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A multi-centre study on the long-term benefits of tinnitus management using Neuromonics Tinnitus Treatment

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Abstract

Introduction: The Neuromonics Tinnitus Treatment is based on individually customized acoustic stimulation and structured counseling. **Objectives:** To assess the long-term clinical outcomes of the Neuromonics Tinnitus Treatment, specifically, to determine whether benefits achieved at the conclusion of the prescribed treatment program were retained over the longer term. **Materials and Methods:** This study involved 70 subjects who had previously undergone the treatment across six clinics located in Australia and United States. Patients had concluded the treatment at least six, and up to 36 months, before the commencement of this study. The Tinnitus Reaction Questionnaire was used to assess tinnitus distress, and patients were asked to report on percentage of time of awareness of and disturbance by their tinnitus. Long-term data were compared to data reported throughout the course of the treatment. **Results and conclusions:** Patients achieved statistically significant improvement of their tinnitus distress. The success rate (at least 40% reduction in TRQ score) for this cohort of patients was 75.7% at the conclusion of the program and the majority of patients sustained the benefits in the long-term. Results revealed that NTT provides a consistent and stable relief of tinnitus distress.

Keywords: rehabilitation, tinnitus, treatment outcome.

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INTRODUCTION

Tinnitus is the perception of sounds in the absence of external stimulus. It is estimated that tinnitus affects 10-14.5% of the population worldwide[1], and that about 25% of the tinnitus population is sufficiently disturbed to seek treatment[2].

The pathophysiological mechanisms involved in the generation, progress and effects of tinnitus are under intensive research. Jastreboff's neurophysiological model postulates that, in clinically significant tinnitus, the autonomic and limbic nervous system are the main systems to account for tinnitus severity, while the auditory system plays a secondary role[3]. It is thought that tinnitus may be related to changes in the auditory and neural systems that are linked to perception, attention and emotion[4-7]. Animal studies have indicated that tinnitus perception following peripheral hearing damage may be linked to reorganization of the tonotopic map and changes in neuron responses[8].

Although knowledge and understanding of tinnitus are developing, the neural basis for tinnitus remains still a hypothesis[8]. Accordingly, access to a tinnitus treatment that is efficient and reliable remains a challenge for researchers and clinicians. The complexity of the tinnitus mechanism and the heterogeneity of the tinnitus patient population exacerbate the challenge for clinicians in deciding which tinnitus treatment to administer to a patient.

A number of tinnitus management approaches are available for use in clinical settings including counseling[5], cognitive behavioral therapy[9], hearing aids[10], Tinnitus Retraining Therapy [11 12] and, more recently, the Neuromonics Tinnitus Treatment (NTT)[13 -15].

NTT is a structured tinnitus rehabilitation program, based on customized acoustic stimulation and collaborative counseling[14-17]. NTT was the subject of three clinical trials over a period of more than a decade. The first clinical study[18] showed that customized music facilitated relaxation and fast decrease in tinnitus disturbance. The second clinical trial[13 15] compared NTT to other modalities of tinnitus treatment including counseling alone and counseling plus masking. The results demonstrated that NTT was more effective in decreasing tinnitus symptoms, with 86% of the patients reporting an improvement in tinnitus disturbance of 40% or greater, as measured by the Tinnitus Reaction Questionnaire (TRQ)[19], compared with 47% of patients in the counseling plus masking group and 23% in the counseling group. Following up on these studies, the third clinical trial[14] evaluated the efficacy of NTT and trialed two variations of the treatment protocol. The findings indicated that both one-stage and two-stage protocols variations were successful in decreasing tinnitus distress, with 91% of the patients across both groups achieving significant improvement in their disturbance. However, the two-stage protocol achieved more consistent outcomes and therefore this was chosen as the standard protocol to be followed in the clinical setting.

NTT was designed to address the multi-factorial nature of tinnitus: auditory, attentional and emotional[17]. The standard protocol uses acoustic stimulus created by combining broad-frequency noise and music at a specific signal-to-noise ratio[14 17]. This combination is then tailored for each individual's hearing profile[16 20]. The noise component of the acoustic stimulus, which is specific to the first stage of the treatment, aims to allow high interaction with the tinnitus perception. During the second stage of the treatment, the noise component is removed from the customized acoustic stimulus allowing intermittent interaction with the tinnitus. The patient is able to cover up their tinnitus during the peaks of intensity and perceive it during the intensity troughs. This approach aims to facilitate habituation to the tinnitus, decreasing patients' attention and reaction to the tinnitus[14 17 21].

