

### **Critical Review:**

## **Does the evidence indicate that when tinnitus therapies, specifically Tinnitus Retraining Therapy, Tinnitus Masking, or Cognitive-Behavioural Therapy are compared, one of these therapies is more effective in the reduction of tinnitus-related distress?**

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This systematic review compares the efficacy of the following therapies used in the treatment of subjective tinnitus: Tinnitus Retraining Therapy (TRT), Tinnitus Masking (TM), and Cognitive-Behavioural Therapy (CBT). Study designs include mixed randomized and mixed nonrandomized clinical trials, single group pre-posttest, and a systematic review. Current research suggests that TRT provides greater long term effects, whereas the effects of TM are not as persistent. Positive outcomes were also observed in studies combining TRT with CBT or other management strategies. Although limited evidence was available to support one specific therapy over another, the benefits of combined approaches incorporating both sound therapy and counseling are apparent. Additional research is required that incorporates standardized protocols and unbiased methodologies.

### ***Introduction***

Tinnitus is the perception of sound in the absence of an external stimulus. It is often associated with hearing loss, but can also occur as an isolated symptom. Tinnitus perception varies widely among individuals, and may consist of ringing, rushing, roaring or chirping sensations that may vary in pitch and loudness. Tinnitus can result in a great degree of distress and irritability, creating sleep, emotional and cognitive disturbances (Roeser, Valente, & Hosford-Dunn, 2008). Therefore, the evaluation of the efficacy of management strategies would prove valuable to individuals suffering from this pathology.

Tinnitus Masking (TM), Tinnitus Retraining Therapy (TRT), and Cognitive-Behavioural Therapy (CBT) are three common interventions in the treatment of tinnitus. TM is a form of sound therapy, whereby a device worn in or on the ear generates broadband noise to reduce the perception of tinnitus. The device can be a hearing aid, noise generator, or a combination of both (Henry, Schechter, Nagler, & Fausti, 2002). The goal of this therapy is to reduce tinnitus-related distress by partially or completely masking the tinnitus. This is achieved by setting the level of the noise to the point where the tinnitus becomes inaudible. TM also incorporates counseling to educate the patient on their tinnitus and use of tinnitus maskers, as well additional suggestions on coping. However, counseling is usually informal and is primarily provided only when the patient presents concerns (Henry et al., 2002).

TRT is another form of sound therapy that incorporates a different rationale and protocol than TM. It was developed by Dr. Pawel Jastreboff from the University

of Maryland (Henry et al., 2002). TRT is based on a neurophysiological model, which suggests that tinnitus-related distress results from negative associations of the tinnitus signal with non-auditory regions of the nervous system. Therefore, the main goal of TRT is to habituate the patient to their tinnitus by reducing these negative neuronal associations (Henry et al., 2002). TRT employs a combination of masking devices and counseling. Masking consists of low-level broadband sounds that match the intensity of the perceived tinnitus. TRT also employs the concept of sound enrichment, whereby individuals are encouraged to listen to sounds in their natural environment to promote the process of habituation. In addition, counseling in TRT is more structured than TM with established TRT protocols, including the TRT Initial Interview and TRT Follow-Up Interview (Henry et al., 2002).

CBT is a psychological approach to tinnitus therapy. It applies cognitive structuring approaches to address an individual's maladaptive emotions and behaviours towards their tinnitus (Gelfand, 2009). Patients are also counseled on the psychological and medical aspects of their tinnitus. The main goal of this therapy is to reduce behaviours considered maladaptive to tinnitus management. Relaxation techniques, positive imagery, and distraction are among the many techniques incorporated in CBT (Gelfand, 2009). CBT was originally only conducted by psychotherapists, but can now be applied by trained audiologists.

### ***Objectives***

The primary objective of this paper is to critically evaluate the evidence associated with the aforementioned tinnitus therapies to determine if one

therapy is most effective in the reduction of tinnitus-related distress.

