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An Investigation of Feasibility and Safety of Bi-Modal Stimulation for the Treatment of Tinnitus: An Open-Label Pilot Study

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Objectives: Tinnitus is the perception of sound in the absence of an external auditory stimulus. It is widely believed that tinnitus, in patients with associated hearing loss, is a neurological phenomenon primarily affecting the central auditory structures. However, there is growing evidence for the involvement of the somatosensory system in this form of tinnitus. For this reason it has been suggested that the condition may be amenable to bi-modal stimulation of the auditory and somatosensory systems. We conducted a pilot study to investigate the feasibility and safety of a device that delivers simultaneous auditory and somatosensory stimulation to treat the symptoms of chronic tinnitus.

Methods: A cohort of 54 patients used the stimulation device for 10 weeks. Auditory stimulation was delivered via headphones and somatosensory stimulation was delivered via electrical stimulation of the tongue. Patient usage, logged by the device, was used to classify patients as compliant or noncompliant. Safety was assessed by reported adverse events and changes in tinnitus outcome measures. Response to treatment was assessed using tinnitus outcome measures: Minimum Masking Level (MML), Tinnitus Loudness Matching (TLM), and Tinnitus Handicap Inventory (THI).

Results: The device was well tolerated by patients and no adverse events or serious difficulties using the device were reported. Overall, 68% of patients met the defined compliance threshold. Compliant patients ($N = 30$) demonstrated statistically significant improvements in mean outcome measures after 10 weeks of treatment: THI (-11.7 pts, $p < 0.001$), TLM (-7.5dB, $p < 0.001$), and MML (-9.7dB, $p < 0.001$). The noncompliant group ($N = 14$) demonstrated no statistical improvements.

Conclusion: This study demonstrates the feasibility and safety of a new bi-modal stimulation device and supports the potential efficacy of this new treatment for tinnitus.

Keywords: Auditory somatosensory stimulation, neuromodulation, tinnitus

Conflict of Interest: Neuromod Devices, Ltd. developed the medical device employed in this study. At the time of the study, the authors had the following competing interests: Caroline Hamilton purchased stock in Neuromod Devices, the company that developed the hardware platform used to conduct this research, after the research was conducted. Barak Pearlmutter and Brendan Conlon owned a small amount of stock in Neuromod Devices during this research. Gloria Crispino and Shona D'Arcy were paid a fee for biostatistics consultancy. Caroline Hamilton, Barak Pearlmutter, and Brendan Conlon all hold some stock in Neuromod Devices. Shona D'Arcy has a small amount of stock options. All stock was awarded after the completion of this study. Since study completion, Caroline Hamilton and Shona D'Arcy have become full-time employees of Neuromod Devices and are named on patents that have resulted from this work. Neuromod Devices provided the devices free of charge for this study.

INTRODUCTION

Tinnitus is the perception of sound in the absence of an external, auditory stimulus and is commonly described as "ringing in the ears" (1–3). The condition is heterogeneous with a diverse range of etiologies (4) but it is commonly accompanied by a sensorineural hearing-loss (SNHL) (5). Tinnitus, as a result of SNHL, is widely believed to be a neurological phenomenon (6). Increased bursting and synchronicity in central auditory structures, as a result of cochlear pathology, have been implicated in the generation of tinnitus (7). A prevailing theory is that tinnitus is a reaction to reduced information in the frequency bands damaged by hearing loss. This has led researchers to investigate methods of acoustically stimulating the damaged frequency bands as a means of alleviating symptoms.

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Studies have found that specifically designed auditory stimuli may reverse neural pathologies (8,9). These findings support the theory that programmable hearing aids, if suitably tuned, could compensate for frequency-dependent deficits and thus alleviate the symptoms of the resulting tinnitus (10,11). Additionally, tinnitus suppression has been observed in cases of cochlear implants (12), which use an electrode array to directly stimulate the auditory nerve. Yet, the clinical evidence to support the longer-term benefit of hearing aids (13) or cochlear implants is limited. The use of other sensory channels may represent an additional option to compensate for the shortcomings of auditory interventions.

Animal studies indicate the involvement of the somatosensory system in the generation of tinnitus (14). It has been observed that pairing auditory and somatosensory stimulation can influence the response characteristics of auditory cortical, collicular and brainstem neurons in noise-damaged guinea pigs (15). This represents a potential approach for suppressing the neural activity hypothesized to be associated with tinnitus (16,17). Combining auditory stimulation with invasive nucleus basalis and vagus nerve stimulation (VNS) has been shown to promote neuroplasticity and modulate the response characteristics of auditory cortical neurons in rats (18). Koehler and Shore (19) found similar effects in auditory brainstem neurons by combining auditory stimulation with somatosensory stimulation. Combining auditory and transcutaneous VNS (tVNS) stimulation has been shown to promote similar effects in humans (20).

