

Treatment of tinnitus with a customized acoustic neural stimulus: a controlled clinical study

Objectives: The purpose of this study was to compare the efficacy of the Neuromonics Tinnitus Treatment with two control tinnitus treatment protocols:

1. A counselling and support program with delivery of a broadband noise stimulus.
2. A counselling and support program only.

Design: The Neuromonics Tinnitus Treatment is a new treatment approach that combines the use of an acoustic stimulus with a structured program of counseling and support by a clinician trained in tinnitus management. The individually customized acoustic stimulus was designed to provide stimulation to auditory pathways deprived by hearing loss, engage positively with the limbic system, and allow intermittent, momentary tinnitus perception within a pleasant and relaxing auditory sensation, thereby facilitating desensitization to the tinnitus perception.

This study comprised 50 patients (26 males and 24 females) who met eligibility criteria including a clinically significant degree of tinnitus disturbance, as indicated by a Tinnitus Reaction Questionnaire (TRQ) score of at least 17¹; mean pre-treatment TRQ score was 39.3 (SD: 18.0; range: 17-91). Mean age was 49.8 ± 15.8 years (range: 17 to 74 years). Patients were randomly assigned to one of four treatment groups:

1. **Neuromonics 1.** Patients received a customized acoustic stimulus in the form of music that was spectrally modified to account for each patient's audiometric profile; the stimulus was transmitted via a portable sound player. They were instructed to listen to the stimulus for a minimum of 2 hours per day, particularly at those times of day when their tinnitus was most disturbing, and to set the volume to a comfortable level that just managed to cover up their tinnitus.
2. **Neuromonics 2.** Patients received similar instructions as the Neuromonics 1 group, but were asked to set the volume to cover up their tinnitus for only about half the time.
3. **Noise + Counseling.** Patients received a stimulus that emulated the output of a typical broadband noise generator, using a portable sound player similar to the Neuromonics groups. They were instructed to listen for a minimum of 2 hours per day, particularly at those times of day when their tinnitus was most disturbing, and to set the volume at the lowest level at which both the acoustic stimulus and the tinnitus could be heard.
4. **Counseling-Only.** Patients received no acoustic stimulus, but all other facets of their program were the same as for the other three groups.

There were 22 patients in the pooled Neuromonics group, and 15 and 13 in the Noise + Counseling and Counseling-Only groups, respectively.

All four groups participated in an in-depth educational, counseling, and support program, and each was given a copy of a self-help book on tinnitus strategies and other written materials.

Clinical data were collected after 3, 6, and 12 months of treatment. The principal measurement instrument was the TRQ². A visual analogue scale (VAS) was also used to quantify changes in tinnitus severity, general relaxation level, and loudness tolerance. Objective audiologic measurements included puretone hearing thresholds and broadband noise mi-

nimum masking levels (MMLs). At 12 months, patients rated their perceived degree of benefit and enjoyment of their acoustic stimulus.

Pooling of Neuromonics treatment groups: Following conclusion of the study, it was discovered that many subjects in the two Neuromonics groups had of their own accord deviated from the volume settings prescribed for them. Many subjects in group 1 had opted for a lower volume setting in order to achieve a more intermittent or partial interaction with their tinnitus perception, while a number of subjects in group 2 had initially used a higher volume setting in order to completely cover up their tinnitus. These deviations appeared to reflect the patients' tendency to self-administer the treatment in a manner that they felt 'worked best' for them on a day-to-day basis. As a consequence, at a practical level, the treatments received by the subjects in the two groups were much more similar than had originally been intended in the group design. Subsequent analysis of the TRQ scores revealed no statistically significant differences between the two Neuromonics groups, either at the global level ($p = 0.744$) or for any individual time interval ($p > 0.28$ at any time point). In light of these considerations, the two Neuromonics groups were pooled for all results analyses reported herein, and are referred to collectively as the "Neuromonics" group.

Results: Patients who received the customized Neuromonics stimulus reported significantly greater and more consistent alleviation of tinnitus symptoms than did patients who participated in a counseling and support program with and without delivery of a broadband noise stimulus.

Tinnitus Reaction Questionnaire. Statistically significant reductions from baseline in mean TRQ scores occurred in the Neuromonics group at 3, 6, and 12 months ($p < 0.001$) (Fig. 1). Mean improvement on this measure was 61% at 6 months and 66% at 12 months. At 12 months, the TRQ scores of the Neuromonics group were significantly better than the scores of the Noise + Counseling group ($p = 0.008$) and the Counseling-Only group ($p = 0.014$). Improvements in the Noise + Counseling and Counseling-Only groups were more modest (mean improvements at completion 22% and 15%, respectively), and were not statistically significant. Differences between Noise + Counseling and Counseling-Only groups were not significant.

After 6 months of treatment, 86% of the Neuromonics patients met the minimum TRQ criterion for clinical success, defined as an alleviation of tinnitus disturbance of at least 40%. By contrast, only 47% of patients in the Noise + Counseling group, and 23% of patients in the Counseling-Only groups reported a successful result by this criterion.

