Technical Report
HCE-TR-2022-001

6/24/2022

Battlefield Acupuncture (BFA) as a Treatment Option for Chronic Tinnitus

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DHA/R&E/HCE
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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

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1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
06-24-2022	Technical Report	June 2019 - June 2022

4. TITLE AND SUBTITLE

Battlefield Acupuncture (BFA) as a Treatment Option for Chronic Tinnitus

5a. CONTRACT NUMBER

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

DOD Hearing Center of Excellence, DHA/R&E/HCE
1100 Wilford Hall Loop, Bldg. 4554
JBSA-Lackland, TX 78236

8. PERFORMING ORGANIZATION REPORT NUMBER

HCE-TR-2022-001

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

Defense Health Agency
7700 Arlington Boulevard, Suite 5101
Falls Church, VA 22042-5101

10. SPONSOR/MONITOR'S ACRONYM(S)

DHA

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT

DISTRIBUTION STATEMENT A: Approved for public release. Distribution is unlimited.

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Tinnitus is the most prevalent service-connected disability among military Veterans. There is a need for cost-effective treatments that can also address stress-related complications often associated with tinnitus. Battlefield acupuncture (BFA) can be used to manage pain and stress-related symptoms. Neuropathic pain and tinnitus may reflect similar central functional pathologies. This report describes findings from eight tinnitus patients who received BFA and were followed for six months post-treatment to identify changes in tinnitus severity or impact, tinnitus-related psychological distress, anxiety, and depression.

15. SUBJECT TERMS

Auricular acupuncture, battlefield acupuncture, BFA, tinnitus, chronic tinnitus, tinnitus-related stress, tinnitus coping, anxiety, depression

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			Col. Samuel A. Spear, M.D.
Unclassified	Unclassified	Unclassified	UU	57	19b. TELEPHONE NUMBER *(Include area code)* 210-292-4100

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INTRODUCTION

Tinnitus is the perception of sound in the absence of an external stimulus. In the United States, tinnitus affects approximately one in ten adults (Bhatt et al., 2016), more than one third (36%) of whom report nearly constant symptoms. For some 20 million Americans, tinnitus is chronic and burdensome (https://www.ata.org/understanding-facts). The Veterans Benefits Administration ranks tinnitus as the most prevalent service-connected disability among new and all compensation recipients; as of June 2021, more than 2.3 million Veterans were receiving compensation for tinnitus (Veterans Benefits Administration Annual Benefits Report, 2020).

Currently, there is no cure for tinnitus. Physicians and audiologists offer individualized treatment strategies to help their patients cope with tinnitus. Available treatment methods include tinnitus retraining therapy (TRT), progressive tinnitus management (PTM), standard-of-care counseling, and the use of sound generators or hearing aids (Bauer et al., 2017; Del Bo & Ambrosetti, 2007; Henry et al., 2008; Sereda et al., 2018). Treatment takes time and can be costly. Some individuals who suffer from tinnitus also struggle with emotional and psychological comorbidities and sequelae, including anxiety, depression, sleep disruption, and lost workdays (Bhatt et al., 2017; Ciminelli et al., 2018). There is a need for cost-effective tinnitus treatments that can also address its possible stress-related complications.

Evidence has been mixed – and is limited -- concerning the potential efficacy of acupuncture as a treatment for tinnitus. A systematic review published in 2000 found that only two of six randomized controlled trials reported positive results of acupuncture on tinnitus (Park et al., 2000). A 2016 systematic review and meta-analysis of randomized controlled studies recognized that tinnitus acupuncture studies are often flawed, but nevertheless suggest that acupuncture offers some advantages over conventional therapies and may have subjective benefit for some tinnitus patients (Liu et al, 2016). A randomized clinical trial in 2018 found that acupuncture was significantly more effective than sham placebo treatment in reducing the loudness and severity of tinnitus (Naderinabi et al., 2018). Reported adverse effects of

acupuncture are typically minor, such as skin irritation, discomfort, mild tenderness or pain and dizziness (Tan et al., 2014).

Based on a method of auricular acupuncture first designed and studied by Dr. Paul Nogier in the 1950s (Wirz-Ridolfi, 2019), a procedure now known as "battlefield acupuncture" (BFA) was developed in 2001 as a strategy to relieve phantom limb pain and chronic pain in military veterans (Niemtzow, 2001). BFA stimulates the vagus nerve through its auricular branch. The vagus nerve is the longest nerve of the autonomic nervous system; it plays a role in parasympathetic control of mood, digestion, and heart rate. Non-invasive or minimally invasive stimulation of the vagus nerve can be effective in treating stress-related disorders and depression, including tinnitus-related mental stress (TRMS) (Bremner et al., 2020; Ylikoski et al., 2020). BFA is also minimally invasive, involving the placement of tiny gold aiguille semi-permanent needles ("darts") at up to five sites in the ears; the needles fall out within 3-4 days. More than 2800 DoD and VA providers have been trained to administer BFA (Levy et al., 2018). Although a recent review of randomized controlled trials did not find a significant efficacy advantage for BFA to reduce pain intensity relative to other interventions (Yang et al., 2021), a growing number of reports have supported BFA as a safe and low-cost intervention option to manage pain and other disorders (Federman et al., 2018; Federman, Radhakrishnan, et al., 2018; Fox et al., 2018; Jan et al., 2017; Murakami et al., 2017; Niemtzow et al., 2008; Taylor et al., 2021; Walker et al., 2016; Yeh et al., 2014; Zeliadt et al., 2020).

There are many similarities between neuropathic pain and tinnitus, which is sometimes described as a 'phantom' auditory sensation (De Ridder et al., 2011). Both conditions are thought to represent neural plasticity with adverse subjective effect, as a consequence of an original peripheral insult possibly involving efferent nerve damage (Marks et al., 1984; Moller, 2000, 2006, 2007; Saunders, 2007). Like phantom pain, tinnitus is an entirely subjective perception that can be temporarily relieved (e.g., by masking) or triggered by hypersensitivity. Stress-related symptoms are commonly associated with both chronic pain and bothersome tinnitus.

Thus far, acupuncture generally has not been demonstrated to reduce tinnitus itself, but studies in this area sometimes point to beneficial effects of acupuncture on stress factors related to tinnitus (Axelsson et al., 1994; Kim et al., 2012; Park et al., 2000; Tu et al., 2019; Wang et al., 2010). Given that BFA can be used to manage pain and stress-related symptoms, and that neuropathic pain and tinnitus may reflect central functional pathology in common, we reasoned that BFA should be studied as a potential intervention for chronic tinnitus perception and coping. Generally, chronic ("persistent") tinnitus is considered to be tinnitus experienced for at least 6 months (Tunkel et al., 2014). There is a need for reliable and cost-effective treatment to improve quality of life for Service members and Veterans who suffer from chronic tinnitus and to reduce the economic burden of tinnitus on the U.S. Department of Defense (DoD) and U.S. Department of Veterans Affairs (VA). Here, we describe findings from eight tinnitus patients who received BFA and were studied for six months post-treatment to identify changes, if any, in tinnitus severity or impact, tinnitus-related psychological distress, and anxiety and depression.

METHODS[1]

Subjects. Participants enrolled in the study were active-duty Service members and/or DoD beneficiaries, 18 years of age or older. Study brochures were placed in ENT and Audiology exam and clinic waiting rooms to recruit interested participants. All participants were provided with pertinent details of the study and were given an opportunity to ask questions prior to signing informed consent. After consent, study participants completed baseline documents to determine eligibility; information was gathered using Demographic and Case History forms, Tinnitus Screener, Tinnitus Reaction Questionnaire (TRQ), Tinnitus Functional Index (TFI), and Hospital Anxiety and Depression Scale (HADS) (see Appendices A-E). To qualify for inclusion in the study, participants had to report chronic/constant tinnitus for at least 6 months (Tinnitus Screener) and score 17 or higher on the TRQ, with no current/ongoing routine (e.g., job-related)

[1] The methods, procedures, and materials described here were approved in an original study protocol, "Battlefield Acupuncture (BFA) as a Treatment Option for Chronic Tinnitus," approved as by the institutional review board of the U.S. Air Force's 59th Medical Wing (FWH20190108H, June 25, 2019).

exposure to loud noise, and must have had an audiometric hearing exam reported to the U.S. military's electronic health within the last year. Candidate participants were excluded if they were or might become pregnant, Basic Military Trainee patients, unable to understand English to complete questionnaires, unable/unwilling to comply with follow-up treatments, prone to bleeding, had known temporomandibular joint (TMJ) problems or Meniere's disease, or diagnosed with immunosuppressive disease. Ten (10) of 16 enrolled participants met inclusion/exclusion criteria. Eight (8) participants completed the study through 6-month follow-up, and are reported here.

Procedures. BFA was performed over two treatment sessions, two weeks apart, for one month by a certified and credentialed BFA provider (Carlos Esquivel, MD, FACs, FAAOA) in the ENT/Audiology clinic at the Wilford Hall Ambulatory Surgical Center (WHASC). At each session, the BFA procedure consisted of 10 auricular semi-permanent (ASP) acupuncture needles, inserted in their respective points by applicator after alcohol prep pad wipe of the ear. Gold needles were used for all participants after determining that none reported gold allergy, upcoming surgery, or magnetic resonance imaging (MRI) scheduled within a few days of treatment. Participants were instructed they could stop the BFA treatment at any time; none did so. After each needle was placed, the participant walked in place or from the exam chair to the clinic room door and back again for 1 minute. Needles were inserted in the following locations and order: 1 – cingulate gyrus left/right ear, 2 – thalamus left/right ear, 3 – omega 2 left/right ear, 4 – Point Zero left/right ear, and 5 – Shen men left/right ear (**Figure 1**; see also King et al., 2013). Needles were left in place to fall out naturally in 3-5 days; participants were given instructions on how to take care of their ears and the needles during the treatment regimen. To ensure no difficulties, each participant received a follow-up call from the research coordinator 2-3 days after the procedure. Participants were also recommended to contact the clinician if needles remained in place after 5 days; no one reported this issue.