NTT is delivered through an FDA-approved Class 2 medical device, which is fully programmed to match each patient's hearing profile. The customization of the stimulus allows patients with a diverse hearing profile to use the treatment at a comfortable listening level[16]. For customization of the device, the manufacturer is informed of the audiological measures, including pure-tone hearing thresholds from 250Hz to 12.5kHz, tinnitus pitch, tinnitus loudness and minimum masking level. The treatment involves the use of this device for a period of approximately six months, in the context of support, education and monitoring from an audiologist[16]. The standard protocol of NTT suggests that the first stage of the treatment lasts for approximately two months followed by approximately four months in the second stage[14 16]. However, as indicated by a number of studies,[17 22-23] some tinnitus sufferers may require modification to the standard protocol.

Clinical results of NTT at 12 months post-start of treatment have been reported previously[14-15] showing that the outcome are stable up to 6 months after concluding the program. However, there is a lack of independent published studies reporting the long-term results for patients in private practice. This study aimed to review the long-term clinical benefits achieved by patients treated with NTT in private practice to determine if the clinical outcomes experienced during the initial minimum six months of the program were sustained in the longer term (at least six months after concluding the treatment). The hypothesis was that patients with clinically disturbing tinnitus would sustain the benefits achieved at the conclusion of the NTT and/or would improve the symptoms in the long-term review.

MATERIALS AND METHODS

This study recruited 70 patients who had completed the NTT program in six private tinnitus clinics around Australia (Western Australia and Queensland) and United States (Minnesota, Illinois and New York). All subjects were full-fee payees. Data were included from all patients from these clinics with the following inclusion criteria: (i) presented with unilateral or bilateral tinnitus, (ii) completed the full NTT program following the protocol recommended by the Neuromonics' guidelines, (iii) reached the maintenance stage of the treatment at least six months prior to the commencement of this study, and (iv) had TRQ scores recorded pre-treatment and at least six-months post-treatment. No maximum time limit was established.

Patients underwent the tinnitus assessment as per the guidelines recommended by Neuromonics. The assessment comprised of completion of a comprehensive tinnitus history questionnaire -the TRQ- and an interview with the audiologist. The objective audiological assessment included pure-tone hearing thresholds from 500Hz to 12.5kHz, tinnitus pitch matching, tinnitus loudness, broadband masking threshold, measurement of loudness discomfort levels at 500, 1000 and 4000Hz, and residual inhibition. Candidacy criteria and other forms of treatment available (such as Tinnitus Retraining Therapy, masker, hearing aids) were discussed with patients. Patients were referred to an ear specialist, orthodontist, physiotherapist, psychiatrist or psychologist when appropriate.

The treatment followed the standard protocol for NTT[16] which suggests approximately six months of treatment, including follow-up appointments at approximately two, four and six months. This schedule varied somewhat according to the individual's needs and clinicians' discretion. During the course of their treatment, patients were asked to complete the TRQ based on their tinnitus experience for the previous week. This questionnaire was completed by patients without clinician involvement.

The patients were classified into suitability levels as proposed by a study in a private clinic setting[24]: Tier 1 - representing the most suitable patients to receive NTT; Tier 2 - patients who present with at least one of the following complicating factors: high level of psychological disturbance, low level of distress (TRQ scores below 17), severe hearing loss, i.e. four frequency (0.5, 1, 2 and 4 kHz) average greater than 50dB in the worst hearing ear; Tier 3 - the least suitable patients for NTT, which includes those with reactive tinnitus, ongoing noise exposure without adequate protection, multi-tone tinnitus, severe hearing loss, i.e. four frequency average greater than 50dB in the better hearing ear, Ménière's disease or poor English comprehension.

This study used TRQ scores, tinnitus awareness and disturbance as measurement of clinical outcomes of NTT to allow comparison to the previous published clinical trials. The threshold of 40% improvement in the TRQ score was considered the minimum criterion for clinical success of the treatment. Tinnitus awareness and tinnitus disturbance were assessed by asking the patients to answer the following questions: *"Over the past week, what percentage of the time while awake were you aware of your tinnitus?"* and *"What percentage of the time were you disturbed by your tinnitus?"* Features of tinnitus such as loudness, pitch, cause or trigger factors were not analyzed in this study.

In this report, appointments will be referred to as "transition" (two month review appointment), "follow up" (four months review appointment), "final" (six months review appointment), and "long-term review" (six to 36 months after termination of the treatment).