Other clinical measures. Subjects receiving the Neuromonics Tinnitus Treatment in the present study reported significant benefits on other tinnitus measures, including VAS scores relating to tinnitus severity ($p < 0.001$), general relaxation ($p < 0.001$), and tolerance of loud sound ($p < 0.001$), as well as audiometric minimum masking levels (MMLs) ($p < 0.001$). On each of these measures, improvements were not significant for the Noise + Counseling and Counseling-Only groups. Differences in VAS scores were significant between Neuromonics and Noise + Counseling and between Neuromonics and Counseling-Only, but not between Noise + Counseling and Counseling-Only.

A high proportion of patients in the Neuromonics group reported improvement at or greater than the minimum threshold defined for a clinically successful outcome on these measures at treatment completion: a 5-dB decrease in the MML (79% of patients), and a 2-point decrease in score on the VAS (95% of patients for tinnitus severity, 82% relaxation, 55% tolerance of loud sound). Less consistent benefit was reported by patients in the other two groups.

Qualitative ratings of benefit were also more consistently positive for Neuromonics than the other groups. Differences between Neuromonics and Noise + Counseling were significant for all rated parameters: improved control ($p = 0.001$), less disturbance ($p = 0.006$), greater relaxation ($p < 0.001$), improved sleep ($p = 0.001$), and softer tinnitus ($p = 0.023$). Differences between Neuromonics and Counseling-Only were significant for greater relaxation ($p < 0.001$) and improved sleep ($p = 0.007$). There were no significant differences between the Noise + Counseling and Counseling-Only groups.

User satisfaction. 73% of the Neuromonics group rated their enjoyment of the acoustic stimulus provided at least a 3 on a scale from 0 'not at all' to 4 'almost all of the time', compared with only 17% who were provided broadband noise.

DISCUSSION

Clinical efficacy. Considerable improvements in tinnitus-related distress were evident among patients who underwent the Neuromonics Tinnitus Treatment program in this study. Mean improvement in TRQ score, which was 61% at 6 months and 66% at 12 months, translates into a large, positive impact on the lifestyle effects of tinnitus. The overall 'success rate' (defined as the proportion of patients who reported an improvement in tinnitus disturbance of 40% or greater) was 86% of all Neuromonics subjects after 6 months of treatment. Patients who underwent Neuromonics treatment in this study reported significant benefits not only in TRQ, but also in other measures, including VAS scores of tinnitus severity and ratings of relaxation and sleep. Significant improvements in MMLs and loudness tolerance were also observed, consistent with neuroplastic change as a result of treatment. These improvements compare favorably with the results of published studies of other approaches in which counseling was combined with acoustic therapy and cognitive behavioral therapy with noise generators^{3,4}.

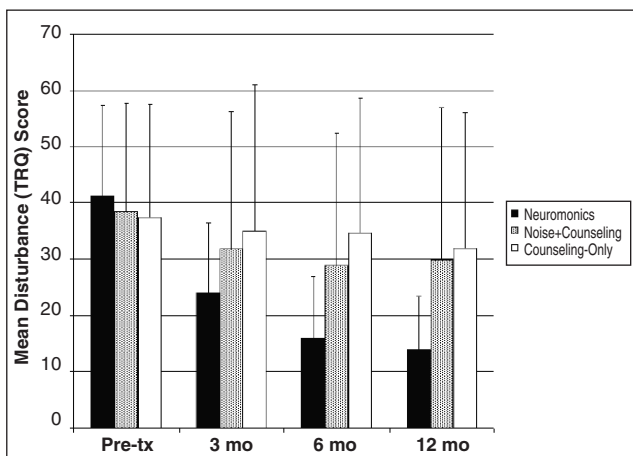


Figure 1. Tinnitus Reaction Questionnaire (TRQ) Scores

Notably, only about 25% of the patients in this study were clear candidates for the use of hearing aids, a finding consistent with those of other specialist tinnitus clinics^{5,6}. This highlights the potential usefulness of the Neuromonics approach for patients who might not be helped by hearing aids.

Another clinical trial of the Neuromonics treatment, carried out after the present study, showed outcomes superior to those reported here⁷, possibly due to enhancements made in the stimulus and treatment process in the interim, including the use of digital technology.

Superior efficacy of Neuromonics relative to Noise + Counseling and Counseling-Only. When compared to patients in the Noise + Counseling and Counseling-Only groups, patients who received the Neuromonics Tinnitus Treatment experienced larger and more consistent improvement on all measures, with significantly larger improvements in TRQ and VAS scores. Patients in the Neuromonics group also rated their stimulus as more enjoyable to listen to than patients who received the broadband noise stimulus.

CONCLUSIONS

The results of this study demonstrated that the Neuromonics Tinnitus Treatment provided significantly greater and more consistent alleviation of tinnitus symptoms than did a counseling and support program with and without delivery of a broadband noise stimulus. It resulted in significant improvements on a number of tinnitus measures, indicating a large, positive impact on the lifestyle effects of tinnitus. It is reasonable to conclude that the enhanced clinical efficacy of the Neuromonics Tinnitus Treatment resulted from the use of the Neuromonics stimulus on the basis that 1) all subjects received an equivalent counseling and support program and so the treatments provided to the various groups differed only in the nature of the acoustic stimulus provided; 2) subjects were assigned to the various treatment groups without any group-selection bias; and 3) there were no significant differences between the treatment groups on any measure prior to treatment.

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