed.</p> <p>Adverse Events: Majority of the patients did not experience negative side effects caused by the treatment</p>

**Appendix D. Table D: Psychological/Behavioral intervention and outcomes (n=19) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Westin, <sup>112</sup> , 2011  Sweden	<p>Baseline sample: n = 64                      Interven1 (ACT): n = 22; Cntrl (WLC): n = 22; Interven2 (TRT): n = 20                      Setting: Audiology department                      Mean age (SD):                      Interven1: 53.5 years (12.84)                      Cntrl: 49.59 years (11.86)                      Interven2: 48.95 (14.3)                      Gender: 53.1% male</p> <p>Presumed etiology of tinnitus: Idiopathic                      Duration of tinnitus: Mean 8.3 y (SD 7.3)                      Severity of tinnitus: score <math>\geq</math>30 on THI                      Number of dropouts: 4                      Reasons for dropouts: NR                      Audiological factors: 12.8 dB hearing level (SD=7.1) for better ear                      Comorbidities: n=49:                      rheumatological conditions (n=35),                      cardiovascular conditions (n=10), respiratory conditions or allergy (n=10), mild to moderate depression (n=9),                      gastroenterological conditions (n=6), sleep problems (n=6), cancer (n=5),                      endocrinological conditions (n=6),                      skin disease (n=2).</p>	<p>Acceptance and Commitment Therapy (ACT)</p> <p>ACT: max 10 weekly individual sessions of 60 minutes                      TRT: one 2.5 hr individual consultation session, 30 min follow-up session over telephone, wearable sound generators used min 8 hrs/day for 18 months                      WLC started CBT treatment after 10 weeks</p> <p>Duration of treatment: 10 weeks to 18 months                      Number of follow ups: 3                      Duration of study: 18 months</p>	<p>Sleep (ISI)</p> <p>TS-QOL (THI)</p> <p>Anxiety (HADS-A)</p> <p>Depression (HADS-D)</p> <p>G-QOL (QOLI)</p>	<p>A comparison between the active treatments, including all assessment points, revealed significant differences in favor of ACT regarding tinnitus impact (Cohen's d = 0.75) and problems with sleep.</p> <p>No significant main effects were found. On QOL, anxiety or depression no time, group or interaction effects were found.</p> <p>.Adverse Events: None</p>

**Appendix D. Table D: Psychological/Behavioral intervention and outcomes (n=19) (cont'd)**

Author Year Setting	Population Description	Intervention	Outcome Measures	Results
Zachriat, <sup>113</sup> 2004  Germany	<p>Baseline sample: Total n = 77 TCT n = 27; HT n = 30 EDU n = 20</p> <p>Setting: University Psychology department</p> <p>Mean age (SD): TCT: 53.8y (11.8); HT: 51.6y (11.0); EDU: 56.1y(10.6)</p> <p>Gender: TCT: 59.3% male; HT: 66.7% male; EDU: 74.0% male</p> <p>Presumed etiology of tinnitus: idiopathic Duration of tinnitus: ≥3 months (range 4 to 324 m) Severity of tinnitus: TQ ≥ 25 Number of dropouts: TCT n = 2; HCT n = 1; EDU n = 3 Reasons for dropouts: NR Audiological factors: NR Comorbidities: no treatable organic disease</p>	<p>HT: Habituation-based treatment, 5 sessions – counseling concentrating on education of factors having an impact on tinnitus and training in sound generator use for ≥6 hours per day</p> <p>TCT: tinnitus coping training, 11 sessions, 90 to 120 minutes in groups of 6 to 8 – relaxation exercises, use of attention distraction strategies; coping techniques</p> <p>EDU: (Cntrl): educational Interven, 1 session informing about physiology and psychology of tinnitus</p> <p>Duration of treatment: 15 weeks Number of followups: 3 to 27 weeks, 53 weeks, 18 to 21 months Duration of study: NR</p>	<p>G-QOL (VEV)</p> <p>TS-QOL (TQ, TCQ, JQ, Diary)</p> <p>Loudness (Diary)</p>	<p>Findings reveal highly significant improvements in both tinnitus coping training and habituation-based treatment in comparison with the Cntrl group.</p> <p>While tinnitus coping training and habituation-based treatment do not differ significantly in reduction of tinnitus disability, improvement in general well-being and adaptive behavior is greater in tinnitus coping training than habituation-based treatment.</p> <p>Adverse events: NR</p>

\*Indicates the test used to measure outcomes which were selected to represent the domain in the forest plots (and subsequent SOE decisions)