TRQ scores, tinnitus awareness and tinnitus disturbance were recorded and plotted in Microsoft Excel. SPSS v19 was used for statistical analysis. Paired-sample T-tests were used to determine significant change in scores between two time periods, with a significance $p<0.05$ representing a significant difference in scores. GLM Multivariate analysis was used to explore relationships between the dependent variables (continuous variables: TRQ, tinnitus awareness and tinnitus disturbance) and independent variables (nominal variable: clinic, Tier and time; continuous variable: age). Included in the analysis were tests for homogeneity and equal variances, to ensure that the statistical analysis could proceed on a valid dataset.

RESULTS

Subject demographics:

The seventy patients included in this study comprised of 48 males and 22 females. Table 1 records details on Tier, age, gender and treatment times. Tinnitus awareness and tinnitus disturbance were not available for some patients at each time point, but these patients were not excluded.

Tinnitus Reaction Questionnaire (TRQ):

The plot of average scores for all subjects (Figure 1) shows a progressive decrease in TRQ scores, overall and for each group, with the largest reduction in score apparent from baseline to the transition appointment (mean duration 11 weeks).

Multivariate analysis showed that there was a significant effect of appointment time on the TRQ score ($p<0.01$ and Partial Eta Squared$=0.879$), with no apparent effect of age, clinic, gender, Tier or their interactions. Tests for homogeneity showed that assumptions of nor-

Table 1. Demographics of patients and treatment times at treatment review point.

	Females	Males	Mean age (SD, range), years	Treatment time Mean (SD, range), weeks			
				Transition Appointment	Follow up Appointment	Final Appointment	Long term Review
Tier 1	6	18	59 (7.7, 46-72)	11 (3, 7-18)	23 (7, 13-41)	36 (11, 21-64)	90 (36, 45-171)
Tier 2	13	18	54 (12.7, 21-74)	10 (5, 7-32)	20 (7, 10-41)	36 (10, 24-60)	99 (43, 51-187)
Tier 3	3	12	51 (10.7, 29-67)	11 (3, 7-19)	23 (6, 16-39)	37 (11, 27-60)	85 (34, 44-177)
All patients	22	48	55 (11.0, 21-73)	11 (4, 7-32)	22 (7, 10-41)	36 (11, 21-64)	94 (39, 44-187)