The Food and Drug Administration (FDA) does not regulate the practice of acupuncture, but regulates acupuncture needles (21 CFR 880.5580) as a 510(k) class II medical device because they are intended for use in the cure, mitigation, treatment, or prevention of disease in humans

and are intended to affect the structure or function of the human body. ASP ear needles are exempt from premarket notification by the FDA for use in acupuncture and were used in accordance with their FDA-approved labeling.

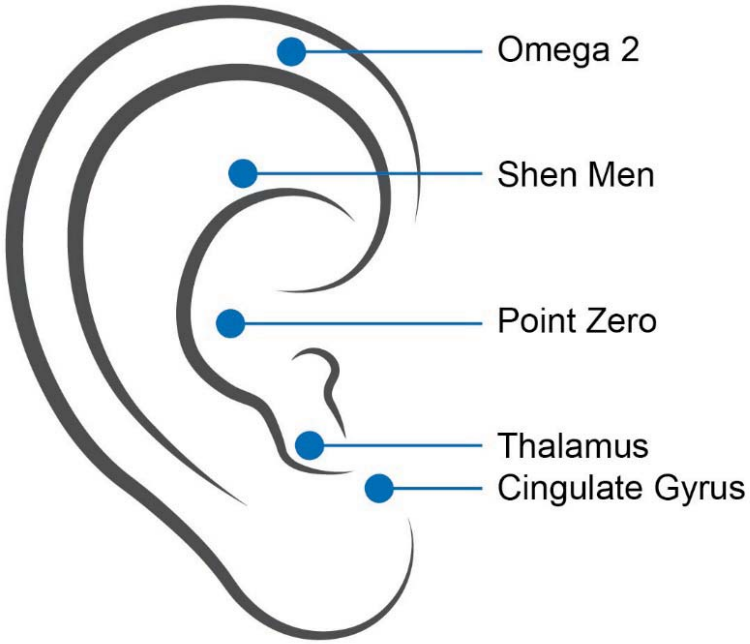

***Figure 1**. Surface view of ASP needle insertion points used for BFA treatment.*

Prior to each BFA treatment session, participants again completed a Case History form as well as the TRQ, TFI, and HADS. At one, two, four, and six months post-BFA treatment, each participant again completed a Follow-up Case History Form, TRQ, TFI, and HADS. All post-treatment measures were performed in person or by phone by a research coordinator.

Materials. Study participants completed baseline documents to determine eligibility; information was gathered using Demographic and Case History forms, Tinnitus Screener, TRQ, TFI, and HADS. Prior to each BFA treatment session, participants again completed a Case History form as well as the TRQ, TFI, and HADS. At one, two, four, and six months post-BFA

treatment, each participant again completed a Follow-up Case History Form, TRQ, TFI, and HADs. These instruments are described below and are included in Appendices A-E.

- *Demographic and Case History forms (Appendix A)*. These forms were based on standard-of-care history and treatment forms widely used in audiology clinics to track patients' symptoms and ailments before and after treatment. Their development was led by U.S. Air Force Major Malisha Martukovich, AuD, who served as the original principal investigator for this study.

- *Tinnitus Screener (Henry et al., 2016; Appendix B).* Originally developed as a 4-item algorithmic instrument, the Tinnitus Screener has since been revised as a 6-item tool to assess for the presence or absence of tinnitus, its temporal characteristics (constant, intermittent, occasional, or temporary), and its duration (acute < 6 months vs. chronic ≥ 6 months). The Tinnitus Screener takes approximately 4 minutes to complete and has been shown to have predictive validity and good short-term test-retest reliability for categorization and classification of tinnitus (Henry et al., 2016; Thielman et al., 2022).

- *Tinnitus Reaction Questionnaire (TRQ; Wilson et al., 1991; Appendix C).* Designed as a measure of tinnitus-related psychological distress, the TRQ is a 26-item questionnaire with each question graded on a 5-point (0-4) scale, providing a total score of 0-104). A total score > 17 is considered to represent significant impact of tinnitus. Specifically, the questionnaire probes respondent emotional reaction to tinnitus (questions 1-5, 8-11, 14-17, 19, 22, 24-26); interference with work, social, and life activities (questions 6, 7, 12, 13, 18, 20, 21); sleep disturbance (question 23); and feelings of hopelessness and suicidal thoughts (questions 22 and 24). If Questions 22 and/or 24 are endorsed, the respondent is given appropriate behavioral health referrals.

- *Tinnitus Functional Index (TFI; Meikle et al., 2012; Appendix D).* The TFI was administered to participants with chronic tinnitus based on their responses to the Tinnitus Screener. The 25-item TFI takes 5-10 minutes to complete. It has documented validity for scaling the severity and negative impact of tinnitus, and for measuring

treatment-related changes in tinnitus. On a scale of 1-100, TFI scores below a value of 25 indicate relatively mild tinnitus, typically requiring little or no intervention. Scores from 25 to 50 suggest more significant tinnitus and a possible or borderline need for professional attention. Scores above 50 represent severe tinnitus, indicating a need for more aggressive efforts to provide relief, possibly involving referral to specialty tinnitus care. The TFI is useful in both clinical and research settings because of its sensitivity to treatment-related change, high construct validity for scaling overall tinnitus severity, and comprehensive coverage of the negative tinnitus impact. The TFI also includes subscale scoring to probe 8 specific domains of negative tinnitus impact: tinnitus unpleasantness, intrusiveness, persistence (items 1, 2, 3); reduced sense of control (4, 5, 6); cognitive interference (7, 8, 9); sleep disturbance (10, 11, 12); auditory difficulties (13, 14, 15); relaxation interference (16, 17, 18); reduced quality of life (19, 20, 21, 22); and emotional distress (23, 24, 25).

- *Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983; Appendix E)*. The HADS consists of 14 questions and takes less than 10 minutes to complete; it has been used extensively in primary care settings (Wilkinson & Barczak, 1988). Half (7) of the HADS questions address anxiety (HADS-A) and half address depression (HADS-D). Each item is scored from 0-3, generating a total score between 0 and 21 for anxiety or depression. For each condition, scores of 0-7 are taken to represent "normal" (non-case); between 8-10 as borderline abnormal (borderline case); and between 11-21 as abnormal (case).

Analyses. To identify possible effects of BFA on tinnitus severity or impact, tinnitus-related psychological distress, or anxiety and depression, we examined individual and group questionnaire responses from both BFA sessions (T1, T2) and four post-treatment follow-ups (FU1, FU2, FU4, FU6). We used hierarchical regression modeling, with random effects for individuals' repeated measures, to evaluate change in scores over time. To reduce the probability of family-wise error from repeated statistical testing, we chose only two follow-up

intervals for analysis: baseline to the follow-up with the greatest degree of change, and baseline to the final (six-month) follow-up.

RESULTS

The original study design envisioned 70 enrollees. The onset of the coronavirus disease 2019 (COVID-19) pandemic forced a halt to study recruitment and enrollment, and interfered with follow-up. Eight enrolled participants (7 males, 1 female) met eligibility requirements, screened positive (Tinnitus Screener) for chronic tinnitus, and completed the study through 6-month follow-up. Observation dates ranged from September 17, 2019 to September 9, 2020 with more than one-third (35%) of these visits occurring between January 16, 2020 and April 29, 2020, the period during which pandemic emergency declarations, advisories, and stay-at-home orders were first issued.

Sample characteristics at baseline

For the eight participants who completed the study, ages ranged from 32 – 57 years, with a mean of 48 and standard deviation of 9 years of age. Three were active-duty (AD) service members; five were military retirees. On baseline case history, five participants reported that they had hearing loss of gradual (n = 4) or sudden onset (n = 1) affecting the left (n = 1), right (n = 1), or both ears (n = 3). All participants reported having tinnitus perception originating from their left ear (n = 1), head (n = 1), or both ears (n = 6) and lasting 1-5 years (n = 2), 6-10 years (n = 1), 11-15 years (n = 4), or 15+ years (n = 1). When asked if their tinnitus interferes with daily activities such as sleep or quiet rest, all participants responded ‘yes.’

Six participants reported previously having tried other treatments to cope with their tinnitus, such as sound masking (n = 6), hearing aids/ear level maskers (n = 1), audiology counseling/education (n = 2), cognitive behavioral training (n = 1), vitamins/supplements (n = 1), or attending a tinnitus class at the ENT clinic (n = 1). Six participants indicated they were currently using prescription and/or over-the-counter (OTC) medications, many of which are reported to cause or exacerbate tinnitus (amlodipine, aspirin, atorvastatin, celecoxib, lisinopril,

sumatriptan, zolmitriptan); a seventh participant reported taking OTC supplements, but did not did not provide specific details. (See **Table 1**.)

Table 1. Overview of participants and information from baseline case history.

