Cochrane Corner: Sound therapy (using amplification devices and/or sound generators) for tinnitus

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\section*{ABSTRACT}

This Cochrane Corner features “Sound therapy (using amplification devices or sound generators) for tinnitus” published in 2018. Sereda et al. identified eight clinical trials including 590 participants receiving sound therapy for tinnitus. None of the included studies addressed three main comparisons of the review (comparing hearing aids, sound generators and combination devices with a waiting list control group, placebo or education/information only). One study compared patients fitted with sound generators versus those fitted with hearing aids and found no difference between them in their effects on tinnitus symptom severity. The use of both types of device was associated with a clinically significant reduction in tinnitus symptom severity. Three studies compared hearing aids with a sound generator to hearing aids alone and measured tinnitus symptom severity. The use of both types of device was again associated with a clinically significant reduction in tinnitus symptom severity. This Cochrane review shows that both hearing aids and sound generators may be beneficial for reducing tinnitus severity in some patients, but that there is insufficient evidence at this stage to recommend one device over another, or whether these devices offer any improvement over a placebo treatment.

\section*{Introduction}

For many people tinnitus is persistent and troublesome, and has disabling effects that may impact an individual’s quality of life, such as insomnia, difficulty concentrating, difficulties in communication and social interaction, anxiety and depression (Hall et al. 2018). In many cases chronic tinnitus is co-morbid with some degree of measurable hearing loss, making it difficult to identify whether tinnitus is the primary cause of these disabling effects (Fowler 1944; Sanchez 2002). The association between hearing loss and tinnitus is neither simple nor straightforward; not all people with hearing loss experience tinnitus, and conversely some people with clinically normal hearing have tinnitus (Baguley 2013). Previously, there was one review examining sound therapy for adults with tinnitus (Hobson 2012) and another examining amplification with hearing aids for adults with tinnitus (Hoare 2014). A strength of Cochrane reviews is the requirement that they be regularly revised (usually every 2 years) to incorporate new evidence and conform to new developments in systematic review methodology. In this instance, the decision was made to combine these two previous reviews into a single review that examine which is the most effective of these two management strategies.\textsuperscript{1}

\section*{Objective}

To assess the effects of sound therapy (using amplification devices and/or sound generators) for tinnitus in adults.

\section*{Search strategy}

The Cochrane ENT Information Specialist searched the Cochrane ENT Register; Central Register of Controlled Trials (CENTRAL, via the Cochrane Register of Studies); Ovid MEDLINE; Ovid Embase; CINAHL; Web of Science; ClinicalTrials.gov; ICTRP and additional sources for published and unpublished trials. The date of the search was 23 July 2018.

\section*{Background}

Tinnitus affects 10\textperthousand–15\textperthousand% of the adult population, with about 20\textperthousand% of these experiencing symptoms that negatively affect quality of life. In England alone there are an estimated \(\frac{3}{4}\) million general practice consultations every year where the primary complaint is tinnitus, equating to a major burden on healthcare services. Clinical management strategies include education and advice, relaxation therapy, tinnitus retraining therapy, cognitive behavioural therapy, sound enrichment using ear-level sound generators or hearing aids, and drug therapies to manage co-morbid symptoms such as insomnia, anxiety or depression. Hearing aids, sound generators and combination devices (amplification and sound generation within one device) are a component of many tinnitus management programmes and together with information and advice are a first line of management in audiology departments for someone who has tinnitus.

\section*{Tinnitus; assistive technology; hearing aids}

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Selection criteria

Randomised controlled trials (RCTs) recruiting adults with acute or chronic subjective idiopathic tinnitus. We included studies where the intervention involved hearing aids, sound generators or combination hearing aids and compared them to waiting list control, placebo or education/information only with no device. We also included studies comparing hearing aids to sound generators, combination hearing aids to hearing aids, and combination hearing aids to sound generators.