## *Methods*

### Search Strategy

Search completed using computerized databases Pubmed and Medline and the following search criteria: (longitudinal study OR follow-up study) AND (outcome OR outcome measure OR clinical outcomes) AND (((masking OR tinnitus masking OR “Perceptual Masking”[MAJR]) AND (tinnitus retraining therapy OR tinnitus retraining)) OR (cognitive behavioural therapy AND (tinnitus retraining therapy OR tinnitus retraining)) NOT “Tinnitus/drug therapy”. The search was limited to studies in the English language conducted only on adult human subjects.

### Selection Criteria

Studies selected for this review were required to comparatively examine the efficacy of the aforementioned tinnitus therapies. All studies were required to define treatment outcome by changes in tinnitus severity and/or tinnitus-related distress, as measured by patient-based outcome measures.

### Data Collection

The literature search resulted in five research studies and one systematic review, in which the latter has a grade V level of evidence. The research studies consisted of various different study designs. There were two mixed nonrandomized clinical trials, each of which has a grade II level of evidence. Two mixed randomized clinical trials were also included, with grade I and II levels of evidence. The final research study is a single group pre-posttest with a grade III level of evidence (Dollaghan, 2007).

## *Results*

### Mixed Nonrandomized Clinical Trials

Henry et al. (2006a) conducted a study to prospectively evaluate the effectiveness of both TRT and TM in US military veterans with severe tinnitus. One hundred twenty-three individuals were selected and asked to complete three questionnaires before commencing treatment. This included the Tinnitus Handicap Inventory, Tinnitus Handicap Questionnaire, and the Tinnitus Severity Index. They were also asked to rate their tinnitus as being a ‘moderate’, ‘big’ or ‘very big’ problem. Afterwards, the patients were assigned alternately into one of two treatment conditions: TRT or TM. The questionnaires were re-administered four times after commencing treatment, up to a period of eighteen months. Change scores from baseline measures were calculated for each treatment group and

at each measurement point (three, six, twelve, and eighteen months). These scores were compared between subjective ratings of tinnitus severity, and effect sizes were calculated to determine the magnitude of the treatment effect. Additionally, one-tailed paired sample t-tests were calculated to determine if the change scores were statistically significant.

Considerable variations were observed between the two treatment groups. Effect sizes for TM appeared to remain stable over time, whereas the effect sizes of TRT improved incrementally. Patients receiving TM treatment demonstrated more improvements at three months, whereas TRT was the more effective treatment by twelve months of treatment. Effect sizes were also largest for individuals that reported that their tinnitus was a ‘very big’ problem.

However, this study has its limitations. All patients were veterans of the U.S. Military. Therefore, the observed outcomes in this study may be very specific to the etiology of disease in this population, and may not generalize to all tinnitus sufferers. Also, the allocation process in which patients were assigned alternately into treatment groups presents a methodological flaw as it increases risk for bias. However, the statistics used in these studies were relevant to the analysis in question by examining variations and statistical differences between the different treatment conditions.

In the second study using a mixed nonrandomized clinical trials study design, Henry et al. (2006b) revisited this data using additional statistical methods and also expanded the data to include additional outcome measures. Five patients were eliminated due to missing data, resulting in one hundred eighteen participants. Two questions from the TRT initial interview were incorporated as the additional outcome measures. These questions assessed awareness of tinnitus (AWARE) and annoyance of tinnitus (ANNOY).

A two-level multilevel modeling approach was used to analyze outcomes for each treatment condition. On the first level, individual patient trajectories were estimated in relation to baseline measures for each outcome measure, and the rate of change for each outcome measure was also determined. On the second level of the analysis, individual patient variations around the average trajectories for each outcome measure were predicted by seven variables: treatment condition, three baseline characteristics (hearing loss, duration of tinnitus, and extent of tinnitus problem), and interaction of treatment condition with each patient characteristic. These variations in patient trajectories were further analyzed by calculating random effects using Pearson’s

Chi-Squared test. Calculations were also performed to examine correlations between the baseline and rate of change for each outcome measure. Reliability coefficients were calculated to examine the degree of variance in the trajectories for each outcome measure. A repeated measures ANOVA was conducted for ANNOY data. This ANOVA analysis included the two treatment groups and the four different time points.