ID	Age	Gender	Status	Other treatments	Medications
1	32	M	AD	Masking, counseling, CBT	Amphetamine/ dextroamphetamine, cetirizine, sumatriptan
3	56	M	R	Masking, ENT tinnitus class	Tamsulosin, atorvastatin, multivitamin, aspirin
6	46	M	AD	Masking, vitamins or supplements	Metformin, lisinopril
8	51	M	R	N/A	Celecoxcib
10	56	F	R	Masking, hearing aids	Loratadine, zolmitriptan
11	49	M	R	N/A	Atorvastatin, amlodipine
13	57	M	R	Masking	OTC supplements
15	39	M	AD	Masking, audiology counseling/education	None

ID: Participant number; ***AD***: *active duty;* ***CBT***: *cognitive behavioral therapy;* ***ENT***: *ear nose and throat clinic;* ***F***: *female;* ***M***: *male;* ***OTC***: *over-the-counter;* ***R***: *retiree*

Each participant's baseline responses to the TFI, TRQ, and HADS at the time of eligibility determination are presented in **Table 2** with summary description. Baseline TRQ and TFI responses indicated all participants had at least significant (and in three cases, severe) tinnitus and tinnitus impact. Baseline HADS responses indicated that most participants (n = 5) scored as "borderline" for either anxiety or depression. One (n = 1) participant scored as "abnormal" for anxiety and as "borderline" for anxiety. Three participants (n = 3) scored as "normal" for both anxiety and depression. Participant 3 had the worst scores at baseline, with a total score of 80 and subscores above 75 for all domains except emotional distress (TFIe = 53.3). For the lowest-scoring participant, participant 1, the overall score was only 35.6 and the worst subscore was for sleep disturbance (TFIs = 56.7).

Table 2. Participants' baseline total scores on the TRQ, TFI, HADS-A, and HADS-D. TFI scores < 25 indicate relatively mild tinnitus; 25 - 50 suggest more significant tinnitus; > 50 represent severe tinnitus. A total TRQ score > 17 represents significant impact of tinnitus. HADS-A and HADS-D scores 0-7 represent "normal," 8-10 "borderline," and 11-21 "abnormal."

ID	TFI	TRQ	HADS-A	HADS-D	Description
1	**35.6**	**25**	6	1	Significant tinnitus and tinnitus impact; "normal" for anxiety and depression
3	**80.0**	**61**	4	**9**	Severe tinnitus, significant tinnitus impact; "normal" for anxiety, "borderline" for depression
6	**57.6**	**18**	3	5	Severe tinnitus, significant tinnitus impact; "normal" for anxiety and depression
8	**44.0**	**27**	**8**	7	Significant tinnitus and tinnitus impact; "borderline" for anxiety, "normal" for depression
10	**38.8**	**29**	3	1	Significant tinnitus and tinnitus impact; "normal" for anxiety and depression
11	**41.6**	**47**	**11**	**10**	Significant tinnitus and tinnitus impact; "abnormal" for anxiety, "borderline" for depression
13	**42.8**	**38**	7	**8**	Significant tinnitus and tinnitus impact; "normal" for anxiety, "borderline" for depression
15	**53.2**	**42**	**9**	4	Severe tinnitus, significant tinnitus impact; "borderline" for anxiety, "normal" for depression

***ID**: participant number; **TFI**: Tinnitus Functional index; **TRQ**: Tinnitus Reaction Questionnaire; **HADS-A**: Hospital Anxiety and Depression Scale – Anxiety Subscale; **HADS-D**: Hospital Anxiety and Depression Scale – Depression Subscale*

Changes over time

Anxiety and depression

Overall group mean scores for the HADS, HADS-A, and HADS-D were in the normal range at baseline. These scores remained low throughout the study, but—as shown in **Figure 2**—clinically and statistically significant decreases were observed at the two-month follow-up visit. Individual paired-sample *t*-tests comparing baseline and two-month follow-up scores were significant for a decrease in the HADS total score (mean change = -2.4 points, 95% CI: -4.1 to 0.6 points, $p = 0.007$) and HADS-D subscore (mean change = -1.8, 95% CI: -3.0 to -0.5 points, $p = 0.008$) but not for the HADS-A subscore ($p = 0.305$). A reversal can be observed after two months, with scores trending upward. By the six-month follow-up, scores were not significantly different from baseline (HADS: p=0.238; HADS-D: p = 0.470). It should be noted that HADS scores were already low at baseline, likely creating a floor effect.

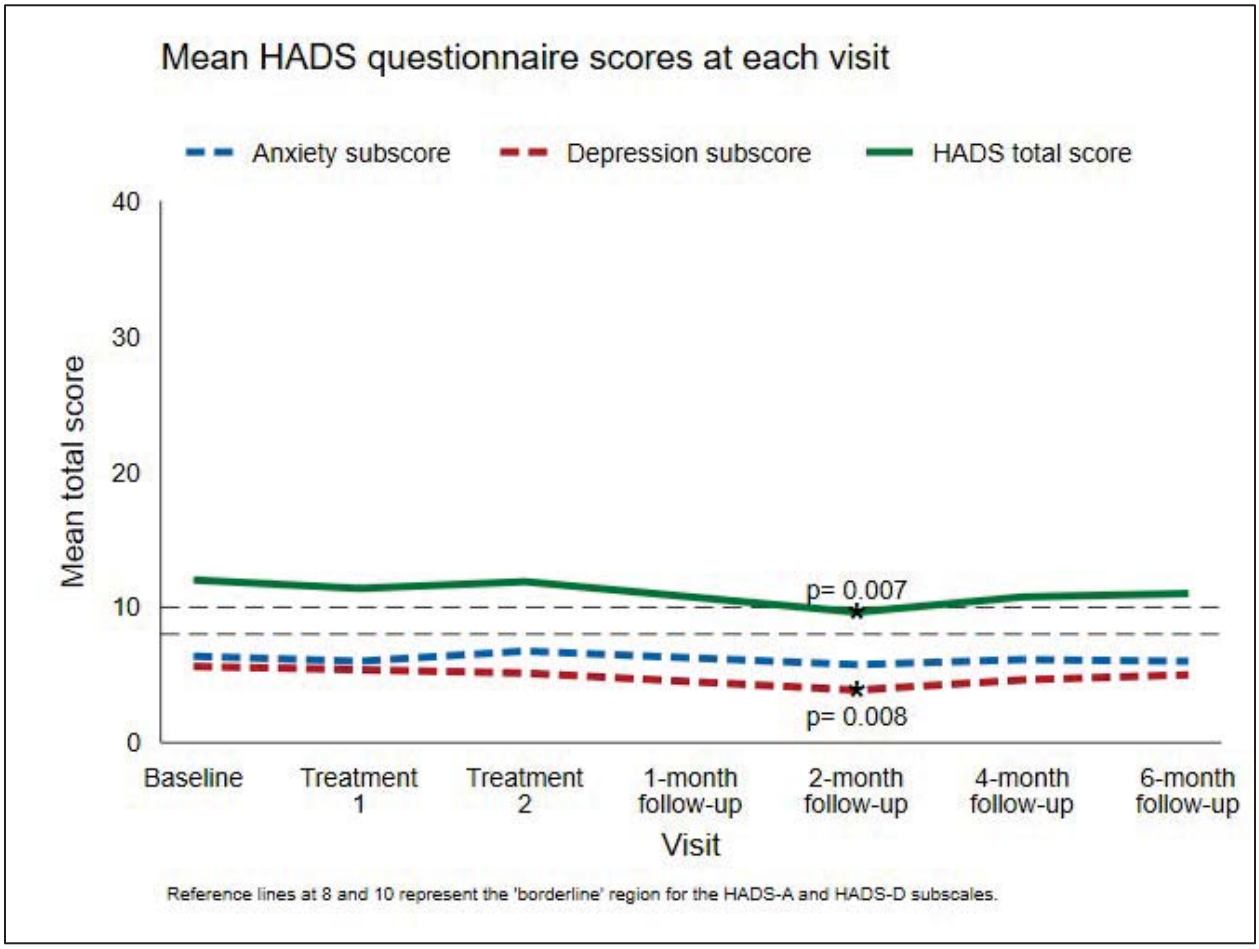

Figure 2. *Mean group HADS-A (anxiety), HADS-D (depression), and total HADS scores at baseline, two BFA treatment sessions (TX1, TX2), and four follow-up (FU) sessions.*

Tinnitus symptoms and impact

As shown in **Figure 3**, group mean baseline scores for the TFI and TRQ were above the clinical threshold for each instrument (> 17 for the TRQ, > 25 for the TFI). At the one-month follow-up, significant change was observed for both instruments, but scores remained above the clinical threshold for each. The mean TFI score decreased by 13.4 points (95% CI: -23.2 to -3.6 points, p = 0.007), and the TRQ decreased by 12.9 points (95% CI: -24.7 to -1.0 points, p = 0.033). As with the HADS, scores increased over subsequent follow-up visits and by the six-month follow-up, the difference from baseline was only about 10 points for each instrument. Although the baseline to six-month difference was statistically significant only for the TRQ (mean change -

10.1, 95% CI: -17.2 to -3.0 points, $p = 0.005$), the TFI results (mean change -10.2, 95% CI: -22.0 to -1.7 points, $p = 0.092$) suggest that a significant decrease might be seen in a study with greater power.