Data collection and analysis

We used the standard methodological procedures expected by Cochrane. Our primary outcomes were tinnitus symptom severity as measured as a global score on multi-item tinnitus questionnaire and significant adverse effects as indicated by an increase in self-reported tinnitus loudness. Our secondary outcomes were depressive symptoms, symptoms of generalised anxiety, health-related quality of life and adverse effects associated with wearing the device such as pain, discomfort, tenderness or skin irritation, or ear infections. We used GRADE to assess the quality of evidence for each outcome; this is indicated in italics.

Main results

This review included eight studies (with a total of 590 participants). Seven studies investigated the effects of hearing aids, four combination hearing aids and three sound generators. Seven studies were parallel-group RCTs and one had a cross-over design. In general, risk of bias was unclear due to lack of detail about sequence generation and allocation concealment. There was also little or no use of blinding.

No data for our outcomes were available for any of our three main comparisons (comparing hearing aids, sound generators and combination devices with a waiting list control group, placebo or education/information only). Data for our additional comparisons (comparing these devices with each other) were also few, with limited potential for data pooling.

Hearing aid only versus sound generator device only

One study compared patients fitted with sound generators versus those fitted with hearing aids and found no difference between them in their effects on our primary outcome, tinnitus symptom severity measured with the Tinnitus Handicap Inventory (THI) at 3, 6 or 12 months (low-quality evidence). The use of both types of device was associated with a clinically significant reduction in tinnitus symptom severity.

Combination hearing aid versus hearing aid only

Three studies compared combination hearing aids with hearing aids and measured tinnitus symptom severity using the THI or Tinnitus Functional Index. When we pooled the data we found no difference between them (standardised mean difference -0.15, 95% confidence interval -0.52 to 0.22; three studies; 114 participants; low-quality evidence). The use of both types of device was again associated with a clinically significant reduction in tinnitus symptom severity.

Adverse effects were not assessed in any of the included studies.

None of the studies measured the secondary outcomes of depressive symptoms or depression, anxiety symptoms or generalised anxiety, or health-related quality of life as measured by a validated instrument, nor the newly developed core outcomes tinnitus intrusiveness, ability to ignore, concentration, quality of sleep and sense of control.

Author’s conclusion

There is no evidence to support the superiority of sound therapy for tinnitus over waiting list control, placebo or education/information with no device. There is insufficient evidence to support the superiority or inferiority of any of the sound therapy options (hearing aid, sound generator or combination hearing aid) over each other. The quality of evidence for the reported outcomes, assessed using GRADE, was low. Using a combination device, hearing aid or sound generator might result in little or no difference in tinnitus symptom severity. Future research into the effectiveness of sound therapy in patients with tinnitus should use rigorous methodology. Randomisation and blinding should be of the highest quality, given the subjective nature of tinnitus and the strong likelihood of a placebo response. The CONSORT statement should be used in the design and reporting of future studies. We also recommend the use of validated, patient-centred outcome measures for research in the field of tinnitus.

Commentary on the Cochrane review

One of the key aims of the IJA Cochrane Corner is to gain some additional insights into the implications of Cochrane reviews for clinical practice. Each review is a significant undertaking for the authorship teams, and they are essential in developing the evidence-base within audiology. Here we present questions regarding the key clinical and research implications of this review with answers from the Cochrane review authors, Dr. Sereda and Dr. Hoare.

Question (Brennan-Jones): What do you think is the likelihood and potential impact of adverse effects using these treatments for patients? In the absence of any data from this review, are there any obvious reasons to favour one intervention over the other based on a real or perceived risk of adverse events occurring?