In addition to the results found in the earlier study, Henry et al. (2006b) found that subjective ratings of tinnitus severity were the strongest predictor of variance for each outcome measure. Also, the effectiveness of TM and TRT did not vary with the duration of a patient's tinnitus or the presence of hearing loss. Reliability for all baseline measures were high. Reliability of slope estimates were very high for all outcome measures except AWARE and ANNOY. ANOVA analysis for ANNOY data revealed a statistically significant reduction in scores for the TM group during the first three months. However, only the TRT group showed significant declines after six months.

The major strength of this study was the use of additional outcome measures and statistical analyses to comparatively examine the effects of TRT and TM. In addition to the aforementioned limitations in patient selection and treatment allocation, both studies by Henry et al. (2006a, 2006b) were limited due to the lack of control groups. This is important because TRT patients received more counseling time than patients receiving TM. Therefore, it is difficult to discern if the beneficial effects of TRT were due to the counseling component or TRT treatment as a whole.

#### Single Group Pre-Post Test

Holdefer, Oliveira, and Venosa (2010) assessed tinnitus perception before and after a group therapy combining elements of both TRT and CBT. Twenty-seven individuals took part in this study, but only nineteen finished. The group treatment consisted of ninety minute weekly sessions for a period of six weeks. Patients began with TRT in their first two weeks, followed by CBT in later sessions. The Tinnitus Handicap Inventory and the Hospital Anxiety and Depression scale were administered before treatment and up to eight weeks after treatment. Mean scores were calculated pre and post-treatment for each outcome measure. This study found that post-treatment scores were lower than the pre-treatment scores on all outcome measures. This suggests that the combined therapy is effective in reducing tinnitus-related distress.

Statistical tests were not incorporated in this study, but the outcome measures applied are statistically validated

measures of tinnitus-related distress (Holdefer et al., 2010; Snaith, 2003). However, this study could have benefitted from additional statistical measures such as a t-test to further examine within group changes over time. The fact that the treatment was administered in a group setting may have exaggerated the outcomes, especially if the group treatment affected morale and motivation among the participants. Also, little detail was provided on how TRT was conducted, so it is unclear if the authors of this study adhered to Jastreboff's structured protocol.

#### Mixed Randomized Clinical Trials

Caffier, Haupt, Scherer and Mazurek (2006) examined psychometric data from patients with compensated and decompensated tinnitus during long-term tinnitus coping therapy. Patients with compensated tinnitus had milder forms of tinnitus with little or no tinnitus-related distress. Conversely, patients with decompensated tinnitus exhibited more severe forms of this symptom and an inability to cope with it. Forty patients with compensated and decompensated tinnitus from a Tinnitus Centre in Berlin were randomly assigned to either a treatment group or a control group. An additional thirty patients with compensated tinnitus were also examined to evaluate the efficacy of tinnitus maskers.

The tinnitus coping therapy consisted of TRT that was modified to include counseling every three months, auditory training, muscle relaxation exercises, binaural tinnitus maskers, and psychosomatic and psychotherapeutic care for patients suffering from depression and/or anxiety. Before treatment, examinations by an audiologist and an otolaryngologist were conducted and the following outcome measures were administered: the Tinnitus Questionnaire (TQ), the Visual Analog Scale (VAS), and a third un-named questionnaire. These measures were repeated at six month intervals post-treatment, up to a period of twenty-four months.

Means and standard deviations were calculated for each measurement collected. Multiple regression analysis and Pearson's correlation were applied to examine the relationship between TQ and VAS scores. ANOVA was also applied to assess for significant differences between the treatment and the control group. Contrast analysis was then used to compare the individual means for each outcome measure, with the significance set at  $p < 0.05$ . Changes in reported tinnitus severity for all outcome measures were also examined using log-linear analysis of frequency tables.

The ANOVA, contrast analysis and log-linear analysis of frequency tables revealed that only the treatment

group improved significantly in their TQ score. Within this group, all patients with decompensated tinnitus showed significant improvements, whereas only seventy percent of patients with compensated tinnitus had reduced TQ scores. Greatest levels of improvements were observed after six months of treatment. In patients with compensated tinnitus, there was not a significant change in TQ scores between the patients with and without tinnitus maskers.