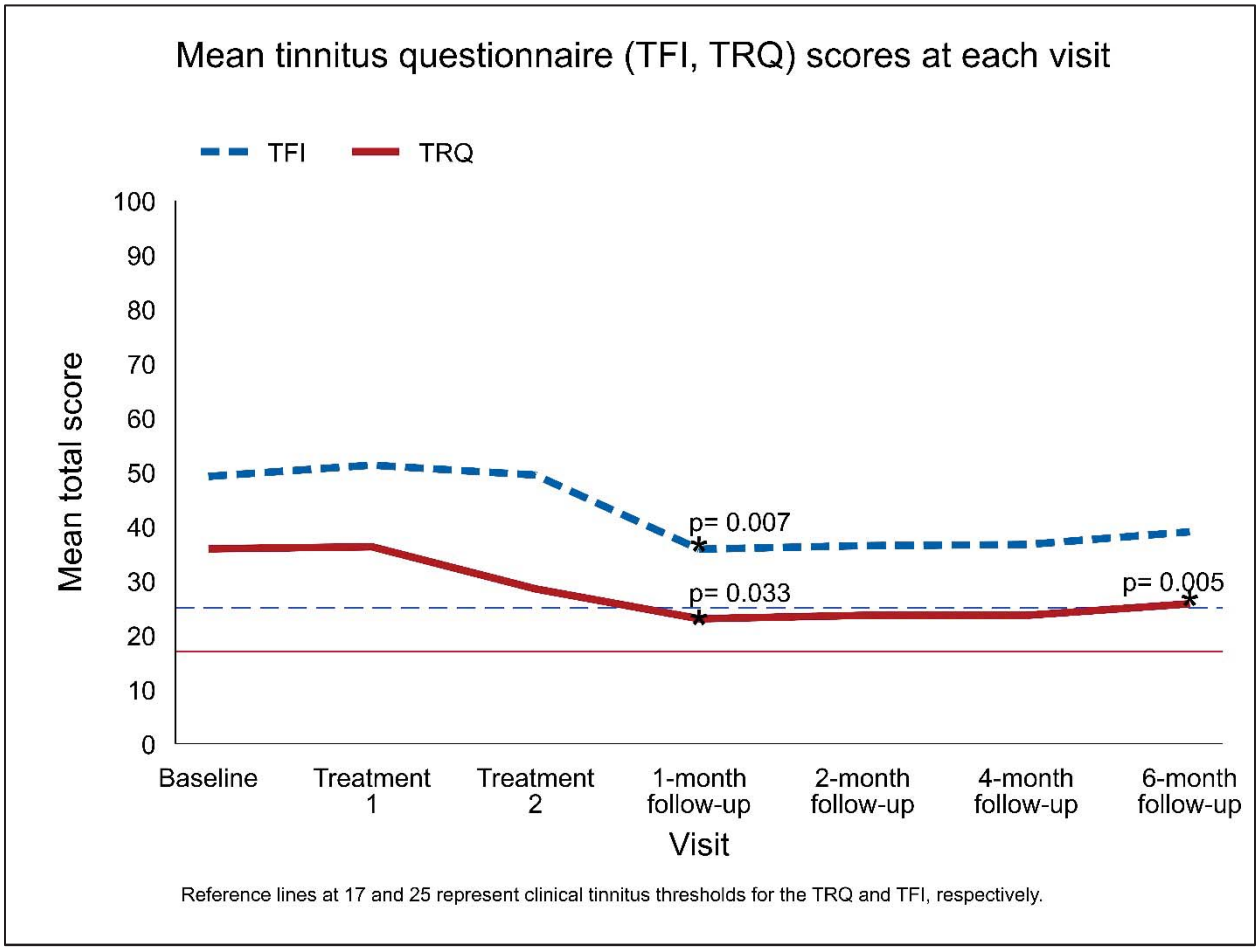

Figure 3. *Mean group TFI and TRQ scores at baseline, two BFA treatment sessions (TX1, TX2), and four follow-up (FU) sessions.*

Tinnitus Functional Index (TFI) subscales

Responses to individual TFI items can be grouped into subscales representing eight specific domains of negative tinnitus impact: tinnitus unpleasantness, intrusiveness, persistence; reduced sense of control; cognitive interference; sleep disturbance; auditory difficulties; relaxation interference; reduced quality of life; and emotional distress.

Figure 4 shows the mean score for each TFI subscale at baseline and all subsequent visits. At baseline, subscales with the highest mean scores were unpleasantness (62.5), relaxation (60.8), and auditory difficulties (57.1), while quality of life and emotional distress had the lowest mean scores (35.3 and 20.8 respectively). While most mean subscale scores were lowest at the one-month follow-up, subscales for cognitive interference, relaxation, and sense of control were lowest at the two-month follow-up. At the four-month and six-month follow-ups, improvements to quality of life and emotional distress appear to persist, while scores increased for most other subscales.

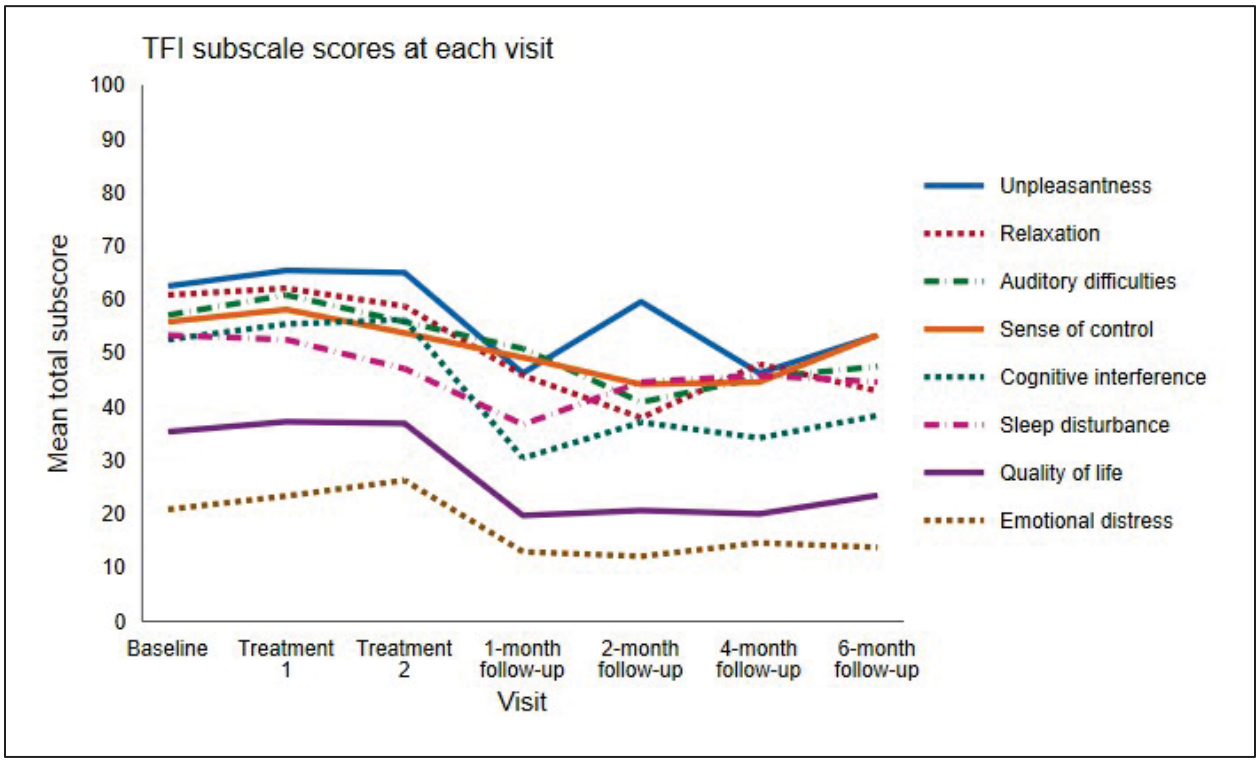

***Figure 4**. Mean group TFI subscale scores at baseline, two BFA treatment sessions, and four follow-up sessions.*

Given the small sample size, subscale scores do not satisfy assumptions of normality. For this reason, we also explored changes over time using non-parametric statistics. The boxplots in **Figure 5** show the distribution of scores for all subscales at baseline and at the one-month follow up visit. At baseline, subscales with the highest median scores were auditory difficulties

(63.3), unpleasantness (58.3), and sense of control (56.7), while quality of life and emotional distress had the lowest median scores (28.8 and 16.7, respectively). Medians for relaxation and sleep disturbance were in the middle of the range at baseline, but these subscales also had the greatest variability. Relaxation and cognitive interference scores are also considerably skewed, which helps to explain why the means for these subscales were among the highest at baseline.