Abbreviations: A/E = Adverse events; AMT = active motor threshold; Bef-Skala = Befindlichkeits-Skala; Bes-Liste = Beschwerden-Liste; CBT = cognitive behavioral treatment; Ctrl = Control; Dep-Skala = Depressivitäts-Skala; ENT = ear, nose and throat; grp = group; G-QOL = global quality of life; HADS = Hospital Anxiety and Depression Scale; interven = Intervention; month = month; ISI = Insomnia Severity Index; N/A = not applicable; NR = not reported; OSI-R = Occupational Stress Inventory- Revised; QOL = quality of life; RCT = randomized controlled trial; SD = standard deviation; TCT = Tinnitus Coping Therapy; THI = Tinnitus Handicap Inventory; TMJ = temporal mandibular joint; TRCS = Tinnitus-Related Control Scale; TRSS = Tinnitus-related Self-Statements Scale; TS = tinnitus specific; TSQ = Tinnitus Severity Questionnaire; VAS = visual analog scale; week = week; WLC = wait list Cntrl; yr = year

Appendix D.

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## **APPENDIX E.**

**List of Ongoing Clinical Trials Evaluating  
Interventions to Treat Idiopathic Tinnitus Registered  
in [clinicaltrials.gov](https://clinicaltrials.gov)**



**Appendix E. Table 1. Ongoing clinical trials evaluating medical surgical interventions**

<b>Med/Surg Intervention Category</b>	<b>Study Title (NCT number)</b>	<b>Intervention</b>	<b>Sponsor</b> <b>Completion date</b>
<i>Psychoactive (Neurotransmitter) drugs</i>	A Study on the Effect of Cilostazol in Patients With Chronic Tinnitus (NCT01378650)	Drug: Cilostazol; Drug: Placebo	Asan Medical Center; Jong Woo Chung; Korea Otsuka Pharmaceutical Co.,Ltd December 2011; this study is currently recruiting participants
<i>Other drugs</i>	Efficacy, Safety and Tolerability of Neramexane in Patients With Subjective Tinnitus (NCT00739635)	Drug: Neramexane mesylate; Drug: Placebo	Merz Pharmaceuticals GmbH February 2010
	Safety Study for NST-001 and the Neuroject Injection Set to Treat Tinnitus (NCT00957788)	Drug: NST-001	NeuroSystem Corporation December 2011
	Efficacy, Safety and Tolerability of Neramexane in Comparison to Placebo in Patients With Subjective Tinnitus (NCT00772980)	Drug: Neramexane mesylate; Drug: Placebo	Merz Pharmaceuticals GmbH June 2010
	Comparison of Single Versus Repeat Doses of AM-101 in the Treatment of Acute Inner Ear Tinnitus (NCT01270282)	Drug: AM-101	Auris Medical, Inc. February 2013
<i>Other</i>	Investigating the Neurobiology of Tinnitus (NCT01294124)	No Intervention: Prospective study	Washington University School of Medicine; Department of Defense May 2014
	A Trial of Magnesium Dependent Tinnitus (NCT01273883)	Dietary Supplement: Magnesium; Other: Placebo	Mayo Clinic December 2012

Abbreviations: med/surg = medical/surgical; NCT = National Clinical Trial

**Appendix E. Table 2. Ongoing clinical trials evaluating medical surgical interventions using rTMS or vagal nerve stimulation**

<b>Med/Surg Intervention Category</b>	<b>Study Title (NCT number)</b>	<b>Intervention</b>	<b>Sponsor</b>  <b>Completion date</b>
Device: Repetitive Transcranial Magnetic Stimulation (rTMS) - ACTIVE; Device: Repetitive Transcranial Magnetic Stimulation (rTMS) - SHAM	Effect of rTMS on Resting State Brain Activity in Tinnitus (NCT00926237)	Device: Repetitive Transcranial Magnetic Stimulation (rTMS) - ACTIVE; Device: Repetitive Transcranial Magnetic Stimulation (rTMS) - SHAM	University of Arkansas; National Institutes of Health (NIH)  March 2016
Device: repetitive transcranial magnetic stimulation (rTMS); Device: placebo rTMS	Transcranial Magnetic Stimulation for Tinnitus (NCT01104207)	Device: repetitive transcranial magnetic stimulation (rTMS); Device: placebo rTMS	Department of Veterans Affairs  December 2014
Device: Bimodal Repetitive Transcranial Magnetic Stimulation	rTMS Bimodal Treatment For Tinnitus: A Pilot Study (NCT01590264)	Device: Bimodal Repetitive Transcranial Magnetic Stimulation	Washington University School of Medicine  November 2012
Device: Repetitive Transcranial Magnetic Stimulation (rTMS)	Repetitive Transcranial Magnetic Stimulation for Tinnitus Treatment (NCT01093872)	Device: Repetitive Transcranial Magnetic Stimulation (rTMS)	Singapore General Hospital  August 2012
Device: tVNS-Device	The Treatment of Tinnitus With Transcutaneous Non-invasive Vagus Nerve Stimulation (NCT01176734)	Device: tVNS-Device	cerbomed GmbH  July 2012
Device: vagus nerve stimulation (VNS)	Proof-of-Concept Study Assessing VNS Paired With Tones for Tinnitus (NCT01253616)	Device: vagus nerve stimulation (VNS)	MicroTransponder Inc.  July 2012