The outcomes of this study may have been exaggerated due to the fact that all patients were already attending a Tinnitus Centre, and thus likely had higher motivation to receive and respond to treatment. This may explain why the therapy was found to be more effective among patients with decompensated tinnitus. Additionally, the success of the tinnitus coping therapy may be largely due to the incorporation of additional therapeutic exercises. This modification away from Jastreboff's structured TRT protocol makes it difficult to evaluate the effectiveness of TRT. Lastly, the second group of subjects with only compensated tinnitus that were used to evaluate the effects of tinnitus maskers was not randomized, presenting a methodological flaw in this study. Nonetheless, the statistical measures applied in this study were relevant to the analysis as they measured within and between group changes over time.

Hiller and Haerkotter (2005) examined the effects of masking devices in patients receiving CBT. They also examined the effects of tinnitus education (TE) on individuals with moderate levels of tinnitus-related distress. One hundred thirty-six patients were asked to complete the Tinnitus Questionnaire and based on their scores they were assigned to receive either CBT or TE. CBT treatment consisted of ten weekly sessions lasting two hours each, and the TE treatment consisted of four weekly sessions lasting ninety minutes each. Sixty-six patients receiving CBT were randomized into two subgroups: those receiving tinnitus masking devices and those not receiving tinnitus maskers. The remaining participants received TE, and were randomized into similar subgroup divisions as CBT. Six outcome measures were administered before and after treatment, and again six and eighteen months post-treatment. This included the Tinnitus Questionnaire (TQ), the Tinnitus Cognition Scale, Tinnitus Diary, Symptom Checklist, Whitely Index, and the Dysfunctional Analysis Questionnaire. The ANOVA statistical analysis was also applied to identify differences between groups, and t-tests were used to analyze within group changes across time. Effect sizes and mean scores for each outcome measure were also calculated.

Patients of both treatments improved significantly when pre and post-treatment TQ scores were compared.

Effect sizes were largest for the TE groups, but only the CBT groups demonstrated long-term effects with reported levels of tinnitus-related distress moderately declining over time. Lastly, the provision of tinnitus masking devices did not produce significant changes in all outcome variables for the TE group. The same results were found for the CBT groups on all outcome measures except the Whitely Index. The Whitely Index is a measure of hypochondriacal beliefs and behaviours. The improvement in scores on this measure suggests that tinnitus masking devices may reduce tinnitus-related anxieties in patients receiving CBT. Additionally, effect sizes were largest in patients with concurrent hyperacusis receiving tinnitus masking devices for both CBT and TE groups, except when hearing loss was present in the CBT group.

This study suggests that the use of low-level tinnitus masking devices does not reduce tinnitus-related distress. Since TRT is a structured therapy including the provision of low-level tinnitus masking devices and counseling, the combination of TE and tinnitus masking devices is comparable to the services provided with TRT. Therefore, the authors of this study questioned the effectiveness of retraining approaches in the treatment of tinnitus. However, they did not follow Jastreboff's structured TRT protocol, which may be the reason for the unfavourable results found in this study. Additionally, the treatment allocation in this study was inconsistent. Some individuals were allowed participation into the treatment group they were most interested in even though they did not meet the requirement. Therefore, the authors repeated the statistical analyses by excluding these individuals from the sample. The scores on the TQ improved and the effect sizes were larger. However, they did not determine if these effects were statistically significant, or report on how this exclusion affected scores on the five other outcome measures used in this analysis.

#### Systematic Review

Hobson, Chisholm and El Refaie (2010) conducted a systematic review on the effectiveness of sound therapy in the management of tinnitus. They searched numerous databases for prospective randomized controlled trials on adults with persistent tinnitus, in which tinnitus masking devices were used as the primary intervention or in combination with other strategies (e.g. relaxation exercises, retraining approaches, etc.). The authors also refined the search to exclude any trials that did not meet their criteria (e.g. non-randomized trials, lack of sound-generating devices). This resulted in six studies, which were subsequently graded on their overall methodological quality in terms of risk of bias.