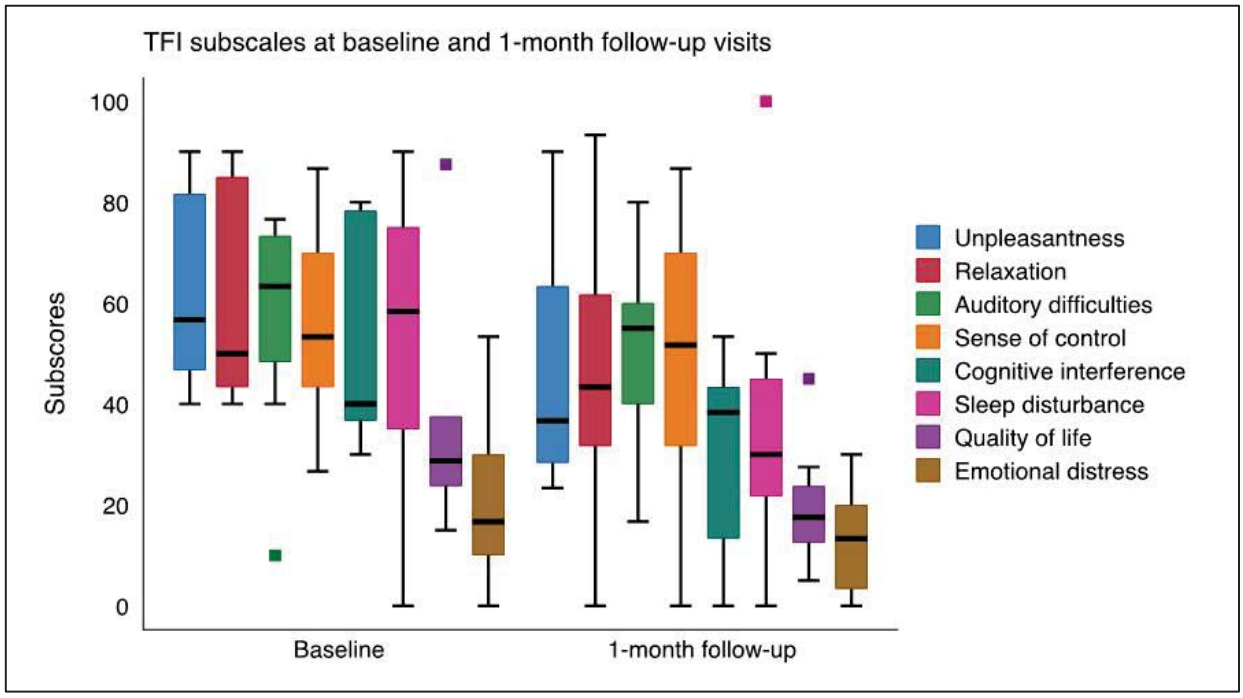

Figure 5. *Boxplot showing the distribution of scores for each TFI subscale. Medians are indicated by the central bar and the shaded box represents the range from the 25th to the 75th percentile (the interquartile range, or IQR). Whisker lines extend an additional 1.5 times the IQR in each direction, and individual data points outside of the whisker lines are considered outliers.*

As observed with means, median subscale scores trended lower across all domains at the one-month follow-up visit. It should be noted that variability increased for most subscales and that trajectories for each subscale median differed over time when compared to subscale means. For example, the mean for cognitive interference decreased by more than 20 points between baseline and the one-month follow up, whereas the median decreased by only two points. The

greatest movement of median values at the one-month follow up visit was observed in the unpleasantness, sleep disturbance, and quality of life domains.

Table 4 presents means and medians for all subscales along with the results of *post hoc* parametric and non-parametric comparisons from baseline to the one- and six-month follow ups. These analyses were for exploratory purposes only, as the small sample size does not provide sufficient power to support repeated statistical testing. Nonetheless, the results may suggest areas of potential interest for further research.

Table 4. Results from parametric (t-tests) and non-parametric (Wilcoxon signed-rank) statistical tests to compare subscale scores from baseline to the one-month and six-month follow-up visits.

	Total	TFIa	TFIu	TFIc	TFIr	TFIs	TFIcog	TFIq	TFIe
Baseline									
Median	43.4	63.3	56.7	53.3	50.0	58.3	40.0	28.8	16.7
Mean	49.2	57.1	62.5	55.8	60.8	53.3	52.5	35.3	20.8
Standard deviation	14.4	22.4	19.7	19.1	21.7	31.2	22.1	22.4	17.2
One-month follow-up									
Median	34.8	55.0	36.7	51.7	43.3	30.0	38.3	17.5	13.3
Wilcoxon p-value	***0.025***	*0.263*	*0.123*	*1.000*	***0.042***	*0.079*	*0.079*	***0.011***	*0.233*
Mean	35.8	50.8	46.3	49.2	45.8	36.7	30.4	19.7	12.9
Standard deviation	16.5	19.6	23.9	28.5	28.5	29.7	19.0	12.2	10.6
t-Test p-value	***0.040***	*0.445*	*0.090*	*0.630*	*0.071*	*0.058*	*0.090*	***0.007***	*0.274*
Six-month follow-up									
Median	39.8	53.3	60.0	60.0	36.7	30.0	38.3	21.3	16.7
Wilcoxon p-value	*0.161*	*0.263*	*0.673*	*0.833*	*0.079*	*0.440*	*0.440*	*0.122*	*0.178*
Mean	39.0	47.5	53.3	53.3	42.9	44.6	38.3	23.4	13.8
Standard deviation	19.1	19.7	25.8	23.7	29.8	37.7	17.9	19.2	11.2
t-Test p-value	*0.159*	*0.287*	*0.443*	*0.849*	*0.071*	*0.453*	*0.257*	*0.105*	*0.225*

***TFIu** = tinnitus unpleasantness, intrusiveness, persistence; **TFIc** = reduced sense of control; **TFIcog** = cognitive; TFIs = sleep disturbance; **TFIa** = auditory difficulties; **TFIr** = relaxation interference; **TFIq** = reduced quality of life; **TFIe** = emotional distress.*

Although inferential statistics are not feasible with only eight participants, the data collected may still be instructive when presented as individual case studies. **Appendix F** contains individual participant trajectories for the HADS, TRQ, TFI, and TFI subscales along with details such as medications, noise exposure, and general health collected at each visit.

DISCUSSION

Findings reported here show responses over a six-month post-treatment study period for eight chronic tinnitus sufferers who received two BFA treatment sessions, two weeks apart. We were primarily interested in post-treatment changes associated with metrics of anxiety, depression, psychological distress, and tinnitus-related functional impact.

In most of our participants, baseline anxiety and depression scores (HADS, HADS-A, HADS-D) were near normal and remained low throughout the study. A small but significant reduction in HADS and HADS-D group mean scores was observed at two months post-treatment, but seemed to reverse by the six-month follow-up, perhaps due to floor effects. Baseline TRQ (psychological distress) and TFI (tinnitus impact) scores reflected tinnitus-related distress and tinnitus impact ranging from significant to severe in all participants prior to treatment. At one-month post-treatment, group mean scores for both the TFI and TRQ were significantly reduced and remained so after six months. Although the 6-month reduction was not statistically significant for the TFI total score, subscale scores for this instrument reflected post-treatment improvement trends in specific domains of tinnitus impact, in particular for tinnitus unpleasantness, sleep disturbance, and quality of life.

Given the small participant sample reported here, it is important to consider individual factors that may have influenced study participation, participant self-reports, trajectories, and outcomes. The largest incidence of participation screening failure was due to TMJ conditions. Six of the eight participants who finished the study reported using medications that may cause or exacerbate tinnitus. Three participants reported having experienced noise exposure events during the course of the study; these participants' TFI scores were notably higher at corresponding study visits (#10 at two months, #6 and #11 at six months). One participant (#8) reported having received hearing aids around the 2-month follow-up visit and subsequently reported discontinued use of a non-steroidal anti-inflammatory drug (NSAID) at the 4-month follow-up.

We note that in general, participants' post-treatment case history self-reports of tinnitus interference bore little correspondence to their TFI scores, subscale scores, and trends over post-treatment follow-up (see Appendix F). This disparity is not surprising, given that the post-treatment Case History form asked simply, "Does the tinnitus interfere with your daily activities, i.e., sleep quiet resting, etc.?" with the limited options to respond 'Yes' or 'No'. By contrast, the TFI presents a more detailed series of activities with which tinnitus might interfere, with response options for ranking degree of interference from 0 (none) to 10 (complete). TFI responses reflect more comprehensive coverage of tinnitus impact, are sensitive to treatment-related change, and thus are more informative.

Taken together, the findings we report here underscore the need for additional research to identify precise and potentially lasting benefits of BFA for at least some tinnitus sufferers. It is advantageous to include multiple instruments to capture the potential breadth of multiple factors, and their interplay in the relationship between tinnitus and its potential psychological and emotional impact over the course of treatment. Our participants received only two BFA treatment sessions, two weeks apart, and their results suggest at least a short-term post-treatment improvement in the degree of tinnitus impact on several specific domains, including qualify of life. Future research should consider the possibility of more lasting benefit through extended treatment, and the potential investigative benefit of including a control (e.g., sham acupuncture treatment) study group. While tinnitus symptom severity was a criterion for enrollment in our study, anxiety and depression severity was not. Participants' HADS scores were generally low at baseline, limiting our ability to identify potentially beneficial effects of BFA treatment on anxiety and depression. This is an additional consideration for future investigations.

Our findings are constrained by a number of obvious limitations. Chief among them is a small sample size, which reflects the study's timing with respect to the COVID-19 pandemic. The original study design envisioned 70 enrollees. The COVID-19 pandemic not only forced a halt to study recruitment and enrollment but also interfered with follow-up. Scheduling was already difficult due to the study protocol requirement to administer two BFA sessions exactly two

weeks apart; further complications to scheduling resulted from COVID-19 restrictions that reduced clinic resources for appointments not considered medically necessary. To examine, and perhaps control for, psychological responses to the unfolding events of the pandemic, we conducted a series of separate analyses with participant data aligned by observation dates (rather than by visit number). No patterns emerged over calendar time, but because it was not possible to survey patients to trace the timing or nature of their individual experiences and perceptions during the pandemic, we cannot rule out the possibility that pandemic-related stress may have disrupted or diminished the potential benefits of BFA on tinnitus-related psychological factors.

External validity is a limitation for any within-subject study design, a limitation made worse by a small participant sample. Our results cannot be considered generalizable to a larger population. The potential for response bias is also a concern for self-reported data. Direct interaction with study personnel presents an additional possible confound; paper-based baseline and pre-treatment questionnaires were self-completed by participants, whereas study data for follow-up visits were gathered via telephone by study coordinators who read questions and response options aloud to participants and recorded their verbal responses.

