



TITLE: Tinnitus Retraining Therapy: A Review of the Clinical Effectiveness

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CONTEXT AND POLICY ISSUES:

Tinnitus is defined as the conscious perception of sound in the absence of external stimuli.¹ Tinnitus retraining therapy (TRT) is based on a neurophysiological model developed by Jastreboff which aims to habituate a person to the reaction and perception of tinnitus through directive counselling, sound therapy, and follow-up consultation.¹ Other treatments that have been used to manage chronic tinnitus include psychotherapy, some medications or herbs, acupuncture, electromagnetic stimulation, hearing aids, hypnosis, and tinnitus masking devices.² This summary will evaluate the data to support TRT for the management of tinnitus.

RESEARCH QUESTION:

What is the clinical effectiveness of tinnitus retraining therapy for patients with tinnitus?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including OVID Medline, The Cochrane Library (Issue 2, 2010), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English language articles published between 2004 and February 2010. Filters were applied to limit the retrieval to health technology assessments (HTAs), systematic reviews, meta-analyses, randomized controlled trials (RCTs), controlled clinical trials, and observational studies.

Only studies that compared TRT to another type of tinnitus therapy, or no therapy were included. Studies that included only one component of TRT, either counselling or sound therapy were excluded and have been listed in Appendix I. Since there were a number of systematic reviews, RCTs, and controlled clinical trials identified in the search, observational studies of TRT were not summarized and have been listed in Appendix I.

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HTIS reports are organized so that the higher quality evidence is presented first. Therefore, systematic reviews are presented first followed by randomized controlled trials and controlled clinical trials.

SUMMARY OF FINDINGS:

The search identified two systematic reviews, three RCTs, and two controlled clinical trials. A brief description of the Tinnitus Questionnaire tool is provided in Appendix II.

Systematic reviews and meta-analyses

Savage et al.² conducted a systematic review of treatments for chronic tinnitus including TRT. The study design criteria for inclusion were published RCTs or systematic reviews of RCTs, where studies were at least single blinded and contained more than 20 patients of whom more than 80% were followed-up. Their search found no RCTs or systematic reviews of TRT and therefore concluded that the efficacy of TRT was unknown.

The Workers Compensation Board of BC (Martin 2004¹) conducted a systematic search of studies evaluating TRT and other treatments for tinnitus.¹ Martin identified one systematic review, one RCT, and 12 case series on TRT or modified TRT. Martin described the systematic review (Leal 1998) which included abstracts of two case series both of which had methodological flaws. Based on the available data, Leal concluded that there was no evidence to suggest TRT was effective. In the 12 case series, improvements in tinnitus of 55% to 90% (measured using different criteria) were reported. Follow up in these series varied from immediately after TRT to 28 months. Martin described one study that compared TRT to tinnitus masking in 123 veterans. Based on information from a preliminary report of findings, Martin identified this study (Henry 2006³) as an RCT. The study was actually a controlled clinical trial and is described in the controlled clinical trial section of this HTIS summary. Considering the limited data available to support TRT, the author recommended that the Workers Compensation Board undertake a study on the effectiveness of TRT. If a formal study was not undertaken, then additional evaluation of the consistency, costs, and outcomes of the existing TRT programs in BC should be considered.¹

Randomized controlled trials

In the report by Hiller et al.,⁴ patients with distressing tinnitus of six months or longer duration were recruited from the community or were referred from a specialist to participate in this study comparing group cognitive behaviour therapy (CBT) to a tinnitus education program, with or without a white noise sound generator. A total of 136 patients enrolled. Seventy patients with less severe tinnitus were assigned to receive four 90 minute tinnitus education sessions and 66 patients with more severe tinnitus were allocated to receive 10 weekly two-hour CBT sessions. Within each group, patients were randomly allocated to use or not use a white noise generator device. The patients in the sound therapy group received a behind the ear broadband white noise generator and were instructed to wear the device for at least six hours per day. Thirteen per cent of patients refused their treatment allocation and received the behaviour therapy of their choice. Twelve patients (9%) withdrew from the study and follow-up evaluation data was available for 116 patients (85%). The average age per group varied from 45 years to 53 years and proportion of females ranged from 32% to 59%. Tinnitus-related distress, as measured by