Bi-modal stimulation is emerging as a compelling approach to tinnitus treatment (21–24). De Ridder et al. (25) paired tones with VNS in 10 tinnitus patients who were previously unresponsive to other treatments. The study found that patients on certain medications did not respond to the treatment. After adjusting for this finding, the mean reduction in Minimum Masking Level (MML) and Tinnitus Handicap Inventory (THI) scores from baseline was 18.8 dB and 28% respectively. Another study of tVNS and auditory stimulation found that 18% of participants responded to the treatment. Responders in this study had a 43% reduction on the Visual Analogue Scale (VAS) loudness score (26). A recent study of 30 patients reported encouraging results for tVNS paired with notched music in some tinnitus outcomes measures (VAS loudness and VAS awareness) but not in others (THI) (27).

In this paper, we present the results of an open-label, single-arm, pilot study to investigate the feasibility and safety of an innovative form of combined auditory and somatosensory stimulation. The intervention delivers sound paired with electrical stimulation of the trigeminal nerve via the tongue. This pilot study forms the beginning of a stepped approach to investigating the efficacy of this intervention and will be followed by parameter optimization and randomized control trials, the recommended approach to evaluating new therapeutic interventions for their feasibility, safety, and efficacy (28).

MATERIALS AND METHODS

Multimodal Stimulation

A combined auditory-somatosensory stimulator was employed in this study (mutebutton$^{@TM}$ model MB2011, Neuromod Devices Ltd., Dublin, Ireland). This device can be programmed to simultaneously deliver auditory stimulation through hi-fidelity headphones and transcutaneous electrical stimulation of the trigeminal nerve through an array of 32 electrical stimulators on the antero-dorsal surface of the tongue. The anterior aspect of the dorsal surface is the most densely innervated part of the tongue offering extensive somatosensory bandwidth for a relatively small stimulator surface area. In addition, the tongue has a persistent electrolytic fluid (saliva) that enhances electrical conductivity between electrodes and the tongue. Somatosensory stimulation was delivered in the form of bi-phasic anodic pulses of 17.5 μs duration and variable amplitude. The high-fidelity headphones were capable of delivering CD quality audio (20 Hz to 20 kHz, −3 dB, 16-bit stereo) with amplitude variable more than a 75 dB range (from 5 dBA to 80 dBA SPL).

The auditory stimulus was spectrally broad (wideband noise) and contained a high rate of temporal events (recording of rainfall) mixed with classical music (recordings of piano works by Erik Satie). The wideband sound stimulates a broad spectrum of auditory pathways while the music provides a focal point in the soundscape to aid the user maintain attention (29). The auditory stimulus was spectrally modified to compensate for the deficit in the patient's hearing profile. A band-boost filter with center frequency correlating to the fall-off frequency, as determined by the patient's audiogram, was applied. Boosting the frequency components of the auditory stimulus in this way stimulates the affected hearing bands most commonly associated with SNHL related tinnitus.

The somatosensory stimulus was derived by temporal-spectral transformation of the auditory stimulus with a tonotopic mapping. The 4-octave range was divided so that all critical bands were covered (maximum six critical bands in an octave within this range) each octave was assigned eight frequency bins. The stimulator was programmed to map each of these frequency bins to a unique electrode. The auditory and somatosensory stimuli were synchronized, with no more than ± 1 ms delay between.

Both stimulation intensities were adjustable by the patient, according to individual comfort levels. The range for the auditory stimulus was from 5 to 80 dBA and was adjustable via a rotary dial with discrete steps of 1.5 dBA. The somatosensory intensity was adjustable via a rotary dial whereby the patient could set the intensity to one of 17 discrete levels. A study by Tyler et al. (30), which administered electro-tactile stimulation of the tongue to address vestibular dysfunction employed a training regime of between 30 and 60 minutes per day. The recommended session duration in this study was set to a minimum of 30 minutes per day for a period of 10 weeks.

