

Neuromonics Tinnitus Treatment: Third Clinical Trial

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Objectives: The purposes of this study were to:

1. Demonstrate the efficacy of the Neuromonics Tinnitus Treatment when enhanced with various modifications since previously reported trials¹, and
2. Test the relative clinical effectiveness of two variations of the treatment protocol:
 - a. One-stage, which involves intermittent tinnitus perception throughout treatment, and
 - b. Two-stage, which involves an initial complete covering of tinnitus perception followed by intermittent perception.

Design: The Neuromonics Tinnitus Treatment is a novel approach that utilizes neural stimulation in the form of a distinctive acoustic stimulus incorporating the principles of systematic desensitization. In this study, 35 subjects with a predominantly moderate-to-severe level of tinnitus-related distress prior to treatment were randomly allocated into one of two treatment groups: one-stage (N=16), which involved intermittent perception throughout; or two-stage (N=19), which involved complete covering of perception for an initial 2-month period, followed by intermittent perception over a subsequent 4-month period. Each participant received a high fidelity personal sound player with earphones, and an acoustic stimulus that had been spectrally modified according to that individual's audiometric profile. The subjects were instructed to use the assigned treatment for 2 hours or more per day, particularly at those times of day when their tinnitus was most disturbing. The amounts of clinician time for education, monitoring and support were equal for each group. Clinical data were collected at 2, 4, 6 and 12 months after the start of treatment.

Results: Significant improvements were reported by a high proportion of subjects on all key measures, particularly during the early months of treatment. After 2 months of treatment, both groups displayed clinically and statistically significant improvements on the primary measure of tinnitus-related distress, the Tinnitus Reaction Questionnaire (TRQ)² ($p < 0.001$), as well as on tinnitus awareness ($p < 0.001$).

Improvements increased with time over the first 6 months of therapy. (See Figure 1.) After 6 months of treatment, 91% of all subjects exceeded the minimum threshold for clinical success, defined as a reduction of at least 40% in the TRQ. The mean improvement in TRQ scores at 6 months was 65% for all subjects in both treatment groups. In addition, 80% of subjects at 6 months reported tinnitus disturbance levels that were no longer clinically significant.

Both treatment groups also experienced clinically and statistically significant improvements in minimum masking levels (MMLs) and loudness discomfort levels (LDLs) at 2, 4, 6 and 12 months after starting treatment. Compared with the TRQ and awareness measures, improvements in MMLs and LDLs were more gradual and progressive over the 12 months. Mean improvements ultimately achieved in the two-stage group were 12.1 dB for MML and 10.4 dB for LDL at 12 months.

There was a clear relationship between the average daily device usage (measured in hours per day) and the observed clinical outcomes in the early stages of treatment. In the case of TRQ improvements, statistically significant differences were found between usage bands (i.e. low, medium and high usage) at 4 months.

Although inter-group differences were not statistically significant, there was some indication of a more consistent benefit over 12 months for the group that initially received a high level of tinnitus interaction.

DISCUSSION

The Neuromonics Tinnitus Treatment is a novel approach that combines distinctive acoustic stimulation with a structured program of counselling and support by a specially trained clinician. This treatment strategy features the home use of an audio recording of a binaurally correlated acoustic signal that intermittently covers up the patient's tinnitus perception. This acoustic signal provides stimulation to auditory pathways deprived by hearing loss, engages positively with the limbic system, and allows intermittent, momentary tinnitus perception within a pleasant and relaxing stimulus, thereby facilitating desensitization to the tinnitus signal.

Impact of Customization on Listening Volume and Stimulus Masking Levels.

A customized acoustic stimulus is the core component of the Neuromonics Tinnitus Treatment. This stimulus comprises a combination of music and noise, customized for each individual's audiometric profile using proprietary, patented algorithms.

The benefits of this customization process were clearly shown by measurements of each subject's Stimulus Masking Level using the same acoustic stimuli with and without processing. Subjects could mask their tinnitus perception at a listening volume that averaged 16 dB lower than the non-customized stimulus used for the two-stage group. Since 6 dB roughly corresponds to a doubling of intensity, this reduction is substantial and represents a considerable advance over previously available approaches,