Because tinnitus is a highly prevalent condition in military Service members and Veterans, and because there is no cure, physicians and audiologists rely on methods that can help patients to manage their symptoms and stress-related complications. There is mixed evidence regarding the potential benefits of acupuncture as a treatment for primary tinnitus symptoms. Benefits have been demonstrated, however, for management of distress related to chronic and phantom pain, suggesting that BFA should be studied further as a safe, low-cost option that may help to relieve tinnitus-related stress factors and improve quality of life for Service members and Veterans who suffer with chronic and burdensome tinnitus. It is anticipated that the findings reported here, though limited, may be helpful to inform the design and development of future studies in this area.

ACKNOWLEDGMENTS

This research was made possible through the support and direction of its original PI, Maj. Malisha Martukovich. We extend our gratitude to the Wilford Hall Ambulatory Surgical Center's ENT and Audiology Clinic staff for allowing us to use their facilities to effectively carry out the study treatments. Finally, we thank Ms. Gabriela Esquivel for her skilled graphics support.

ABBREVIATIONS AND ACRONYMS

Active-duty (AD)

Auricular semi-permanent (ASP) acupuncture needles

Battlefield acupuncture (BFA)

Department of Defense (DoD)

Food and Drug Administration (FDA)

Hospital Anxiety and Depression Scale (HADS)

Magnetic resonance imaging (MRI)

Non-steroidal anti-inflammatory drug (NSAID)

Over-the-counter medication (OTC)

Progressive Tinnitus Management (PTM)

Temporomandibular joint (TMJ)

Tinnitus Functional Index (TFI)

Tinnitus Reaction Questionnaire (TRQ)

Tinnitus Retraining Therapy (TRT)

Tinnitus-related mental stress (TRMS)

Department of Veterans Affairs (VA)

Wilford Hall Ambulatory Surgical Center (WHASC)

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APPENDICES

Appendix A

Demographic and Case History Forms

ID _____ Date: _____

Demographics

Filled out at Baseline

Name (Last, First) _____

Phone Number _____

Email _____

Date of Birth _____

DoD ID # _____

Circle one: AD Retiree AD dependent Retiree dependent

Male Female

ID _____ Date: _____

Tinnitus/Acupuncture Case History Form
Baseline

	Pt states their tinnitus issues have been worked up by ENT and/or Audiology
	Pt states they do not have a bleeding disorder
	Pt does not feel they are pregnant
	Do you have hearing loss? ☐Yes ☐ No If yes, is it most prominent in: ☐ Right Ear ☐ Left Ear ☐ Both Ears Onset: ☐ Gradual ☐ Sudden
	Do you have Tinnitus? ☐Yes ☐ No If yes, is it most prominent in: ☐ Right Ear ☐ Left Ear ☐ Both Ears or in ☐ Head How long? 6-12 months 1-5 yrs 6-10 yrs 11-15 yrs 15+ yrs Describe it: _____
	Have you ever been diagnosed with: Meniere's Disease ☐Yes ☐ No Temporomandibular Joint (TMJ) dysfunction ☐Yes ☐ No
	Have you tried any other treatments to cope with tinnitus: 1. Sound masking 2. Hearing aids/ear-level maskers 3. Psychological counseling 4. Audiology counseling/education 5. Relaxation training 6. Cognitive behavioral training 7. Vitamins/supplements: which ones? 8. Other treatment: what?
	Does the tinnitus interfere with your daily activities i.e. sleep, quiet resting, etc? ☐ Yes ☐ No
	Within the last week, have you been exposed to loud noise without hearing protection i.e. shooting weapons, mowing grass, rock concerts? ☐ Yes ☐ No
List current medications:	

ID _____ Date: _____

Tinnitus/Acupuncture Case History Form
Treatment 1

	Pt states their tinnitus issues have been worked up by ENT and/or Audiology
	Pt states they do not have a bleeding disorder
	Pt does not feel they are pregnant
	Do you have hearing loss? ☐Yes ☐ No If yes, is it most prominent in: ☐ Right Ear ☐ Left Ear ☐ Both Ears Onset: ☐ Gradual ☐ Sudden
	Do you have Tinnitus? ☐Yes ☐ No If yes, is it most prominent in: ☐ Right Ear ☐ Left Ear ☐ Both Ears or in ☐ Head How long? 6-12 months 1-5 yrs 6-10 yrs 11-15 yrs 15+ yrs Describe it: _____
	Have you ever been diagnosed with: Meniere's Disease ☐Yes ☐ No Temporomandibular Joint (TMJ) dysfunction ☐Yes ☐ No
	Have you tried any other treatments to cope with tinnitus: 1. Sound masking 2. Hearing aids/ear-level maskers 3. Psychological counseling 4. Audiology counseling/education 5. Relaxation training 6. Cognitive behavioral training 7. Vitamins/supplements: which ones? 8. Other treatment: what?
	Does the tinnitus interfere with your daily activities i.e. sleep, quiet resting, etc? ☐ Yes ☐ No
	Within the last week, have you been exposed to loud noise without hearing protection i.e. shooting weapons, mowing grass, rock concerts? ☐ Yes ☐ No

List current medications:

PROCEDURE NOTE

Symptoms before tx			Acupuncture site	Symptoms post tx
	L	R	Cingulate Gyrus	
	L	R	Cingulate Gyrus	
	L	R	Thalamus	
	L	R	Thalamus	
	L	R	Omega 2	
	L	R	Omega 2	
	L	R	Point Zero	
	L	R	Point Zero	

ID _____ Date: _____

	L	**R**	**Shen Men**	
	L	**R**	**Shen Men**	

POST PROCEDURE MANAGEMENT
-Patient was instructed on proper needle and site care and is aware to remove needles in 5 days if still present -Patient tolerated the procedure well without complications -Follow-up tx was arranged by pt signing up in appointment book

ID _____ Date: _____

Tinnitus/Acupuncture Case History Form
Treatment 2

	Pt states their tinnitus issues have been worked up by ENT and/or Audiology
	Pt states they do not have a bleeding disorder
	Pt does not feel they are pregnant

Do you have hearing loss? ☐ Yes ☐ No

If yes, is it most prominent in: ☐ Right Ear ☐ Left Ear ☐ Both Ears

Onset: ☐ Gradual ☐ Sudden

Do you have Tinnitus? ☐ Yes ☐ No

If yes, is it most prominent in: ☐ Right Ear ☐ Left Ear ☐ Both Ears or in ☐ Head

How long? 6-12 months 1-5 years 6-10 years 11-15 years 15+ years

Describe it: _____

How is your overall tinnitus condition now, compared to your first visit to this clinic?

Much Improved Moderately-improved Slightly improved No change Slightly worse
Moderately worse Much worse

Does the tinnitus interfere with your daily activities i.e. sleep, quiet resting, etc. ☐ Yes ☐ No

Within the last week, have you been exposed to loud noise without hearing protection i.e. shooting weapons, mowing grass, rock concerts? ☐ Yes ☐ No

Have you noticed any other improvements with overall health/less pain? ☐ Yes ☐ No ☐ NA

If yes, please describe: _____

List current medications:

PROCEDURE NOTE

Symptoms before tx			Acupuncture site	Symptoms post tx
	L	R	Cingulate Gyrus	
	L	R	Cingulate Gyrus	
	L	R	Thalamus	
	L	R	Thalamus	
	L	R	Omega 2	
	L	R	Omega 2	
	L	R	Point Zero	
	L	R	Point Zero	
	L	R	Shen Men	
	L	R	Shen Men	

POST PROCEDURE MANAGEMENT

-Patient was instructed on proper needle and site care and is aware to remove needles in 5 days if still present
-Patient tolerated the procedure well without complications
-Follow-up tx was arranged by pt signing up in appointment book

ID _____ Date: _____

Tinnitus/Acupuncture Case History Form
Post-Treatment (circle): 1 2 3 4

	Pt states their tinnitus issues have been worked up by ENT and/or Audiology
	Pt states they do not have a bleeding disorder
	Pt does not feel they are pregnant

Do you have hearing loss? ☐ Yes ☐ No

If yes, is it most prominent in: ☐ Right Ear ☐ Left Ear ☐ Both Ears

Onset: ☐ Gradual ☐ Sudden

Do you have Tinnitus? ☐ Yes ☐ No

If yes, is it most prominent in: ☐ Right Ear ☐ Left Ear ☐ Both Ears or in ☐ Head

How long? 6-12 months 1-5 years 6-10 years 11-15 years 15+ years

Describe it: _____

How is your overall tinnitus condition now, compared to your first visit to this clinic?

Much Improved Moderately-improved Slightly improved No change Slightly worse
Moderately worse Much worse

Does the tinnitus interfere with your daily activities i.e. sleep, quiet resting, etc. ☐ Yes ☐ No

Within the last week, have you been exposed to loud noise without hearing protection i.e. shooting weapons, mowing grass, rock concerts? ☐ Yes ☐ No

Have you noticed any other improvements with overall health/less pain? ☐ Yes ☐ No ☐ NA

If yes, please describe: _____

List current medications:

Appendix B

Tinnitus Screener

Name/ID: _____ Date: _____

Tinnitus Screener

Tinnitus is ringing, buzzing, humming or other noises in your ears or head.