Tinnitus Severity Measures

Several outcome measures were sampled throughout the study. These were assessed in the clinical environment at the enrolment visit and every two weeks at "review" visits. The instrument chosen to assess the subjective outcome was the THI. The THI is a 25-item self-reporting questionnaire for the measurement of tinnitus (31). The instruments employed to assess psychoacoustic outcomes were the Tinnitus Loudness Matching (TLM) (32), and (MML) (33). These measures determine the intensity of the perceived tinnitus and lowest level of noise required to mask the tinnitus. Both measures are expressed in dB HL.

Subjects

Self-referred tinnitus patients that met inclusion/exclusion criteria (see below) were recruited in the order in which they presented at the clinic and not preselected in any way. Sixty-four patients were screened for eligibility. Written informed consent was obtained from 54 patients with chronic tinnitus (19 female; mean = 45 years, range 28–64 years, 35 male; mean = 47 years, range 21–64 years). The exact definition of chronic tinnitus varies in the literature, for the purposes of this study chronic tinnitus is defined as tinnitus that has not

Table 1. Demographic Profile of Participants.

	Included in analysis, $N = 54$
Age	47.5 ± 11
Men	34 (63%)
Tinnitus type: pure tonal/narrowband	31 (66%)/16 (34%)
Persistence of tinnitus: >2 years/<2 years	36 (78%)/10 (22%)
Tinnitus presence: one ear/both ears	12 (26%)/34 (74%)
Tinnitus severity, (VAS)*	6.5 ± 2.2
Tinnitus Handicap Inventory	41 ± 22.6
Minimum Masking Level (dB HL)	51.6 ± 19.7
Tinnitus Loudness Matching (dB HL)	42.65 ± 19.9
Hyperacusis: yes/no	13 (28%)/ 41 (72%)
Tinnitus type: constant/fluctuating/other	31 (57%)/15 (28%)/8 (15%)
Taking anti-depressant medications	5 (11%)

*Self-rated Visual Analogue Scale, scale 1–10.

self-resolved within six months. Constant tinnitus refers to tinnitus that is present every day (34–36). The eligibility of study participants was determined by the following inclusion and exclusion criteria:

Inclusion Criteria

- Aged between 18 and 65 years
- Suffering from constant, subjective tinnitus > six months
- Age or noise related sensorineural hearing loss (>25 dBHL in at least one ear and at least one frequency up to and including 8 kHz).

Exclusion Criteria

- Ulceration of oral cavity or tongue, oral mucosa or significant intra-oral disease
- Meniere's Disease
- Current medical legal cases regarding tinnitus
- Currently undergoing any pharmacological or electrical stimulation-based treatment for tinnitus
- Pacemakers

Study Design

This was a 14-week pilot study to assess the feasibility and safety of a device that delivers a combination of auditory and somatosensory stimulation and investigate the potential efficacy of this intervention. Patients visited the clinic every two weeks for the duration of the study. Patients were assessed without any intervention in a clinical setting for the first three screening visits, the run-in phase, to establish baseline outcome measures of tinnitus (pretreatment). The patients were not required to perform any tasks in-between these visits. In addition to the THI, TLM, and MML, tinnitus related information such as the type of tinnitus, pure tone/narrowband, tinnitus duration and the VAS loudness was collected, Table 1.

There are several nontreatment factors that can affect the perceived benefit from any treatment of tinnitus. Hesser et al. (37) reviewed the response rates of patients on a waitlist for tinnitus treatments and found that distress can reduce over short wait periods. This improvement can be attributed to the attention and reassurance the patient expects to receive from the investigator and/or knowledgeable professional, as well as anticipation of an improvement from the study. The run-in phase of this study was employed to address this anticipatory effect from study participation. Assessment scores from the third screening visit were used as baseline values. It was expected that any improvement from the anticipatory effect of study participation would be mitigated by the third visit.

At the third visit patients were provided with the stimulation device to take home for the remainder of the study and asked to use it for between 30 and 60 minutes every day for 10 weeks. Patients were shown how to use the device and told to set the auditory and somatosensory stimulation to the most comfortable levels for them. Instructions for use included information on cleaning and storing the device, i.e. sterilizing the tongue tip before initial use and storing the device in a dry location without extreme temperatures. There were no specific cleaning instructions to be completed during the study. Patients were asked to return to the clinic every two weeks to repeat the assessments carried out in the run-in phase. Where it was not possible for participants to return to the clinic, they completed the paper version of the THI remotely and sent the copy to the investigator site by post. These interim assessments were employed to monitor any significant changes in tinnitus symptoms. Patients were advised to terminate device use and to contact the investigator if they experienced any side effects or adverse events. Patients were provided with email and phone numbers and instructed to contact the research team regarding any device malfunction or safety concerns.