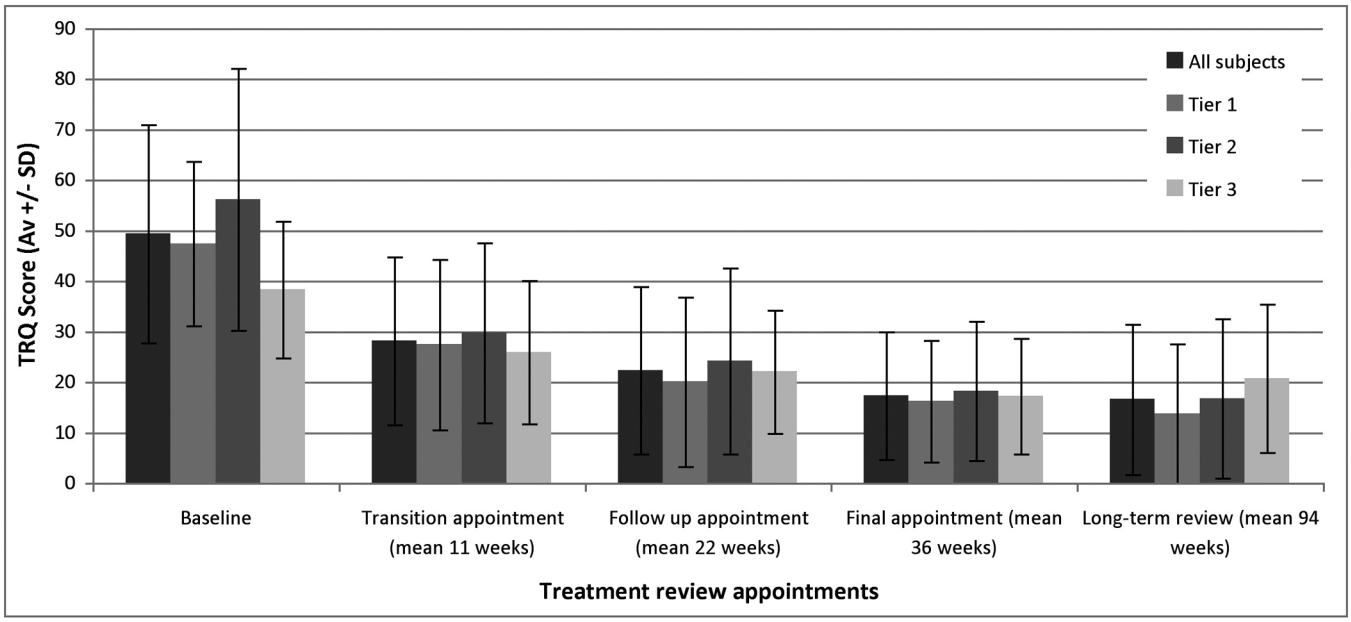

Figure 1. Outcome of NTT: mean of TRQ scores at the various review appointments for all subjects and by Tier.

mal distribution and equal variances of variables (for all variables in this study) were valid.

Analysis using Paired-sample T-test (Table 2) shows that there is a significant difference ($p<0.05$) in TRQ scores between almost every pair of time point during treatment. Of note was that there was no statistically significant change in mean TRQ scores from the time of the conclusion of the treatment to the long-term review for the whole cohort and for each Tier. The overall group mean improvement in TRQ scores was 40% at two months (transition appointment), 60% at the termination of the program (final appointment), and 60% at the long-term review.

The success rate (40% reduction in TRQ score) at the conclusion of the program was 75.7% of all patients (Table 3), with the best outcomes for patients from Tier 1, followed by those from Tier 2. There was a progressive increase in the number of subjects who achieved the 40% improvement over time, except that one patient in Tier 3 reported an increase in tinnitus distress after concluding the treatment.

Table 2. Statistical significance (p) for Paired-sample T-tests on TRQ scores between all treatment periods follow up appointments, for all subjects.

	Significance (p)			
Time periods compared	All	Tier 1	Tier 2	Tier 3
Baseline – transition appointment	0.000	0.000	0.000	0.001
Baseline – follow up appointment	0.000	0.000	0.000	0.000
Baseline – final appointment	0.000	0.000	0.000	0.000
Baseline – long-term review	0.000	0.000	0.000	0.001
Transition – follow up appointment	0.000	0.009	0.025	0.087
Transition – final appointment	0.000	0.001	0.000	0.002
Transition – long-term review	0.000	0.001	0.000	0.122
Follow up – final appointment	0.001	0.202	0.006	0.034
Follow up – long-term review	0.001	0.117	0.001	0.526
Final appointment – long-term review	0.443	0.229	0.415	0.464

Table 3. Number and percentage of subjects who improved their TRQ score by 40% from the pre-treatment assessment to the long-term review.

	All		Tier 1		Tier 2		Tier 3	
Appointments	*n*	%	*n*	%	*N*	%	*n*	%
Transition	36	51.4	10	41.7	19	61.3	7	46.7
Follow up	49	70.0	17	70.8	23	74.2	9	60.0
Final	53	75.7	19	79.2	23	74.2	11	73.3
Long-term	53	75.7	20	83.3	23	74.2	10	66.7

Awareness and disturbance:

Tinnitus awareness and tinnitus disturbance were available for 69 patients at pre-treatment and long-term appointments, and for 49 patients at the end of the treatment period, with no data available at the transition or follow up periods. There was a decrease in the mean percentage of the time that participants, as a group, were aware of their tinnitus and were disturbed by it (Figure 2).

Multivariate analysis showed that, as for TRQ scores, there was a significant effect ($p<0.01$) of appointment time on tinnitus awareness and tinnitus disturbance, and no effects of age, clinic, Tier and gender.

Analysis using Paired-sample T-test confirmed this, showing that there was a significant decrease in both scores at the end of the treatment and at the long-term appointment, relative to the scores before treatment started. However, there was no significant change in either score between the end of the treatment and long-term appointments (awareness $p=0.271$; disturbance $p=0.566$).

DISCUSSION

Clinical outcome of NTT at treatment conclusion:

The results of this study are in agreement with those in previous reports for NTT (summarized in table 4). Davis et al.[15] stated that 86% of all patients treated with NTT reported improvement in their tinnitus distress, as assessed by the TRQ of 40% or more after six months of treatment. Furthermore, the mean improvement in TRQ score was 61% after six months. Goddard et al.[25] reported a success rate of 78.6% and a mean TRQ reduction of 61.6% for a group of 14 patients who had completed the treatment.