During the PAST YEAR:

1. Have you experienced tinnitus lasting more than 2 – 3 minutes?

- ○ **No** (STOP HERE)
- ○ **Yes** (GO TO #2)

2. Have you experienced tinnitus for at least 6 months?

- ○ **No** (GO TO #3)
- ○ **Yes** (GO TO #3)

3. In a quiet room, can you hear tinnitus?

- ○ **Always** (STOP HERE)
- ○ **Usually** (STOP HERE)
- ○ **Sometimes/Occasionally** (GO TO #4)

4. When you heard tinnitus this past year, was it caused by a recent event? (Examples: loud concert, head cold, allergies, some medications)

- ○ **No** (GO TO #6)
- ○ **Yes, sometimes** (GO TO #5)
- ○ **Yes, always** (STOP HERE)

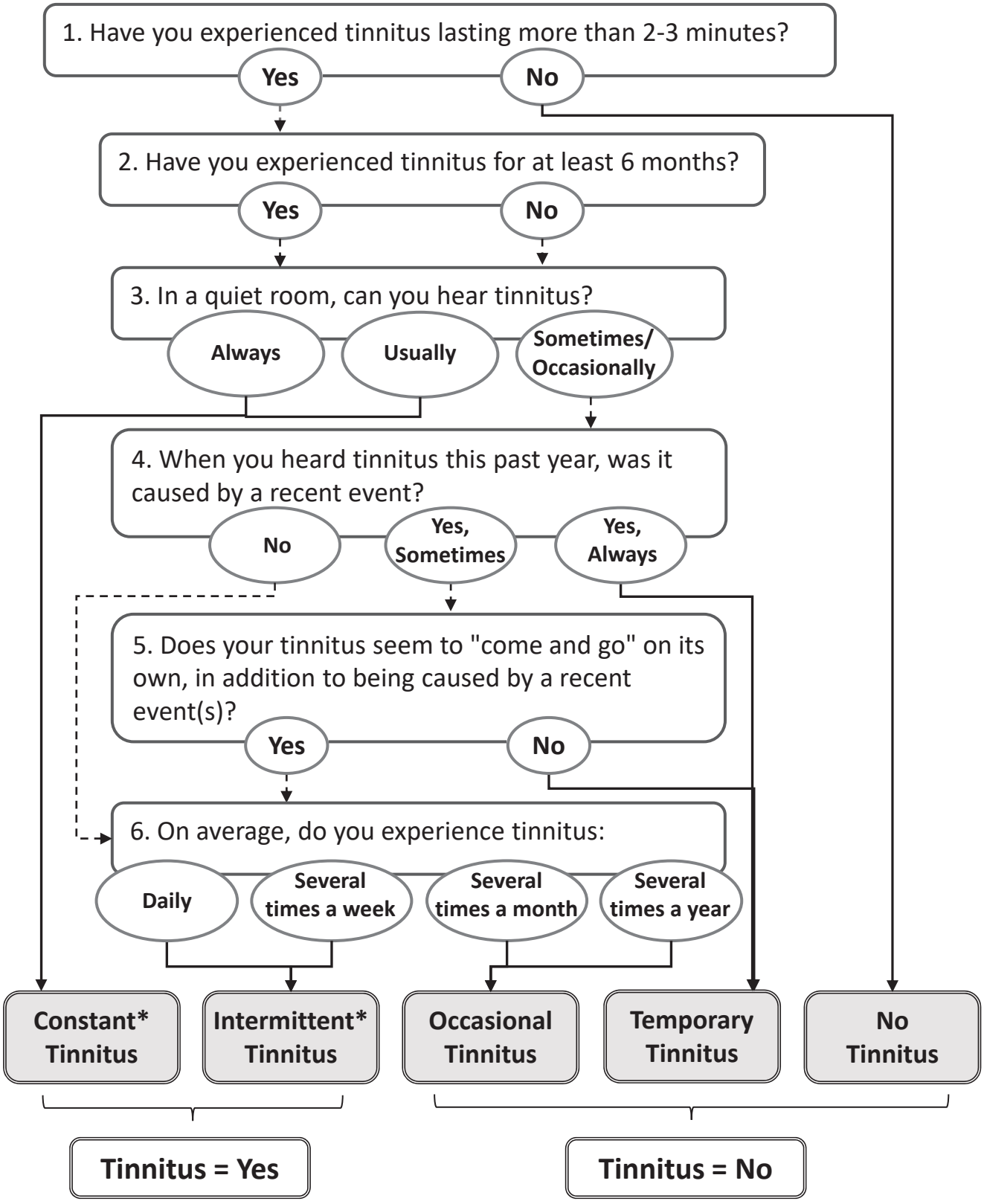
5. Does your tinnitus seem to "come and go" on its own, in addition to being caused by a recent event(s)?

- ○ **No** (STOP HERE)
- ○ **Yes** (GO TO #6)

6. On average, do you experience tinnitus:

- ○ **Several times a year**
- ○ **Several times a month**
- ○ **Several times a week**
- ○ **Daily**

Decision tree of the 6-item Tinnitus Screener. Each question on the screener is shown, with the possible responses in bubbles below the question. The arrows from each response indicate either the tinnitus categorization (solid arrow) or the next question to be asked (dashed arrow). Resulting tinnitus categories, and classifications, are shown along the bottom.



* If Q2=Yes, tinnitus is *Chronic*; if Q2=No, tinnitus is *Acute*

Appendix C

Tinnitus Reaction Questionnaire (TRQ)

For Patient

Tinnitus Reaction Questionnaire (TRQ)

Subject ID#_____ Date Completed:

This questionnaire is designed to find out what sort of effects tinnitus has had on your lifestyle, general well-being, etc. Some of the effects below may apply to you, some may not. Please answer **all** questions by circling the number that best reflects how your tinnitus has affected you **over the past week**.

	Not at all	A little of the time	Some of the time	A good deal of the time	Almost all of the time
1. My tinnitus has made me unhappy.	0	1	2	3	4
2. My tinnitus has made me feel tense.	0	1	2	3	4
3. My tinnitus has made me feel irritable.	0	1	2	3	4
4. My tinnitus has made me feel angry.	0	1	2	3	4
5. My tinnitus has led me to cry.	0	1	2	3	4
6. My tinnitus has led me to avoid quiet situations.	0	1	2	3	4
7. My tinnitus has made me feel less interested in going out.	0	1	2	3	4
8. My tinnitus has made me feel depressed.	0	1	2	3	4
9. My tinnitus has made me feel annoyed.	0	1	2	3	4
10. My tinnitus has made me feel confused.	0	1	2	3	4
11. My tinnitus has "driven me crazy".	0	1	2	3	4
12. My tinnitus has interfered with my enjoyment of life.	0	1	2	3	4
13. My tinnitus has made it hard for me to concentrate.	0	1	2	3	4
14. My tinnitus has made it hard for me to relax.	0	1	2	3	4
15. My tinnitus has made me feel distressed.	0	1	2	3	4
16. My tinnitus has made me feel helpless.	0	1	2	3	4
17. My tinnitus has made me feel frustrated with things.	0	1	2	3	4
18. My tinnitus has interfered with my ability to work.	0	1	2	3	4
19. My tinnitus has led me to despair.	0	1	2	3	4
20. My tinnitus has led me to avoid noisy situations.	0	1	2	3	4
21. My tinnitus has led me to avoid social situations.	0	1	2	3	4
22. My tinnitus has made me feel hopeless about the future.	0	1	2	3	4
23. My tinnitus has interfered with my sleep.	0	1	2	3	4
24. My tinnitus has led me to think about suicide.	0	1	2	3	4
25. My tinnitus has made me feel panicky.	0	1	2	3	4
26. My tinnitus has made me feel tormented.	0	1	2	3	4
Total					

Wilson et al. 1991

Appendix D

Tinnitus Functional Index (TFI)

TINNITUS FUNCTIONAL INDEX

Today's Date _____ Subject ID# _____
Month / Day / Year

Please read each question below carefully. To answer a question, select *ONE* of the numbers that is listed for that question, and draw a *CIRCLE* around it like this: (10%) or (1).

I Over the PAST WEEK...

1. What percentage of your time awake were you consciously **AWARE OF** your tinnitus?

Never aware ► 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% ◄ *Always aware*

2. How **STRONG** or **LOUD** was your tinnitus?

Not at all strong or loud ►0 1 2 3 4 5 6 7 8 9 10 ◄ *Extremely strong or loud*

3. What percentage of your time awake were you **ANNOYED** by your tinnitus?

None of the time ► 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% ◄ *All of the time*

SC Over the PAST WEEK...

4. Did you feel **IN CONTROL** in regard to your tinnitus?

Very much in control ►0 1 2 3 4 5 6 7 8 9 10 ◄ *Never in control*

5. How easy was it for you to **COPE** with your tinnitus?

Very easy to cope ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Impossible to cope*

6. How easy was it for you to **IGNORE** your tinnitus?

Very easy to ignore ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Impossible to ignore*

C Over the PAST WEEK, how much did your tinnitus interfere with...

7. Your ability to **CONCENTRATE**?

Did not interfere ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Completely interfered*

8. Your ability to **THINK CLEARLY?**

Did not interfere ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Completely interfered*

9. Your ability to **FOCUS ATTENTION** on other things besides your tinnitus?

Did not interfere ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Completely interfered*

SL Over the PAST WEEK...

10. How often did your tinnitus make it difficult to **FALL ASLEEP** or **STAY ASLEEP**?

Never had difficulty ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Always had difficulty*

11. How often did your tinnitus cause you difficulty in getting **AS MUCH SLEEP** as you needed?

Never had difficulty ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Always had difficulty*

12. How much of the time did your tinnitus keep you from **SLEEPING** as **DEEPLY** or as **PEACEFULLY** as you would have liked?

None of the time ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *All of the time*

Please read each question below carefully. To answer a question, select *ONE* of the numbers that is listed for that question, and draw a *CIRCLE* around it like this: (10%) or (1).

