Expert Opinion
“Tinnitus masking and [Tinnitus Retraining Therapy] TRT are two frequently used methods for clinical management of tinnitus. Both of these methods have a long history of development, application, and refinement, as well as a track record of clinical success.” Henry et al. (2002, p.560).

The “VA is committed to implementing nationally developed, evidence-based practice guidelines to improve health-care outcomes and efficiency in the veteran patient population.” Management Decision and Research Center, Department of Veterans Affairs, 1998; Feussner 1998).

Introduction

Tinnitus Retraining Therapy (TRT) and Tinnitus masking (TM) are the two most common therapies designed to treat tinnitus, both prescribe sound therapy in the moderate and severe cases. TRT is a therapy protocol that is designed to help the sufferer habituate to their tinnitus according to a neurophysiologic model. In the TRT, once the assessment of the tinnitus is made, a combination of direct counseling and sound therapy is provided. The sound therapy is a critical component that allows an externally generated sound to “blend” with the sufferers’ tinnitus. Generally, the therapy can last up to 18 months. TM, on the other hand, is a protocol designed for immediate relief. In that regard, the sound therapy is presented at a level that masks the tinnitus, therefore providing relief to the sufferer.

Tinnitus sufferers fit into one of five categories as described by Jastreboff and Hazell (2004). AudioFusion, Inc.’s primary target includes Categories 1 and 2, and are generally the more severely afflicted. Category 1 includes patients that “have tinnitus of high severity as their predominant complaint and do not have other hearing-related problems (p. 82). These patients are prescribed direct counseling along with a wearable sound generator played at a loudness that blends with the tinnitus. Category 2 includes patients who “have tinnitus coexisting with hearing loss” (p. 83). These patients are prescribed direct counseling and hearing aids. They are also instructed to enrich their listening experience with outside sounds to alleviate the effects of tinnitus.

Review of Literature

Several studies have been performed assessing the efficacy of the TRT and TM. The more recent studies employed a more rigorous and controlled methods. Therefore, the more recent studies will be reviewed and the less controlled studies will be used as supporting evidence to the more recent, controlled studies.

Henry et al. (2006) conducted a controlled, clinical study which included 118 patients from a pool of in an 18-month study investigating the efficacy of TRT and TM. Five
validated assessment tools were used to assess the severity of the tinnitus before, during and after the treatment. These tools have been validated for internal consistency and reliability. Of their extensive findings, TRT was found to be more effective in severe cases of tinnitus, though TM was effective. However, in moderate cases of tinnitus, both TRT and TM were similarly effective. Specifically, the more severely afflicted patients were aware of their tinnitus 77.8% of the time before the TM therapy and only 33.2% after 18 months of TM therapy. Patients treated with TRT were aware of their tinnitus 66.5% of the time before treatment and only 14.7% of the timer after 18 months. In terms of how much of the time patients were annoyed by their tinnitus, the TM-treated patients were annoyed 52.6% of the time before and 24.2% of the time after 18-months of the TM therapy, while TRT-treated patients were annoyed 47.3% of the time before and 6.3% of the time after treatment. Overall, 88% of their patients treated with TRT showed significant improvements (≥5 point improvement on the Tinnitus Severity Index) (Henry as cited in Jastreboff & Jastreboff, 2006).

In an interesting study investigated the effectiveness of the use of ear-level devices, which included hearing aids and noise generators (Folmer & Carroll, 2006). 150 patients were split evenly into three groups: a hearing aid group, a noise generator group, and a control group that did not use any ear-level device. All three groups participated in other aspects of tinnitus treatment that did not include sound therapy. While all three groups showed improvement after 18 months, the groups that used ear-level devices showed greater improvement. They concluded that ear-level devices offer benefits beyond that of other tinnitus therapy (e.g. counseling) alone.

Herraiz et al. (2005) studied TRT using 158 tinnitus patients over a period of 12 months. According to a self evaluation of the patients, a 78% and 82% improvement was observed after 6 and 12 months, respectively. Patients who followed through on the TRT treatment improved more so than patients who dropped out.

Jastreboff (1998) reported 152 consecutive patients who received treatment for a six-month period. Success was defined as a minimum of 20 percent improvement in two of three outcome areas (performance of daily activities affected by tinnitus, annoying owing to tinnitus, and percentage of time of tinnitus awareness). 129 of 152 patients used sound therapy and direct counseling. They reported 81.4% of these patients met the success criteria. Similarly, Jastreboff (1999) reported date from 223 patients from his clinic, all of which used sound therapy. Employing the same criteria for success as Jastreboff (1998), he reported an 81% improvement.