Another clinical trial of NTT[14] indicated that the overall success rate according to the 40% improvement criterion was 91%, with a mean improvement of 65% in TRQ scores. This current study shows a more modest clinical success rate (75.7%) and a reduction in TRQ scores of 60% at the conclusion of the treatment. However, it is relevant to note that our cohort includes patients from all the three suitability categories, whilst the latter study reported only on the most suitable candidates for NTT. Inclusion of the candidates less suitable for NTT reduced our whole cohort's mean scores as success rate for Tier 3 patients were lower than those in the other two tiers (Table 3).

This study showed that the mean percentage of awareness tended to decrease to approximately half of the time from the baseline to the final appointment, agreeing with the findings reported by Davis et al.[14]. It is

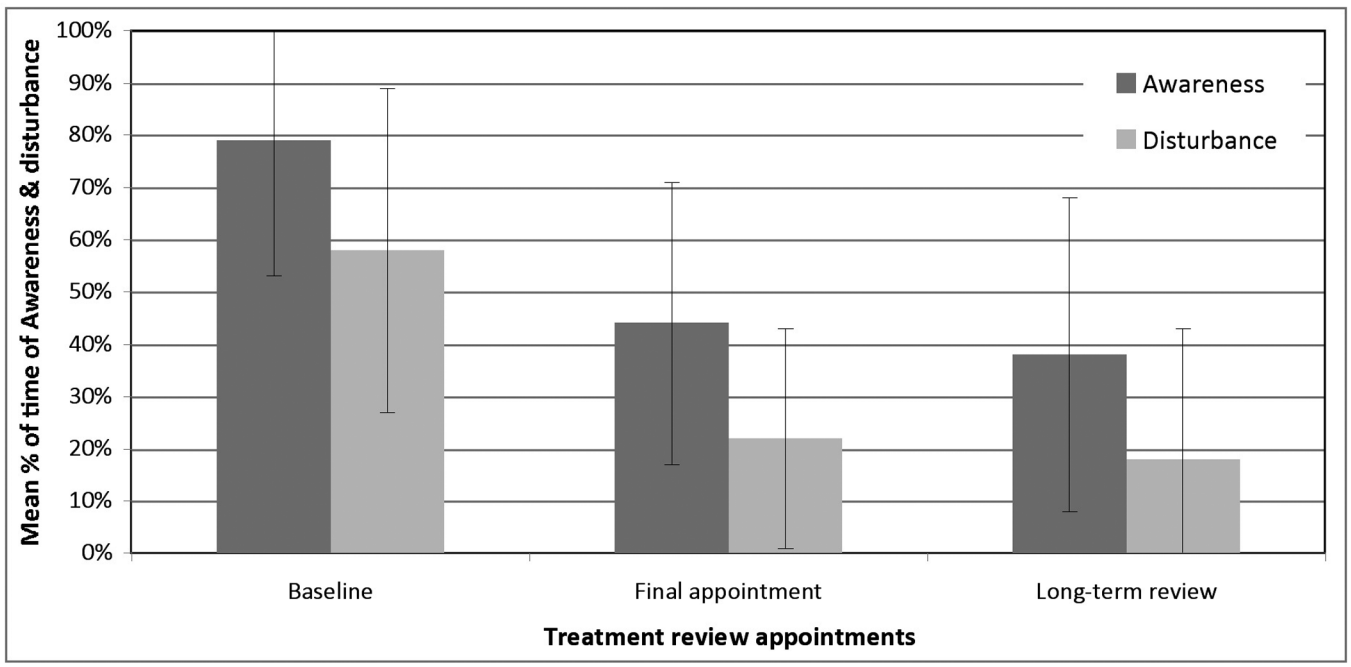

Figure 2. Mean percentage of time aware of and disturbed by tinnitus.

Table 4. Comparison between previous results.

		Davis et al. (15)	Davis et al. (14)	Goddard et al. (25)	Hanley et al. (24)	This study
Success rate	All patients	86%	91%	78.60%	N/A	75.7%
	Tier 1	N/A	N/A	N/A	92%	83.3%
	Tier 2	N/A	N/A	N/A	60%	74.2%
	Tier 3	N/A	N/A	N/A	39%	66.7%
Reduction in TRQ from baseline	All patients	61%	65%	61.60%	N/A	60%
	Tier 1	N/A	N/A	N/A	72%	62%
	Tier 2	N/A	N/A	N/A	49%	58%
	Tier 3	N/A	N/A	N/A	32%	54%

relevant to note that the measurement of tinnitus awareness has not been validated, and included only to allow comparison with published reports.