Answer (Sereda and Hoare): Sound therapy, including amplification, is widely used in clinical practice for people with hearing loss and/or tinnitus. For tinnitus, it is a frontline treatment in many countries, although whether management of tinnitus or management of co-morbid hearing loss is the priority may be debated. Side effects of sound therapy (primarily associated with physical; i.e., sounds uncomfortably loud, ear pain, poor sound quality or psychological domain; i.e., afraid of missing out in conversation) are not commonly reported and are usually mild (Manchaiah et al. 2018). In clinical trials of tinnitus treatments outcomes such as safety, tolerability, side effects, and withdrawal are in general underreported (Hall et al. 2016). Of course, this is not a problem specific to tinnitus trials; it has been concluded before that reporting harms-related data for clinical trials in other areas needs improvement (Lineberry et al. 2016). Given that the studies included did not report adverse effects it would be difficult to draw any conclusions that would favour one intervention over another based on safety. Hence, recent clinical practice guidance makes no recommendation for or against particular forms of sound therapy (Cima et al. 2019).
Amplification has a proven benefit for listening ability (Ferguson et al. 2017), and therefore is recommended for patients with hearing loss. In that Cochrane review only one trial attempted to measure harms due to hearing aids, and none were reported. One gap in our knowledge is the consequences of very long term use of therapeutic sound (long term follow-up in trials is typically 1 year or less).

**Question (Thomas):** What can be done in the design of future studies, particularly around blinding, to improve the quality of research in this field to enable better recommendations for practice?

**Answer (Sereda):** In controlled trials the term blinding refers to keeping study participants, those involved with their management, and those collecting and analysing clinical data unaware of the assigned treatment, so that they should not be influenced by that knowledge (Day and Altman 2000). In the case of sound therapy, blinding of participants or clinicians involved in the management of patients is not always easy or possible, particularly if the goal of the study is to compare two very different interventions (e.g. hearing aids and sound generators) or where the comparator to the sound therapy is no intervention, waiting list, or education. However, in those cases, blinding of those collecting and analysing data can still be applied. Use of blinding will also depend on the study aim. For early phase explanatory trials where the aim is to evaluate the efficacy of the intervention and potential mechanisms of action in a well-defined and controlled setting, blinding would be more important. Pragmatic trials on the other hand assess the effectiveness of the intervention in routine clinical practice, and usually compare the new intervention to ‘usual care’. What that usual care is will determine to what extent blinding can be applied.

One interesting approach is the use of placebo devices as a control for amplification (hearing aids). Such an approach was used in two RCTs investigating the effects of amplification in patients with mild to moderate hearing loss (Adrait et al. 2017; Humes et al. 2017). Placebo hearing aids in those studies were programmed to provide zero gain. In principle, if placebo hearing aids are visibly identical to active hearing aids, and the fitting procedure is indistinguishable, blinding of participants and personnel should be possible (Ferguson et al. 2017). However, those studies recruited participants with mild or moderate hearing loss and it is unlikely such a method could be applied to participants with more severe hearing losses. The cost of providing placebo hearing aids also needs to be considered.

In summary, decisions about the use of blinding in clinical trials are complicated, and the relevance of blinding will vary according to circumstances. Transparent and detailed reporting of the none-use of blinding, or the procedures used for blinding, are crucial to understanding the relevant risk of bias.

**Question (Brennan-Jones):** Both comparisons in this review found small improvements in patient-reported tinnitus severity following intervention, regardless of the type of intervention. However, your conclusion is that “using a combination device, hearing aid or sound generator might result in little or no difference in tinnitus symptom severity”. Is this conclusion primarily based on the low quality of evidence of included trials, the limited effect size, or other factors?

**Answer (Sereda):** Studies comparing hearing aids to sound generators (Parazzini et al. 2011) and hearing aids to combination hearing aids (dos Santos et al. 2014; Henry et al. 2015; Henry et al. 2017) were designed to determine relative effectiveness, rather than to determine the specific efficacy of one of the interventions in a controlled way. Therefore, it is not possible to determine whether observed changes were due to the use of particular intervention or due to other factors such as the amount of clinician contact, natural history of the illness, or another undefined factor that occurred at the same time as the intervention. In general, all limitations of uncontrolled before and after design apply here.

**Question (Thomas):** This review focussed on non-pharmacological interventions for tinnitus but found a lack of data comparing sound therapy to your main comparisons. Over the past 10 years there have been a number of Cochrane reviews of other pharmacological and non-pharmacological interventions for tinnitus. Most have found little or no evidence, or only very low quality evidence. What do you think are the specific challenges for clinical trials in this field and how can the quality of research in this field be improved for future studies?