Sheldrake et al. (1999) performed a retrospective study of 483 patients from the London Tinnitus and Hyperacusis Center. Of this pool, 224 patients received the full TRT. Their criteria for improvement were a 40% improvement in annoyance and awareness, or a 40% improvement in annoyance or awareness plus an improvement/facilitation of a life factor. 83.9% of the 224 TRT patients met these rather strict criteria.

McKinney et al. (1999) included 182 patients to study the benefit of tinnitus therapy. Success was met when a minimum of a 40% percent improvement in two or more scales
evaluating the effects of tinnitus, including annoyance (from the tinnitus), impact of
tinnitus on quality of life, tinnitus loudness, and percentage of time of awareness. Of the
182 patients, 148 received counseling and sound therapy (54 counseling only; 72 ear-
level sound generators; 56 hearing aids). Of those that received counseling only, 72.2% improved. Of those who used hearing aids only, 70.7% improved. 75% of the patients
improved with sound generators set to ‘just audible level’, which is below what would
normally be prescribed. For those receiving the ‘truest’ form of TRT (higher level of
sound presentation), 83.3% improved. These various success figures give a range of
what would be a reasonable expected benefit given the various treatments. However,
data from this and the other studies discussed support the notion that benefit is
maximized when sound therapy is used as part of TRT.

Bartnik et al. (1999) studied the benefits of TRT by randomly selecting 120 patients from
a pool of 556. They created five groups based on severity. Each group included 24
patients. All patients were treated for at least 12 months. Overall, 77.6% of the patients
improved. 75% of patients with hyperacusis as the primary complaint improved. 93% of
the patients with mild tinnitus (Category 0) Improved. Patients with severe tinnitus
(Category 1) and severe tinnitus with hearing loss (Category 2) improved at a rate of 83%
and 71%, respectively. Finally, 67% of the patients with prolonged, loud tinnitus
(Category 4) improved. It should be reiterated that the Category 1 and 2 patients have
been identified as the best candidates for the AudioFusion, Inc.’s, device.

Herraiz et al. (1999) reported follow-up evaluations from 84 patients after a year of
tinnitus treatment. Three criteria were used to determine significant improvement:
patient report of improvement (better, worse, or no change), Tinnitus Handicap Inventory
(Newman et al., 1998), and visual analog scale of tinnitus intensity. Of their patient pool,
37% received direct counseling, 37% received counseling plus sound therapy, 46%
received counseling plus hearing aids. Of those that received counseling only 93.7% improved. For the patients that received counseling along with sound therapy, 83.3%
Improved. For those that received counseling plus hearing aids, 84.2% improved.
Overall, 88.1% success rate was noted for all three groups combined.

Conclusion

From the nine studies reviewed, several trends become apparent. First, that most
therapies are some form of TRT or TM that include sound therapy with or without
counseling. Second, there is a great deal of variability in how the TRT and TM are
employed. Finally, despite the variability of treatment protocol, the use of sound therapy
as part of tinnitus therapy show a consistent success rate that typically exceeds 80%. The
consistency and high-level of success across all these studies supports the use of sound
therapy in tinnitus therapy regimens.
References


Henry JA. Effectiveness of TRT judged by Tinnitus Severity Index, pers. Communication.


The effectiveness of sound therapy-based tinnitus treatment
An initial response prepared by James A. Henry, Ph.D.

1. Loosely defined, “sound therapy” refers to any use of sound to mitigate the negative reactions caused by tinnitus. Sound therapy can include the use of environmental sound as well as sound-generating devices that couple directly to the ear. Virtually all methods of treatment for tinnitus utilize some form of sound therapy as a component of the intervention. The most well-known methods of treatment for tinnitus are Tinnitus Masking (TM), Tinnitus Retraining Therapy (TRT), and Cognitive-Behavioral Therapy (CBT). TM and TRT utilize ear-level devices for most patients with severe tinnitus. CBT does not normally use ear-level devices, but patients are advised to take advantage of environmental sound.