A Clinical Audiologist under the clinical supervision of a Senior Consultant Otolaryngologist Head & Neck Surgeon conducted the study. The same audiologist performed all assessments. Assessment scores were recorded in a paper-based system. While the audiologist was not blinded from previous results, they did not refer to previous assessment scores during evaluation.

Compliance Monitoring and Data Inclusion Criteria

Patient compliance was assessed using an embedded data logging function on the device. This data was used to determine the total number of completed sessions per day and the duration of each session. The protocol required participants to use the device for between 30 and 60 minutes per day, 7 days per week. The compliance rate describes the proportion of protocol compliant sessions achieved by patients over the course of 10 weeks.

In pharmaceuticals studies, patients are considered compliant if their adherence is greater than 80% (38). Given the investigational nature of this study a more generous compliance threshold was employed, i.e. 66% or 46 sessions in 10 weeks. The cohort was divided into compliant and noncompliant groups according to this threshold.

Analysis

Log data from the devices provided details on patient's device usage including auditory and somatosensory stimulation levels. Analysis of this data was employed to provide insights into device acceptability. The device was certified for electrical and biocompatibility safety prior to the study. Therefore study safety was assessed through changes in tinnitus outcome measures and reported side effects or adverse events.

The exploratory efficacy analysis investigated whether any statistical improvement in THI, TLM, or MML was observed after 10 weeks of treatment. Patient's data was included in the analysis if symptom scores were available for Baseline (V2) and the penultimate or final visit, and if they met the minimum compliance threshold.

Baseline THI scores were not normally distributed, so the Wilcoxon signed rank test was employed to test for statistical significance between Baseline (V2) and final values. TLM and MML datasets were found to be normally distributed and a paired *t*-test was employed to test for statistically significant differences between Baseline (V2) and final values. The proportion of patients achieving

Table 2. Average Usage Statistics for Compliant and Noncompliant Groups.

	Average number of compliant days (SD)	Average session duration, mins (SD)
Compliant (30)*	59 (12.3)	52 (18)
Noncompliant (14)†	33 (9.4)	33 (17)

*> 46 days with at least 1 daily session duration >30 min.
†< 46 days with at least 1 daily session duration >30 min.

clinically significant improvements was also assessed. Clinical meaningfulness was informed by the literature. Jastraboff et al. (39) reported that a decrease in 5.3 dB on the MML scale significantly correlated to patients reporting improvements in their tinnitus. While Zeman et al. (40) demonstrated that a 7-point drop in THI score also reflects a clinically significant improvement. Equivalent analysis for TLM was not included as no values for the clinically significant reduction for TLM could be found in the literature. Subanalysis was completed by comparing differences in symptom scores between compliant and noncompliant groups.

Study Registration

The study was approved by the Research Ethics Committee (REC) of the National University of Ireland, Maynooth. Nether the REC or the Hermitage Medical Centre required registration to a clinical trials registry. The study was considered a feasibility study, and was therefore exempted from registration under FDAAA 801.

RESULTS

Demographic Data

A cohort of 54 patients was recruited as part of this study; each patient was required to complete three intervention free assessments and five subsequent assessments while using the device. The total duration of the study was 14 weeks.

Two patients dropped out of their own accord. Log data from the devices of six additional patients showed very little use of the device over the study period (< 10% compliance). Two additional patients were excluded from analysis; while their corresponding log data showed active use of the device, they did not return for any assessment visits after the third assessment. In total ten patients were excluded from the final analysis. Table 1 presents the demographic data of the 54 participants enrolled in the study.

Feasibility and Safety

No adverse events or side effects, in terms of safety, comfort or tolerability of the device, related or unrelated to tinnitus, were reported over the course of this study. Two patients demonstrated clinically significant increases in THI scores between Baseline (V2) and final values; from 50 pts to 60 pts and 18 pts to 36 pts respectively, but did not report a corresponding increase in tinnitus loudness scores (MML or TLM). Two other patients demonstrated clinically significant increases in MML scores between Baseline (V2) and final values; from 60 dB to 68 dB and 38 dB to 52 dB, but did not report increased psychological impact (THI). None of these patients reported corresponding clinically significant increases in tinnitus loudness or psychological impact nor did they report the changes as adverse events or side effects. Log data showed that these patients were noncompliant to the protocol.