**Answer (Sereda):** There are many different tinnitus treatment options in use in clinical practice, despite the evidence for their efficacy being low. Landgrebe et al. (2012) identified several methodological limitations of clinical trials in tinnitus including inappropriate outcome measures and statistical methods, insufficient sample sizes, poorly defined interventions, problems with study blinding and randomisation and insufficient reporting of the study details. There is no reason why generally accepted criteria for clinical trials could not be applied for tinnitus trials. The CONSORT statement, an evidence-based set of recommendations for reporting randomised trials, should be consulted when reporting results of the tinnitus trials (Schulz et al. 2010).

Given tinnitus is a subjective percept, assessment is not straightforward. Firstly, there is no objective outcome measure (EEG, MRI, blood parameter, etc.) that provides a biomarker of tinnitus that could be used in clinical trials. The use of standardised and validated patient-reported (subjective) outcome measures in tinnitus research has been recommended in the current review. This includes multi-item questionnaires of tinnitus symptom severity, validated instruments measuring depression, anxiety and health-related quality of life. Adverse effects of the interventions should also be reported. Core outcome domains for sound-based, psychological-based and drug-based treatments for tinnitus have been defined (Hall et al. 2018). Core outcome sets (the measures to use) for adults with subjective tinnitus are currently under development; these represents the minimum outcomes that should be measured and reported in all clinical trials, to allow meaningful comparison and synthesis of results from similar trials.

The heterogeneity of tinnitus is also a challenge in clinical trials of tinnitus treatments (Cederroth et al. 2019). Tinnitus can differ in localisation, sound characteristics, time course, underlying cause, co-morbid conditions, and so on, and it is likely that different forms of tinnitus respond differently to treatment (Landgrebe et al. 2012). This might explain the between-participant variability in outcomes. However, the relationships between certain characteristics of tinnitus and outcome of different treatments are not well understood. It is therefore important that an exact description of the patient population in clinical trials is provided.

In summary, there are immediate actions that can be taken to improve the quality of evidence for tinnitus treatments. Trials need to be designed and reported to the highest recommended standards. Specific challenges around lack of standardised outcome measures and tinnitus subtyping are important future research directions.
you expand on the rationale for this and whether you are planning for future updates to include children with tinnitus?

**Answer (Hoare):** There have been many prevalence studies indicating that similar percentages of adults and children experience troublesome tinnitus. That said, children are much less likely to spontaneously tell others about their tinnitus, and may use descriptions in unfamiliar terms, so the true scale of the problem is really unknown (British Society of Audiology, 2015). In general, research on tinnitus in children is at a much earlier stage than that in adults. Clinical practice is also less standardised for children than for adults. To our knowledge, there has never been a RCT of sound therapy using ear level devices in a paediatric population (certainly none were encountered in conducting this review). There is also no valid self-report measure of tinnitus symptom severity in children (in adults there are at least 25), although some are now in development (Smith, 2018). At this time there is no indication to conduct a Cochrane review of any sound therapy option. However, absence of evidence of an effect does not imply that there is not an effect; the quality of research in this field requires significant improvement in terms of the design and conduct of randomised clinical trials to account for the strong likelihood of a placebo response. Future high-quality studies are needed and have the potential to substantially alter the conclusions of this review, when it is next updated by Drs. Sereda and Hoare and their colleagues.

**Conclusion**

This review highlights the lack of evidence to support the use of sound therapy for tinnitus over waiting list control, placebo or education/information with no device. There was insufficient evidence for the authors to determine the superiority or inferiority of any sound therapy option. However, absence of evidence of an effect does not imply that there is not an effect; the quality of research in this field requires significant improvement in terms of the design and conduct of randomised clinical trials to account for the strong likelihood of a placebo response. Future high-quality studies are needed and have the potential to substantially alter the conclusions of this review, when it is next updated by Drs. Sereda and Hoare and their colleagues.