**Appendix E. Table 3. Ongoing clinical trials evaluating psychological/ behavioral interventions**

<b>Psych/Beh Intervention</b>	<b>Study Title (NCT number)</b>	<b>Intervention</b>	<b>Sponsor</b> <b>Completion date</b>
<i>CBT / CBT combination</i>	Cognitive Behavioral Therapy (CBT) for Tinnitus (NCT00724152)	CBT/Education Training/Usual Care	Department of Veterans Affairs; Yale University May 2012
	Treatment of Chronic Bothersome Tinnitus Using Cognitive Training and D-cycloserine (NCT01550796)	Behavioral: Cognitive Training; Drug: placebo	Washington University School of Medicine June 2012
<i>Other psych / behavioral</i>	Cognitive Training for Firefighters With Tinnitus (NCT01458821)	Brain Fitness Program - Tinnitus	Washington University School of Medicine; Federal Emergency Management Agency June 2012
	Mindfulness Based Tinnitus Reduction (MBTR): A Symptom Perception Shift Program (NCT01229709)	Mindfulness Based Tinnitus Reduction/Treatment as Usual	University of California, San Francisco January 2015
	Multi-Site Evaluation of Progressive Tinnitus Management (NCT01015781)	Progressive Tinnitus Management/Treatment as Usual	Department of Veterans Affairs June 2013
	Telephone Tinnitus Education for Patients With Traumatic Brain Injury (TBI) (NCT01129141)	Telephone Tinnitus Education/Wait List Control	Department of Veterans Affairs September 2014
	Neuro-Music Therapy for Recent Onset Tinnitus: Evaluation of a Therapy Concept (NCT01566708)	Neuro-Music Therapy immediately/after waiting time/Music-therapeutical stress management coaching	German Center for Music Therapy Research; University Hospital for Ear, Nose, and Throat, University of Heidelberg, Germany; Clinic of Diagnostic and Interventional Neuroradiology, Saarland University Clinic, Homburg, Germany July 2013
	New Therapy for Patients With Severe Tinnitus (NCT01480193)	Other: Sound Based and Educational (SBE) Therapies; Other: Integrated Medicine Therapies and Sound Based Education Therapies; Other: Integrated Medicine Therapies and SBE	Duke University; National Institutes of Health (NIH); National Institute on Deafness and Other Communication Disorders (NIDCD) October 2013

Abbreviations: CBT = cognitive behavioural therapy

**Appendix E. Table 4. Ongoing clinical trials evaluating sensory modulation or other devices**

<b>Devices Category</b>	<b>Study Title (NCT number)</b>	<b>Intervention</b>	<b>Sponsor</b> <b>Completion date</b>
Coventional/ Placebo Sound Generator	Tinnitus Retraining Therapy Trial (NCT01177137)	Coventional/Placebo Sound Generator (SG)	Johns Hopkins Bloomberg School of Public Health; National Institute on Deafness and Other Communication Disorders (NIDCD); University of Alabama, Tuscaloosa; David Grant U.S. Air Force Medical Center; Wilford Hall Medical Center; United States Naval Medical Center, San Diego; United States Naval Medical Center, Portsmouth; National Naval Medical Center; Naval Hospital Camp Pendleton  February 2015
Device: CR Neuromodulation	Evaluation of the CR Neuromodulation Treatment for Tinnitus (NCT01541969)	Device: CR Neuromodulation	Nottingham University Hospitals NHS Trust; University of Nottingham; University College, London  August 2013
Device: BrainSTIM Transcranial Stimulator	Transcranial Direct Current Stimulation (tDCS) for the Treatment of Tinnitus (NCT01575496)	Device: BrainSTIM Transcranial Stimulator	Centre Hospitalier Universitaire Vaudois  January 2015
The Inhibitor™ <b>Tinnitus</b> Masking Device	Inhibitor Masking Device & SCN9 Gene Expression (NCT01412918)	The Inhibitor™ Tinnitus Masking Device	Medical College of Wisconsin  December 2016
Device: P-Stim	Somatosensory Based Treatments for Tinnitus (NCT01066273)	Device: P-Stim	Massachusetts Eye and Ear Infirmary  December 2015
Device: ANM T30 CR®- System	Acoustic Coordinated Reset (CR®) Neuromodulation for the Treatment of Chronic Tonal Tinnitus ("RESET Real Life") (NCT01435317)	Device: ANM T30 CR®- System	ANM Adaptive Neuromodulation GmbH; Ceres GmbH evaluation & research  July 2013

Abbreviations: PSTIM = pulse stimulation treatment