The risk of bias for the selected papers ranged from medium to high. Analysis of each individual paper revealed that sound therapy is an effective treatment strategy. However, no statistically significant differences were observed between the sole use of sound therapy, in comparison to other management strategies. Significant effects were observed when masking devices were used in combination with education and counseling, or as part of TRT. The authors of this review concluded that tinnitus treatment consisting of sound therapy alone is not beneficial. Therefore, they encouraged combining sound therapy with additional strategies in the treatment of tinnitus.

The results agree with the systematic review presented here, in that the provision of sound therapy varied among the included studies, and a large degree of heterogeneity in the intervention methods and outcome measures was apparent. Some studies incorporated low-level noise generators as outlined by Jastreboff's TRT protocol, whereas others used high-level noise generators. This inconsistency may distort the comparisons made between the different studies. These conditions also limited the use of a meta-analysis. This study is also limited by the fact that the included articles were rated as having medium to high risk of biases, thereby questioning the validity of the analysis.

### *Discussion*

The evidence suggests that the use of a combined approach in the treatment of tinnitus is highly effective. This was also supported by the systematic review by Hobson, Chisholm and El Refaie (2010). However, the combinations varied and were not well-controlled. The interpretation is also confounded by differences in TRT administration, persistence of therapy, perceived tinnitus severity, and the study population. Therefore, it is difficult to determine which factors contributed to optimal outcomes.

Some combinations of management strategies may not be as effective as others. For instance, the study by Caffier, Haupt, Scherer and Mazurek (2006) demonstrated that the provision of tinnitus masking devices is not effective when combined with CBT or tinnitus education. Most of the evidence supports a combination of sound therapy and counseling, thereby supporting both TM and TRT. Since counseling in TRT is more formal, it may be the more effective strategy.

Some studies did not adhere to the standard TRT protocol as established by its creator Dr. Jastreboff. For instance, Caffier et al. (2006) modified TRT to include additional strategies. These inconsistencies may have

distorted the comparisons made between TRT and other therapies, thereby limiting the validity of their analysis.

Differences in short-term and long-term outcomes were observed across studies. The studies by Henry et al. (2006a, 2006b) demonstrated that TM provides greater short term benefits, whereas the effects of TRT are more persistent. This suggests that TRT would be most beneficial to patients choosing to receive treatment over a continuous period of time. However, this may vary depending on tinnitus severity and perceived disability.

The severity of tinnitus has significant implications in treatment outcomes. TRT is most effective in patients with more severe (i.e. decompensated) forms of tinnitus (Caffier et al., 2006; Henry et al., 2006a; Henry et al., 2006b). TM is also more effective in patients with greater perceived tinnitus severity (Henry et al., 2006a; Henry et al., 2006b). Therefore, TM may be preferable over TRT in patients with severe tinnitus, due to the reported short-term benefits (Henry et al., 2006a; Henry et al., 2006b).

The populations in the discussed studies varied likely with respect to etiology of tinnitus, which may or may not have included hearing loss. For instance, the studies by Henry et al. (2006a, 2006b) were limited to veterans of the U.S. Military, suggesting that the nature of their tinnitus may be due to exposure to noise or ototoxic chemicals, which may also be accompanied by hearing loss. However, tinnitus is a symptom of various etiologies and can occur with or without hearing loss. Therefore, these affects may be very specific to the etiology of disease in this military population, and may not generalize to all tinnitus sufferers.

### *Conclusion*

In conclusion, the evidence suggests that TRT, TM and CBT all have their own unique benefits in the treatment of tinnitus. Given the confounding variables that include length of therapy, tinnitus severity, and subject population, the overall level of evidence is equivocal. Nonetheless, the benefits of combined approaches appear to be most promising. Future studies must focus on determining which evidence-based therapy components are most promising for which group of patients. The use of more robust methodology with well-defined control groups, as well as randomization of clinical trials in future studies would increase the quality of evidence in the study of tinnitus management. This would not only avoid criticism by reducing bias, but may also promote avenues for more conclusive evidence regarding the effectiveness of various tinnitus therapies.

### ***Clinical Recommendations***

Combined therapies appear suggestive in the treatment of tinnitus, but the evidence is not sufficient enough to support a specific treatment method. The research is lacking in terms of which specific factors are most critical in the reduction of tinnitus-related distress.

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