Three devices were reported as malfunctioning over the course of the study. One was dropped and physically damaged by the patient and the remaining two devices were reported as not delivering any stimulation on the tongue. It was found that the patients had incorrectly followed the cleaning instructions and had compromised their operation. These devices were replaced by courier within 24 hours. At the end of the study the Technical Investigation Team checked all returned devices and all device were found to be functioning correctly.

Device Usage

Log data from the devices provided details on patient's usage including auditory and somatosensory stimulation levels. Data from three patients was excluded from this analysis due to errors in the electronic logging system on their devices. On the days the device was used, the average session duration for all patients was 47 min ($N = 44$, SD = 20 min). The average treatment duration across all patients was 67 days. Table 2 presents the usage statistics of the compliant and noncompliant groups.

The average somatosensory and auditory stimulation settings after the first week of use were 6 pts (SD = 4.2) (min 0 and max 17) and 71.5 dBA (SD = 8.1 dBA) respectively. The average somatosensory and auditory stimulation settings extracted from log data for the final week were 7.4 pts (SD = 5.4) and 64 dBA (SD = 6.6 dBA) respectively. There was no statistically significant difference between the stimulation setting at the beginning and end of treatment. Patients were able to modify the volume of the audio and the intensity of the somatosensory stimulation over the 10 weeks of treatment. From the log data it was observed that patients varied the somatosensory stimulation much more than the auditory stimulation; the average coefficient of variation (COV) for the full cohort was 35% and 15% for somatosensory and auditory stimulation settings respectively. There was no significant relationship observed between stimulation settings and changes in outcome measures.

Efficacy

Efficacy of this intervention was determined by measuring changes in THI, TLM and MML scores between baseline and final values. The symptom scores were assessed without intervention at the three run-in phase visits, i.e. V0, V1, and V2, to better understand the variability and improvements in symptoms that may be attributed to noninterventional influences. Average THI, TLM, and MML scores dropped by 7.8 pts ($p < 0.001$), 1 dB ($p = 0.54$), and 5.7 dB ($p < 0.01$) between V0 and V2. The average intra-subject COV for the THI, TLM, and MML scores over the three baseline visits were 21%, 16%, and 13% respectively. Baseline values for analysis were taken from the third screening visit, i.e., Baseline(V2). The average and standard deviation for Baseline(V2) and final values can be seen in Table 3. The most significant improvement in symptom scores was observed for the compliant group. The average values for THI, TLM, and MML reduced by a further 11.7 pts ($p < 0.001$), 7.5 dB ($p < 0.001$), and 9.8 dB ($p < 0.001$) respectively, beyond the changes observed over the run-in phase. No significant improvements were observed for the noncompliant group. The average values for THI, TLM, and MML reduced by 1.9 pts, 0.9 dB and, 4.7 dB respectively.

Table 4 presents the number of patients who achieved clinically significant improvements, per outcome measure, for compliant and noncompliant groups. The highest proportion of improvers are seen

Table 3. Average Tinnitus Symptom Scores for Baseline and Final Visit.

	THI (pts)		TLM (dB)		MML (dB)	
	V2 (SD)	V7 (SD)	V2 (SD)	V7 (SD)	V2 (SD)	V7 (SD)
Full Cohort (41)	33.7 (24)	25.1 (20)***	42.9 (15)	37.5 (17)	47.3 (15)	39.2 (17)***
Compliant (30)	35.8 (25)	24.1 (20)***	44.8 (16)	37.3 (16)***	49.0 (15)	39.2 (18)***
Noncompliant (14)	29.3 (24)	27.4 (23)	38.6 (14)	37.7 (19)	43.8 (17)	39.1 (18)

*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

Table 4. Number of Improvers/Nonimprovers for Each Tinnitus Symptom in Each Compliance Group.

	Improvers: THI*	Improvers: MML†
Full Cohort (41)	20 (45%)	28 (64%)
Compliant (30)	17 (57%)	22 (73%)
Noncompliant (14)	3 (21%)	6 (43%)

*Improvers achieve a minimum drop of 7 points on THI scale.
†Improvers achieve a minimum drop of 5.3 dB on MML scale.

on the MML scale with 73% of the 30 compliant patients demonstrating a clinically significant improvement in MML.