With TM, patients are fitted with “maskers,” hearing aids, or combination instruments (masker and hearing aid combined). Most TM patients receive combination instruments. The purpose of any ear-level devices used with TM is to provide a sense of immediate relief from tinnitus. Conceivably, any type of sound can be used for this purpose. Maskers and combination instruments, however, have been limited to the availability of broad-band (masking) sound. We conducted a study providing patients with more options, and certain sounds were selected as being more effective in providing relief than others (Henry JA, Rheinsburg B, Zaugg T. Comparison of custom sounds for achieving tinnitus relief. Journal of the American Academy of Audiology, 15:585-598, 2004). This was considered a pilot study, and further work is needed to systematically evaluate a variety of different sounds to determine which ones are most effective for providing relief, and to develop an algorithm for selecting tinnitus-relief sounds for patients. There is no question that sound can provide relief to many tinnitus patients, although this form of therapy has thus far been limited primarily to the use of broad-band sound.

With TRT, patients use essentially the same devices as for TM. However, “maskers” are referred to as “sound generators” (SGs). SGs used for TRT must be a specific type, and only one or two manufacturers make SGs (or combination instruments) that meet the criteria for TRT. Broad-band noise is used with the SGs and is set to a specific level in relation to the tinnitus. The objective is not to achieve a sense of relief, but to create a background of constant sound that facilitates habituation to tinnitus (i.e., causing patients to stop thinking about their tinnitus). Habituation usually takes 6-24 months. A limitation of SGs is that they can only produce broad-band noise. It is unknown if habituation can be improved through the use of different sounds, which has not yet been evaluated.

2. Patients complain of tinnitus in all audiology and ENT clinics. Methods were developed in the early 1980s to psychoacoustically “quantify” tinnitus, and most patients who are evaluated for their tinnitus receive some sort of a tinnitus psychoacoustic evaluation. Performing this method properly requires special equipment that is not normally available to audiologists. Also, audiologists are not generally trained in obtaining these measures (nor in the clinical management of tinnitus). Various adaptations of these psychoacoustic methods are usually attempted using clinical audiometers. There is currently no consensus on how these methods should be performed. The TES performs these methods in a consistent fashion, and enables...
The effectiveness of sound therapy-based tinnitus treatment
An initial response prepared by James A. Henry, Ph.D.

additional tinnitus measurements to be obtained. The computer does all of the work, so audiologists without specialized training can run the TES. In addition, other health care professionals can learn to operate the TES with minimal training. The TES has the potential to become a world-wide standard method of psychoacoustic evaluation of tinnitus. Because of its flexibility, the TES also has potential for use with tinnitus clinical research.

3. In reference to #1 above, the TTD will be capable of delivering virtually any sound directly to a patient’s ears. Using special algorithms (to be developed), a patient would be able to listen to a variety of sounds to select those that are most capable of providing relief (similar to the method of TM). Once the sounds are selected, they would be downloaded to the TTD and available to the patient as needed. The device could also be used with TRT, and could be superior to any device that is presently used with TRT by providing an enhanced frequency range for broad-band noise, frequency shaping, and potentially the use of different types of sound to facilitate enhanced habituation.

A new method of treatment (Neuromonics) uses music (various passages of baroque and new age) in an MP3-type device, combined with broad-band noise. Their device can be configured to the patient’s hearing configuration (to compensate for hearing loss) and the device is capable of reproducing sound up to 12-16 kHz (SGs and hearing aids are usually limited to frequencies up to about 4-6 kHz). These features should be achievable with the TTD. The TTD has the potential to be utilized with any form of tinnitus therapy, and to provide maximum flexibility with respect to the use of an unlimited variety of sounds, combinations of sounds, selectable bandwidths, shapeable sound, etc.

Another untapped method of treatment that has potential is “residual inhibition” (RI). RI is the common effect of reduction in tinnitus loudness in response to stimulation with certain sound. It is an effect that is achievable for 80-90% of tinnitus patients. The RI testing protocol involves 1 min. of broadband noise presented at a level 10 dB above the minimum masking level (i.e., 10 dB above the level at which the tinnitus is just masked). RI has received relatively little study, and has potential to be a new form of treatment. This will require the development of algorithms to determine the most effective form of sound presentation to achieve RI in individual patients. Once the sound has been determined (as well as temporal parameters of the sound), then that sound can be downloaded to the TTD to facilitate RI in patients on an ongoing basis.