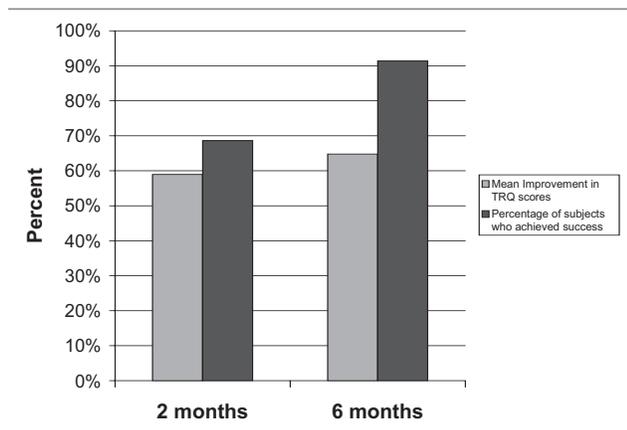


Fig. 1. Improvement in Tinnitus Disturbance

such as broad band noise. According to some researchers, the broad band noise commonly used in Tinnitus Retraining Therapy (TRT)³ does not provide broad band stimulation in practice, when patients' hearing loss is considered. This may contribute to the extended timeframe required when using the broad band noise approach⁴.

Customization is especially beneficial when music is used as an acoustic stimulus. Without customization, the highly dynamic nature and low frequency bias of music typically result in uncomfortably loud listening volumes before the patient can achieve a high level of interaction with tinnitus perception.

Clinical Efficacy of the Neuromonics Tinnitus Treatment.

Significant improvements on all key measures were reported by a large proportion of subjects at 2, 4, 6 and 12 months after beginning the Neuromonics Tinnitus Treatment. Both the one-stage and two-stage treatment groups displayed clinically and statistically significant improvements in tinnitus distress, awareness, and MMLs as well as LDLs, particularly during the early months of treatment. When compared with the improvements in TRQ and awareness, the improvement in MMLs and LDLs were more gradual and progressive, a finding which may reflect a more gradual process of neuroplastic change.

Notably, the percentage of time that subjects reported being aware of their tinnitus progressively decreased as the mean usage of the device progressively decreased. This observation suggests a large permanent treatment effect, rather than just the relief gained during the specific times of processor use.

The clinical outcomes of this study compare favourably with published results from alternative approaches that combine counselling with some form of acoustic therapy (e.g., TRT, Tinnitus Masking) or cognitive behavioural therapy with noise generators. However, compared to recently reported studies using these approaches⁵, improve-

ments observed with the Neuromonics Tinnitus Treatment were larger and were achieved more rapidly and more consistently. This apparently greater efficiency may be primarily due to the nature of the Neuromonics acoustic stimulus, which is customized for each individual's specific hearing loss profile. This approach is consistent with the findings in recently published animal studies, which suggest that tinnitus treatments provide acoustic signals tailored to correct for hearing loss, with stimulation provided across the broadest range of neurons.⁶

Relationship Between Usage and Clinical Outcomes.

Observed clinical outcomes appeared to be related to the average hours of daily device usage in the early stages of treatment, i.e. after 2 to 4 months of therapy. Differences in TRQ improvements varied among low, medium and high users at 4 months. These findings suggest a potential "dosage effect" of the acoustic stimulus, in which increased usage is reflected in improved clinical outcomes over the ¼ - 4½ hour range of reported daily usage.

CONCLUSIONS

The results of this study demonstrated that the Neuromonics Tinnitus Treatment provides rapid and profound improvements in the severity of tinnitus symptoms and their effect on the subject's quality of life. This treatment effect was consistent, and subjects reported that the treatment was pleasant to use. Both the one-stage and the two-stage variations of the treatment strategies tested in this study were successful in achieving these outcomes.

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- ² Wilson, P.H., Henry, J., Bowen, M., & Haralambous, G. (1991). Tinnitus reaction questionnaire: Psychometric properties of a measure of distress associated with tinnitus. *Journal of Speech and Hearing Research*, 34: 197-201.
- ³ Jastreboff, P.J. & Hazell J.W.P. (2004). *Tinnitus Retraining Therapy. Implementing the Neurophysiological Model*. Cambridge University Press, Cambridge.
- ⁴ Baguley, D.M., Beynon, G.J., & Thornton, F. (1997). A consideration of the effect of ear canal resonance and hearing loss upon white noise generators for tinnitus retraining therapy. *The Journal of Laryngology and Otology*, 111: 810-813.
- ⁵ Henry, J.A., Schechter, M.A., Loovis, C., Zaugg, T., Kaelin, C. & Montero, M. (2005). Clinical management of tinnitus using a "progressive intervention" approach. *Journal of Rehabilitation Research & Development*, 42: 95-116; Hiller, W. & Haerkotter, C. (2005). Does sound stimulation have additive effects on cognitive-behavioural treatment of chronic tinnitus? *Behaviour Research and Therapy*, 43:595-612.
- ⁶ Eggermont, J. (2005). Cortical map reorganization and its implications for the treating of tinnitus. *Presented at the Eighth International Tinnitus Seminar*, Pau, France. 7 September 2005.