**Note**

1. The Abstract of the Cochrane review by Sereda et al. (2018) is included below. Full details of the rationale for various parts of the methodology, a full list of included and excluded studies, all analyses, risk of bias assessments and a detailed discussion of findings can be found in the original review. [https://www.cochranelibrary.com/cdrr/doi/10.1002/14651858.CD013094.pub2/full](https://www.cochranelibrary.com/cdrr/doi/10.1002/14651858.CD013094.pub2/full).

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**References**

Adrait, A., X. Perrot, M.-F. Nguyen, M. Gueugnon, C. Petitot, L. Collet, A. Roux, et al. 2017. “Do Hearing Aids Influence Behavioral and Psychological Symptoms of Dementia and Quality of Life in Hearing Impaired Alzheimer’s Disease Patients and Their Caregivers?” *Journal of Alzheimer’s Disease* JAD 58 (1):109–121. doi:10.3233/JAD-160792.

Baguley, D., D. McFerran, D. Hall. 2013. “Tinnitus.” *Lancet* 382 (9904): 1600–1607. doi:10.1016/S0140-6736(13)60142-7.

British Society of Audiology. 2015. *Tinnitus in Children Practice Guidance*. Available at [http://www.thebsa.org.uk/wp-content/uploads/2015/03/2015-Paed-Tin-Guidelines-FINAL.pdf](http://www.thebsa.org.uk/wp-content/uploads/2015/03/2015-Paed-Tin-Guidelines-FINAL.pdf)

Cederroth, C. R., S. Gallus, D. A. Hall, T. Kleinjung, B. Langguth, A. Marotti, M. Meyer, et al. 2019. “Towards an Understanding of Tinnitus Heterogeneity.” *Frontiers in Aging and Neuroscience* 11:53. doi:10.3389/fnagi.2019.00053

Cima, R. F. F., B. Mazurek, H. Haider, D. Kikidis, A. Lapira, A. Norena, D. J. Hoare. 2019. “A Multidisciplinary European Guideline for Tinnitus: Diagnostics, Assessment, and Treatment.” *HNO* 67 (Suppl 1):10.

Day, S. J., and D. G. Altman. 2000. “Statistics Notes: Blinding in Clinical Trials and Other Studies.” *BMJ* (Clinical Research ed.) 321 (7259):504. doi:10.1136/bmj.321.7259.504.

dos Santos, G. M., R. F. Bento, I. R. de Medeiros, J. Oiticica, E. C. da Silva, and S. Penteado. 2014. “The Influence of Sound Generator Associated with Conventional Amplification for Tinnitus Control: Randomized Blind Clinical Trial.” *Trends in Hearing* 18:233121651454265. doi:10.1177/233121651454269.

Ferguson, M. A., P. T. Kitterick, L. Y. Chong, M. Edmondson-Jones, F. Barker, and D. J. Hoare. 2017. “Hearing Aids for Mild to Moderate Hearing Loss in Adults.” *The Cochrane Database of Systematic Reviews* 9: CD012023. doi:10.1002/14651858.CD012023.pub2.

Fowler, E. P. 1944. “Head noises in normal and in disordered ears: significance, measurement, differentiation and treatment.” *Archives of Otolaryngology* 39 (6):498–503. doi:10.1001/archotol.1944.00680010517007.

Hall, D. A., H. Haider, A. J. Szczepek, P. Lau, S. Rabau, J. Jones-Diette, A. Londero., et al. 2016. “Systematic Review of Outcome Domains and Instruments Used in Clinical Trials of Tinnitus Treatments in Adults.” *Trials* 17 (1):270. doi:10.1186/s13636-016-1399-9.

Hall, D. A., H. Smith, A. Hibbert, V. Colley, H. F. Haider, A. Horobin, A. Londero., et al. 2018. “The COMiTID Study: Developing Core Outcome Domains Sets for Clinical Trials of Sound-, Psychology-, and Pharmacology-Based Interventions for Chronic Subjective Tinnitus in Adults.” *Trends in Hearing* 22:233121651881438. doi:10.1177/233121651814384.