the Tinnitus Questionnaire (TQ), showed improvement after tinnitus education or CBT counselling was complete, and these reductions in TQ scores were maintained in all groups after six and 18 months of follow-up. There was no difference between the tinnitus education groups with and without noise generators. The TQ scores were reduced by 41% in the education group without noise generators and by 35% in the education group with noise generators (baseline to 18 months). Similar results were reported in the CBT groups. The TQ scores were reduced 44% and 29% from baseline to 18 months in the CBT group without, and those with a noise generator, respectively (not statistically significant). In the education and CBT groups respectively, 74% and 42% of patients were still wearing their noise generators for at least an hour a day at the six month follow-up. The authors stated that all patient groups showed improvement in tinnitus-related distress and concluded that noise generators provided no additional benefit to CBT in patients with severe tinnitus, or to tinnitus education in patients with moderate tinnitus-related distress.⁴

In the study by Caffier et al.,⁵ adults with tinnitus for longer than six months duration were recruited from a German tinnitus center. A total of 48 patients (mean age 51 years, 54% male) were enrolled, however, eight (17%) were excluded from the analysis due to lack of compliance, withdrawal, or incomplete records. The patients were randomized to a wait-list control or a modified TRT program that included counselling, a sound generator, relaxation, and psychotherapeutic care if needed. After 12 months, the control group was offered TRT. Initial TQ scores were similar between groups and remained unchanged for the control group. The mean TQ score decreased 16 points in the TRT group ($p < 0.001$) after 12 months. The authors concluded that the modified TRT program represented a successful treatment strategy for patients with mild to severe tinnitus.⁵

Zachriat et al.⁶ evaluated the efficacy of a habituation-based treatment compared to cognitive behaviour tinnitus coping training, and to an educational control group. Patients were recruited from the community and were enrolled if they had tinnitus of greater than three months duration and a tinnitus disability score ≥ 25 on the TQ. A total of 83 patients were enrolled and randomly allocated to the treatment groups (29 in the coping training, 31 in the habituation-based treatment, and 23 in the control group). The mean age per group varied from 52 years to 56 years and 59% to 74% of participants were male. Coping training consisted of 11 weekly group sessions of 90 to 120 minutes duration. A total of five group habituation-based treatment sessions of 90 to 120 minutes in duration were spaced over a period of six months. Patients in the habituation-based treatment group also received bilateral wide band noise generators and were instructed to wear the devices for at least six hours per day. Patients in the control group received a single educational session which provided similar information as was given in the first session of the other two programs. Patients in the control group were followed for 14 weeks and those in the other two groups were followed for 18 or 21 months. Eleven per cent of patients withdrew from the study. At 14 weeks, tinnitus coping therapy and habituation-based treatment were more efficacious in reducing tinnitus-related disability than the control group ($p < 0.05$) but did not differ from one another. Reductions in TQ scores in the coping and habituation-based treatment groups were maintained to the end of follow up, however no information was available to compare these differences to the control group. Tinnitus perception was not statistically significantly different between groups. At 18 months, 23% of patients in the habituation-based treatment group were still using the noise generators. Based on the results of the trial the authors recommended that patients with chronic tinnitus be offered an educational

session first, and then those with continuing complaints be offered further treatment with either habituation-based treatment or coping training.⁶

Controlled clinical trials

The study by Henry et al.³ recruited veterans with clinically significant tinnitus from the community and from an audiology clinic to participate in this 18 month clinical trial. A total of 123 patients were alternately assigned to either tinnitus masking or TRT treatment groups (95% male, mean age 60 years). Patients in the TRT group received structured counselling according to TRT methods and those in the masking group received informal counselling. Two different audiologists treated all the patients in each group. Both groups also received sound therapy using a sound generator, hearing aid, or other ear level devices. The TRT group was asked to use the sound therapy for at least eight hours per day, whereas the masking group was to use the sound device as needed. Patients were assessed using three validated tools (Tinnitus Severity Index [TSI], Tinnitus Handicap Questionnaire [THQ], Tinnitus Handicap Inventory [THI]), and a visual analog scale assessing tinnitus awareness and annoyance. The authors analyzed data using a multilevel regression model appropriate for this type of data. However, reporting of the results was unclear making it difficult to interpret the impact of treatment on tinnitus. Analysis was limited by missing data with only 37% of patients having complete data for all outcomes at each assessment period over the 18 month follow-up. Data for TSI, awareness, and annoyance were the most complete (>70% of patients had data for all outcome periods). The authors reported that both treatment groups showed improvement in the outcome measures over time, with the TRT showing a greater rate of improvement (statistical significance unclear). The authors concluded that those patients whose tinnitus had the greatest impact in their lives showed the strongest benefit to TRT therapy (statistical significance unclear).³