Hanley et al.[24] presented the clinical outcomes for the first 470 patients to undertake the NTT in general private practice. The clinical outcomes for the most suitable patients (Tier 1) were somewhat better than the earlier published data, with a success rate of 92%, and mean improvement in tinnitus distress of 72%. More modest outcomes were achieved by those patients assigned to Tier 2 and Tier 3. In comparison, this current study also found that Tier 1 candidates presented better clinical outcomes at treatment conclusion.

These outcomes also compare favorably with earlier published data from other treatment methods. Baracca et al.[26] found that 68% of tinnitus patients who underwent TRT reported an improvement in tinnitus symptoms after 18 months of treatment, and 64.7% reported improvement in quality of life. Herraiz et al.[27] reported that 82% of tinnitus patients who underwent TRT achieved an improvement of their tinnitus according to a self-evaluation tool after 12 months of treatment, with a decrease to 68% after 18 months of therapy. A recent controlled trial of TRT[28] showed that both TRT and general counseling are effective in improving tinnitus symptoms, with TRT providing a larger impact. However, it is important to note that direct comparison is complicated by the difference in measurement tools and criteria for treatment success.

Clinical outcome of NTT at long-term follow up:

This study is the first reported independent study on the clinical benefits of NTT beyond six months of treatment. The results reveal that the treatment outcome was stable beyond the conclusion of the NTT treatment program, since there was no statistically significant change in mean TRQ scores from the time of the conclusion of the treatment to the long-term review (up to 36 months post-treatment).

To date the longest follow up evaluations have reported a 12 month review (6 month post-treatment). One study[14] showed that the majority of patients sustained or further improved the treatment benefit; 89% of the patients in the standard protocol retained the benchmark of 40% improvement in TRQ score at 12 months review. Furthermore, mean tinnitus awareness was 37% at 12 months. Another study[15] reported that TRQ scores had significantly improved from baseline to the 12 months follow up, and that the mean improvement in TRQ score increased from 61% at the conclusion of the program to 66% at the 6 months post-treatment review. Although direct comparison is constrained, the results of our study seem in line with Davis et al.[14 15]. It indicated that there was no deterioration on clinical outcome after treatment conclusion, since the same percentage of patients (75.7%) who had achieved improvement of 40% or greater in TRQ score at treatment conclusion was also calculated in the long-term review, i.e., the success rate was constant beyond treatment termination. In addition, mean tinnitus awareness was 38% at the long-term follow up.

It is good to note that the majority of subjects who achieved significant improvement during the treatment retained the outcome in the long term. Those with more modest outcomes during treatment maintained the same modest results at the long-term review. This is a subject of further investigation; however, this may be related to numerous factors such as specific suitability criteria, and the positive impact that an early improvement may have on further decrease in tinnitus annoyance during the treatment (clinical benefits seem to occur slower for Tier 3 candidates).

Our patient population was diverse, displaying heterogeneous hearing profile, health history, tinnitus triggers, tinnitus characteristics and complicating factors, which were not considered in this analysis. It is known that it is likely that the tinnitus clinicians' diagnostic and counseling skills will influence the outcome of the treatment, and those aspects were not accounted for either. A further limitation of this research concerns comparison with the results of other approaches reported in the literature, due to difference in the statistical analysis and, more importantly, in the tool used to assess the outcome; while we used TRQ as the assessment tool of clinical outcomes, many studies of other approaches have used

Tinnitus Handicap Inventory (THI) and/or Visual Analog Scale (VAS).

CONCLUSION

Neuromonics Tinnitus Treatment has proved through clinical trials and independent studies to be a simple, well-structured, time-efficient, effective and reliable management program for tinnitus. The results of this study confirmed the original hypothesis that clinical outcomes provided by NTT are stable beyond the termination of the treatment. It was found that there was a statistically significant improvement in tinnitus distress from pre- to post-treatment, but no further significant difference between treatment completion and a long-term follow up at least six months, and up to 36 months after the commencement of treatment. 76% of the patients reported a clinically significant improvement in tinnitus disturbance at treatment completion (improvement in TRQ score of at least 40%) and this success rate was sustained at long-term follow up. Therefore, the clinical outcome of NTT is stable at the conclusion of the program. This research independently replicated the earlier published data. It strongly suggests that NTT provides a clinically significant improvement in tinnitus distress as early as two months and patients sustained the clinical outcomes up to 36 months after commencing the treatment.

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DECLARATION OF INTEREST

The authors report no declarations of interest.

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