Henry, J. A., M. Frederick, S. Sell, S. Griest, and H. Abrams. 2015. “Validation of a Novel Combination Hearing Aid and Tinnitus Therapy Device.” *Ear and Hearing* 36 (1):42–52. doi:10.1080/AUD.0000000000000093.

Henry, J. A., G. McMillan, S. Dann, K. Bennett, S. Griest, S. Theodoroff, S. P. Silverman., et al. 2017. “Tinnitus Management: Randomized Controlled Trial Comparing Extended-Wear Hearing Aids, Conventional Hearing Aids, and Combination Instruments.” *Journal of the American Academy of Audiology* 28 (6):546–561. doi:10.3766/jaaa.16067.

Hoare, D. J., M. Edmondson-Jones, M. Sereda, M. A. Akeroyd, D. Hall. 2014. “Amplification with hearing aids for patients with tinnitus and co-existing hearing loss.” *Cochrane Database of Systematic Reviews* 1. doi:10.1002/14651858.CD010151.pub2.

Hobson, J., E. Chiisholm, A. Refaie. 2012. “Sound therapy (masking) in the management of tinnitus in adults.” *Cochrane Database of Systematic Reviews* 11. doi:10.1002/14651858.CD006371.pub3.

Humes, L. E., S. E. Rogers, T. M. Quigley, A. K. Main, D. L. Kinney, and C. Herring. 2017. “The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial.” *American Journal of Audiology* 26 (1): 53–79. doi:10.1044/2017.AJA-16-0111.

Landgrebe, M., A. Azevedo, D. Baguley, C. Bauer, C. Coelho, C. Roux, et al. 2017. “Methodological Aspects of Clinical Trials in Tinnitus: A Proposal for an International Standard.” *Journal of Psychosomatic Research* 73 (2):112–121. doi:10.1016/j.jpsychores.2012.05.002.

Lineberry, N., J. A. Berlin, B. Mansi, S. Glasser, M. Berkwits, C. Klem, A. Bhattacharya., et al. 2016. “Recommendations to Improve Adverse Event Reporting in Clinical Trial Publications: A Joint Pharmaceutical Industry/
Journal Editor Perspective.” *BMJ (Clinical Research ed.)* 355:i5078. doi:10.1136/bmj.i5078.

Manchaiah, V., H. Abrams, A. Bailey, and G. Andersson. 2018. “Negative Side Effects Associated with Hearing Aid Use in Adults with Hearing Loss.” *Journal of the American Academy of Audiology* 30(6):472–481. [Epub ahead of print]. doi:10.3766/jaaa.17118.

Parazzini, M., L. Del Bo, M. Jastreboff, G. Tognola, and P. Ravazzani. 2011. “Open Ear Hearing Aids in Tinnitus Therapy: An Efficacy Comparison with Sound Generators.” *International Journal of Audiology* 50 (8): 548–553. doi:10.3109/14992027.2011.572263.

Sanchez, T. G., G. M. S. Ferrari. 2002. “The control of tinnitus through hearing aids: suggestions for optimal use.” *Pró-Fono Rev Atualização Cient* 14: 111–118.

Sereda, M., J. Xia, A. El Refaie, D. A. Hall, D. J. Hoare. 2018. “Sound therapy (using amplification devices and/or sound generators) for tinnitus.” *Cochrane Database of Systematic Reviews* 12. Art. No.: CD013094. doi:10.1002/14651858.CD013094.pub2.

Schulz, K. F., D. G. Altman, and D. Moher, for the CONSORT Group 2010. “CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomised Trials.” *BMC Medicine* 8 (1):18. doi:10.1186/1741-7015-8-18.

Smith, H. 2018. How to measure tinnitus in children. *Proceedings of the British Tinnitus Association Annual Conference*, 11 September, Birmingham, UK.