Davis et al.⁷ described a study evaluating three different TRT programs compared to a counselling only control group. Eighty-eight patients were enrolled (selection process not reported) and allocated by alternation to each of the four treatment groups. Two groups received Neuromonics customized acoustic stimulation, but at different volume levels. The third group received broadband noise generator for the sound therapy portion of treatment. All groups received counselling. Tinnitus related distress was measured using the Tinnitus Reaction Questionnaire (TRQ; score range 0 to 104) with a change of 40% required to mark a clinically important improvement from baseline. From the patients enrolled, 38 (43%) were excluded from the analysis for various reasons. The patients had a mean age of 50 years, 52% were male, and had moderate to severe tinnitus. The two Neuromonics groups were combined since patients did not adhere to the prescribed volume settings and analysis of results showed no difference between groups. TRQ scores in the Neuromonics group were statistically significantly lower at 3, 6, and 12 months, compared to baseline. No statistically significant differences in TRQ scores over time were detected for the counselling and the broadband noise group. TRQ scores were statistically significantly lower in the Neuromonics group compared to the other groups at 12 months. The authors concluded that the Neuromonics therapy was superior to counselling or noise plus counselling.⁷

Limitations

Overall the studies were of low methodological quality, with a high risk of bias. The patient selection criteria and randomization methods used were unclear. It appears that intention to treat analysis was not followed in many studies. In some cases, randomization was not followed and patients were allowed to select the treatment, or randomization resulted in treatment groups of uneven size. Reporting of the patients' baseline characteristics was also poor making it difficult to determine if treatment groups were similar. Sample size in studies was limited, ranging from 48 to 136, often with substantial numbers of patients lost to follow up, excluded from the analyses, or with missing data. Follow up time varied according to treatment group in one study. Blinding of outcome assessors was not mentioned in any of the studies. The amount of contact time between patients and investigators was often different for treatment groups within the studies. In some studies, outcomes data was selectively reported (eg, authors reported six month data for one outcome and 12 month data for another).

Studies enrolled a wide range of patients with tinnitus, varying from those with clinically insignificant tinnitus to those with severe tinnitus-related disability. Some studies reported that patients with more severe tinnitus experienced larger treatment effects than those with more moderate tinnitus however these subgroups lacked adequate statistical power, making it difficult to draw strong conclusions from the results. One study enrolled patients with more severe tinnitus to CBT and those with less severe tinnitus to TRT, although the data appears to have been analyzed separately.

The authors of the systematic review stated several limitations to the TRT studies. Data from well designed RCTs are not available. Case series were limited by the lack of a control group, un-blinded assessment of outcomes, and the possibility of bias when patients were selected for study. Different modifications of the TRT protocol exist in practice and often the protocol used is poorly described in the studies. Un-validated outcome measures were used in some studies. The applicability of studies of veterans, who experienced sudden hearing loss and tinnitus from blast trauma or gunfire noise exposure, to other patient groups is unclear.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

Due to the low methodological quality of the studies available it is difficult to draw any firm conclusions on the effectiveness of TRT in the management of tinnitus. Compared to baseline measures, most TRT treatments showed improvement in outcomes over time. However, most studies had substantial losses to follow-up which may have biased results in favour of the treatment if patients with poor outcomes were excluded from the analysis. The potential for bias in the selection of patients, lack of blinding of outcome assessors, and use of non-equivalent comparator groups was also a concern and may be a consideration for decision-making about TRT for patients with tinnitus.