DISCUSSION

This open-label, pilot study assessed the feasibility, safety and initial efficacy of an innovative medical device for treating tinnitus. The feasibility of deploying this device is supported by the compliance data; 67% of patients achieved the minimum number of sessions required over the study period. The remaining patients continued to use the device sporadically for the duration of the study. The study found no systematic safety issues, adverse events or side effects from use of the device. These findings suggest that noncompliance was due to disengagement with the treatment rather than difficulty using the device. More research is required to understand the balance between minimally acceptable session duration and the minimum session duration required for efficacy of the treatment.

The protocol allowed patients to modify the stimulation settings to allow for individual comfort levels. This resulted in significant variability in the dataset and no relationships between stimulation settings and changes in tinnitus symptoms were observed. However, there is evidence in the literature that stimulation settings can impact the efficacy of tinnitus treatments (42,43). This will be further investigated in future studies.

Compliance appears to be a significant factor in achieving improvement in tinnitus symptoms with this treatment. The compliant group ($N = 30$) were found to have achieved significant improvement in all outcome measures; average THI was reduced by 11.7 pts (34% relative decrease), average TLM by 7.5 dB and MML by 9.7 dB, Table 3. These values are not only statistically significant but 57% and 73% of the compliant patients achieved clinically significant improvements for THI and MML respectively. The noncompliant group ($N = 14$) achieved an average 1.9 pt (6% relative decrease), 0.9 dB and 4.9 dB reduction in THI, TLM, and MML respectively. This relationship between compliance and improvement requires further investigation as this finding may be associated with a selection effect as opposed to a dose effect, i.e., patients who did not feel a benefit from the treatment are likely not to use the device.

The THI is a subjective assessment tool and is one of the most widely reported outcome measures in tinnitus research. The lack of a minimum THI score in the inclusion criteria for this study resulted in a large standard deviation of scores and a large proportion of included patients who had low baseline values. While this is representative of the heterogeneous tinnitus population, patients with higher baseline THI scores largely drive the improvement in THI scores observed in this study. In the compliant group, the average improvement for patients with THI scores of 30 or less ($n = 17$) was 6 pts (SD = 5 pts). The average improvement for patients with THI scores greater than 30 was 17 pts (SD = 15 pts). Many studies now employ minimum scores on tinnitus questionnaires as inclusion criteria (41,43,44). The findings of this study support the use of a minimum threshold of THI as inclusion criteria.

Determining reliable baseline values is essential when measuring clinical effect of any intervention. Our analysis shows that ascertaining baseline values for tinnitus symptoms is challenging. The results of this study show that the anticipation of treatment can contribute to improvements in outcome measures. The clinically significant improvements observed in the run-in phase were not continued into the treatment phase for the noncompliant group. During the run-in phase the intra subject variability of THI was higher (COV 21%) than that of the more objective measures of TLM and MML (COV 16% and 13% respectively). Our findings support the use of a run-in phase in tinnitus studies to address the anticipatory effect and determine reliable baseline values. Researchers should consider including an appropriate run-in phase when designing clinical trial protocols for tinnitus treatment evaluation. The tinnitus research community is addressing the lack of consistency across clinical trials, such as patient assessment and outcome measures (45). The study reported here has highlighted the need for guidelines on establishing valid baselines for tinnitus outcome measures and recommendations for the minimum threshold of tinnitus severity for inclusion in trials.

The present study demonstrates the feasibly of this device and provides evidence of improvements in tinnitus symptoms. The results of this study support the continued evaluation of this intervention as a treatment for tinnitus. The next step is a series of clinical trials to disassociate the specific and unspecific effects of this therapeutic intervention. Parameter optimization studies will investigate the association of the bi-modal stimuli to determine the optimal stimulation settings. These studies will be followed by a Randomised Control Trial to compare this intervention to a sham treatment. Finally follow-up assessments will be included in all subsequent studies to examine the permanency of the effect observed in treatment groups.

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Authorship Statement

Caroline Hamilton and Brendan Conlon designed the study protocol. The device employed in this study was a version of technology developed by Barak Pearlmutter and informed by Edmund Lalor. Brendan Conlon and Caroline Hamilton carried out recruitment for the study. Caroline Hamilton conducted the study, completed data collection and contributed to manuscript preparation. Gloria Crispino and Shona D'Arcy completed the data analysis for this study and Shona D'Arcy contributed to manuscript preparation. All authors approved the final manuscript and had complete access to the study data.

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COMMENT

This is an interesting pilot study about a new treatment strategy for tinnitus that combines two different types of stimulation, which are well established as suitable for tinnitus treatment. I hope to see a randomized placebo controlled study soon.

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Comments not included in the Early View version of this paper.