PREPARED BY:

Health Technology Inquiry Service

Email: htis@cadth.ca

Tel: 1-866-898-8439

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APPENDIX I: Additional studies of potential interest

RCT of tinnitus retraining counselling without noise generator

Henry JA, Loovis C, Montero M, Kaelin C, Anselmi KA, Coombs R, et al. Randomized clinical trial: group counseling based on tinnitus retraining therapy. *J Rehabil Res Dev*. 2007;44(1):21-32. [PubMed: PM17551855](#)

RCT of two different TRT programs

Davis PB, Paki B, Hanley PJ. Neuromonics Tinnitus Treatment: third clinical trial. *Ear Hear*. 2007 Apr;28(2):242-59. [PubMed: PM17496674](#)

Controlled observational studies

Seydel C, Haupt H, Szczepek AJ, Klapp BF, Mazurek B. Long-term improvement in tinnitus after modified tinnitus retraining therapy enhanced by a variety of psychological approaches. *Audiol Neurootol*. 2010;15(2):69-80. [PubMed: PM19657182](#)

Hatanaka A, Ariizumi Y, Kitamura K. Pros and cons of tinnitus retraining therapy. *Acta Otolaryngol (Stockh)*. 2008 Apr;128(4):365-8. [PubMed: PM18368566](#)

Herraiz C, Hernandez FJ, Plaza G, de los SG. Long-term clinical trial of tinnitus retraining therapy. *Otolaryngol Head Neck Surg*. 2005 Nov;133(5):774-9. [PubMed: PM16274808](#)

Uncontrolled observational studies

Bessman P, Heider T, Watten VP, Watten RG. The tinnitus intensive therapy habituation program: a 2-year follow-up pilot study on subjective tinnitus. *Rehabil Psychol*. 2009 May;54(2):133-7. [PubMed: PM19469602](#)

Forti S, Costanzo S, Crocetti A, Pignataro L, Del Bo L, Ambrosetti U. Are results of tinnitus retraining therapy maintained over time? 18-month follow-up after completion of therapy. *Audiol Neurootol*. 2009;14(5):286-9. [PubMed: PM19372645](#)

Gudex C, Skellgaard PH, West T, Sørensen J. Effectiveness of a tinnitus management programme: a 2-year follow-up study. *BMC Ear Nose Throat Disord* [Internet]. 2009 Jun 26;9:6. [cited 2010 Feb 17]. [PubMed: PM19558680](#) Available from: <http://www.biomedcentral.com/content/pdf/1472-6815-9-6.pdf>

Ito M, Soma K, Ando R. Association between tinnitus retraining therapy and a tinnitus control instrument. *Auris Nasus Larynx*. 2009 Oct;36(5):536-40. [PubMed: PM19269119](#)

Aazh H, Moore BC, Glasberg BR. Simplified form of tinnitus retraining therapy in adults: a retrospective study. *BMC Ear Nose Throat Disord* [Internet]. 2008 Nov 3 [cited 2010 Feb 17];8:7. [PubMed: PM18980672](#) Available from: <http://www.biomedcentral.com/content/pdf/1472-6815-8-7.pdf>

Hanley PJ, Davis PB, Paki B, Quinn SA, Bellekom SR. Treatment of tinnitus with a customized, dynamic acoustic neural stimulus: clinical outcomes in general private practice. *Ann Otol Rhinol Laryngol*. 2008 Nov;117(11):791-9. [PubMed: PM19102123](#)

Herraiz C, Hernandez FJ, Toledano A, Aparicio JM. Tinnitus retraining therapy: prognosis factors. *Am J Otolaryngol*. 2007 Jul;28(4):225-9. [PubMed: PM17606035](#)

Mazurek B, Fischer F, Haupt H, Georgiewa P, Reissauer A, Klapp BF. A modified version of tinnitus retraining therapy: observing long-term outcome and predictors. *Audiol Neurootol*. 2006;11(5):276-86. [PubMed: PM16717441](#)

APPENDIX II: Outcome measures

Tinnitus questionnaire (TQ)

A 52 item scale that measures tinnitus related psychological complaints including emotional and cognitive distress, intrusiveness, auditory perceptual difficulties, sleep disturbances, and somatic complaints.⁴ The score ranges from 0 to 84 points with four severity levels: low (1 to 30), moderate (31 to 46), severe (47 to 59), and very severe impairment (60 to 84).⁵ Patients with TQ scores ≤ 46 were considered to have compensated tinnitus (no secondary symptoms) and those with scores >46 have decompensated tinnitus (permanent annoyance and psychological strain with secondary symptoms such as depression, anxiety, impaired sleep, and concentration).⁵