A	**Over the PAST WEEK, how much has your tinnitus interfered with...**	*Did not interfere*									*Completely interfered*
13. Your ability to **HEAR CLEARLY**?		0	1	2	3	4	5	6	7	8	9	10
14. Your ability to **UNDERSTAND PEOPLE** who are talking?		0	1	2	3	4	5	6	7	8	9	10
15. Your ability to **FOLLOW CONVERSATIONS** in a group or at meetings?		0	1	2	3	4	5	6	7	8	9	10
R	**Over the PAST WEEK, how much has your tinnitus interfered with...**	*Did not interfere*									*Completely interfered*
16. Your **QUIET RESTING ACTIVITIES**?		0	1	2	3	4	5	6	7	8	9	10
17. Your ability to **RELAX**?		0	1	2	3	4	5	6	7	8	9	10
18. Your ability to enjoy "**PEACE AND QUIET**"?		0	1	2	3	4	5	6	7	8	9	10
Q	**Over the PAST WEEK, how much has your tinnitus interfered with...**	*Did not interfere*									*Completely interfered*
19. Your enjoyment of **SOCIAL ACTIVITIES**?		0	1	2	3	4	5	6	7	8	9	10
20. Your **ENJOYMENT OF LIFE**?		0	1	2	3	4	5	6	7	8	9	10
21. Your **RELATIONSHIPS** with family, friends and other people?		0	1	2	3	4	5	6	7	8	9	10

22. How often did your tinnitus cause you to have difficulty performing your **WORK OR OTHER TASKS**, such as home maintenance, school work, or caring for children or others?

Never had difficulty ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Always had difficulty*

E **Over the PAST WEEK...**

23. How **ANXIOUS** or **WORRIED** has your tinnitus made you feel?

Not at all anxious or worried ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Extremely anxious or worried*

24. How **BOTHERED** or **UPSET** have you been because of your tinnitus?

Not at all bothered or upset ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Extremely bothered or upset*

25. How **DEPRESSED** were you because of your tinnitus?

Not at all depressed ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Extremely depressed*

INSTRUCTIONS FOR SCORING THE TINNITUS FUNCTIONAL INDEX (TFI)

1. PREPARATION FOR SCORING:

A. **Two items to be transformed:** Items #1 and #3 require a simple transformation from a percentage scale to a 0-10 scale, achieved by dividing the values circled by the respondent by 10. The examiner should write the transformed value in the margin beside the relevant item, preferably using ink of a different color than that used by the respondent.

B. **Ambiguous items:** Because respondents differ in regard to how clearly they circle or mark their answers on the 0-10 scale for each item, the examiner should review every item to resolve any ambiguities. It is helpful if examiners note their decision about each answer in the margin beside the given item, using the differently-colored ink. Some commonly-occurring ambiguities and how to handle them are as follows:

(1) **More than one value marked on the 0-10 scale for a given item**—Typically done by respondents whose tinnitus undergoes large variations over time. The clinic or the examiner should settle on a consistent procedure for all such responses, such as (a) averaging the multiple values indicated for a given item, or (b) marking the item "cannot code", thus removing that item from consideration in the overall TFI score. (The latter choice reduces the information available for calculating the respondent's overall score, and may be desirable only in extremely variable cases where the respondent's reliability is questionable.)

(2) **Respondent marks a value between the 0-10 values on the item scale**— Again, the clinic or the examiner should settle on a consistent procedure for handling all such ambiguous responses in the same way, such as (a) noting a value of 3.5 in the margin, for a respondent who marked the scale between 3 and 4, or (b) collapsing the intermediate value either to the right (to 4) or to the left (to 3).

(3) **Respondent does not make any response to a given item**—The clinic or examiner should decide beforehand how they will indicate missing values, and that notation (e.g. "NA" for "No Answer") should be entered in the margin. If the data will be entered into a computer database, a standard missing value such as "99" can be entered in the margin beside the relevant item. Of course, care must be taken to exclude "99" values if the examiner performs a manual calculation of the overall TFI score.

C. **Unambiguous items:** To facilitate rapid scanning and summing of all valid answers to obtain the respondent's overall TFI score, all of the unambiguous values indicated by the respondent should also be noted in the margin, each such value beside its corresponding item. The examiner can then quickly generate a valid score for the overall TFI.

2. CALCULATION OF OVERALL TFI SCORE:

(1) Sum all valid answers from both TFI pages (maximum possible score = 250 if the respondent were to rate all 25 TFI items at the maximum value of 10).
(2) Divide by the number of questions for which that respondent provided valid answers (yields the respondent's mean item score for all items having valid answers).
(3) Multiply by 10 (provides that respondent's overall TFI score within 0-100 range).

CAUTION—Overall TFI score is **not valid** if respondent **omits 7 or more** items. To be valid as a measure of tinnitus severity, the respondent must answer **at least 19 items** (76% of items).

3. CALCULATION OF SUBSCALE SCORES

The 8 subscales address 8 important domains of negative tinnitus impact as indicated below. Each subscale has a brief title (in capital letters) and a 1- or 2-letter abbreviation (e.g. I for Intrusive , SC for Sense of Control):

SUBSCALE NAME (and conceptual content)	ITEMS IN SUBSCALE
I: INTRUSIVE (unpleasantness, intrusiveness, persistence)	#1, #2, #3
SC: SENSE OF CONTROL (reduced sense of control)	#4, #5, #6
C: COGNITIVE (cognitive interference)	#7, #8, #9
SL: SLEEP (sleep disturbance)	#10, #11, #12
A: AUDITORY (auditory difficulties attributed to tinnitus)	#13, #14, #15
R: RELAXATION (interference with relaxation)	#16, #17, #18
Q: QUALITY OF LIFE (QOL) (quality of life reduced)	#19, #20, #21, #22
E: EMOTIONAL (emotional distress)	#23, #24, #25

Each of the 8 subscales consists of 3 items except for the Quality of life subscale, which consists of 4 items (SEE ITEMS LIST ABOVE). For valid subscale scores, no more than 1 item should be omitted. Computation of subscale scores is as follows:

1) Sum all of that respondent's valid answers for a given subscale.

2) Divide by the number of valid answers that were provided by that respondent for that subscale.

3) Multiply by 10. For the respondent in question, this procedure generates a subscale score in the range 0-100 for each valid subscale.

CAUTION—Do not attempt to compute a respondent's overall TFI score by combining that respondent's valid subscale scores, as the valid subscales may encompass a total number of items that is different from the number of items accepted as valid for the overall TFI score.

Appendix E

Hospital Anxiety and Depression Scale (HADS)

Subject ID#_____

Hospital Anxiety and Depression Scale (HADS)*

The purpose of this questionnaire is to identify feelings and emotions that you may be having. Each of the statements below gives an example of an emotion that may or may not apply to you. Do not analyze the statements in detail. Circle the answer that best fits your current situation.

1. I feel tense or wound up:
    a. Most of the time
    b. A lot of the time
    c. From time to time, occasionally
    d. Not at all
2. I still enjoy the things I used to enjoy:
    a. Definitely as much
    b. Not quite as much
    c. Only a little
    d. Hardly at all
3. I get a sort of frightened feeling as if something is about to happen:
    a. Very definitely and quite badly
    b. Yes, but not too badly
    c. A little, but it doesn't worry me
    d. Not at all
4. I can laugh and see the funny side of things:
    a. As much as I always could
    b. Not quite as much now
    c. Definitely not so much now
    d. Not at all
5. Worrying thoughts go through my mind:
    a. A great deal of the time
    b. A lot of the time
    c. From time to time, but not too often
    d. Only occasionally
6. A feel cheerful:
    a. Not at all
    b. Not often
    c. Sometimes
    d. Most of the time
7. I can sit at ease and feel relaxed:
    a. Definitely
    b. Usually
    c. Not often
    d. Not at all
8. I feel as if I am slowed down:
    a. Nearly all the time
    b. Very often
    c. Sometimes
    d. Not at all
9. I get a sort of frightened feeling like "butterflies" in the stomach:
    a. Not at all
    b. Occasionally
    c. Quite often
    d. Very often
10. I have lost interest in my appearance:
    a. Definitely
    b. I don't take as much care as I should
    c. I may not take quite as much care
    d. I take just as much care as ever
11. I feel restless as if I have to be on the move:
    a. Very much indeed
    b. Quite a lot
    c. Not very much
    d. Not at all
12. I look forward with enjoyment to things:
    a. As much as I ever did
    b. Rather less than I used to
    c. Definitely less than I used to
    d. Hardly at all
13. I get a sudden feeling of panic:
    a. Very often indeed
    b. Quite often
    c. Not very often
    d. Not at all
14. I can enjoy a good book or radio or TV program:
    a. Often
    b. Sometimes
    c. Not often
    d. Very seldom

*Modified from Zigmond and Snaith (1983).

Subject ID#_____

HADS Scoring Instructions: Assign point values (0-3) to answers to the 14 questions according to the scoring grid below. For patients with dizziness, an Anxiety or Depression Score ≥ 8 or Total Score ≥ 12 suggests clinically significant psychiatric symptoms.

Question No.	Item Answers				Item Score
	A	B	C	D	
1	3	2	1	0	
3	3	2	1	0	
5	3	2	1	0	
7	0	1	2	3	
9	0	1	2	3	
11	3	2	1	0	
13	3	2	1	0	
Anxiety Score (sum from odd-numbered questions)					
2	0	1	2	3	
4	0	1	2	3	
6	3	2	1	0	
8	3	2	1	0	
10	3	2	1	0	
12	0	1	2	3	
14	0	1	2	3	
Depression Score (sum from even-numbered questions)					
Total Score (Anxiety + Depression)					

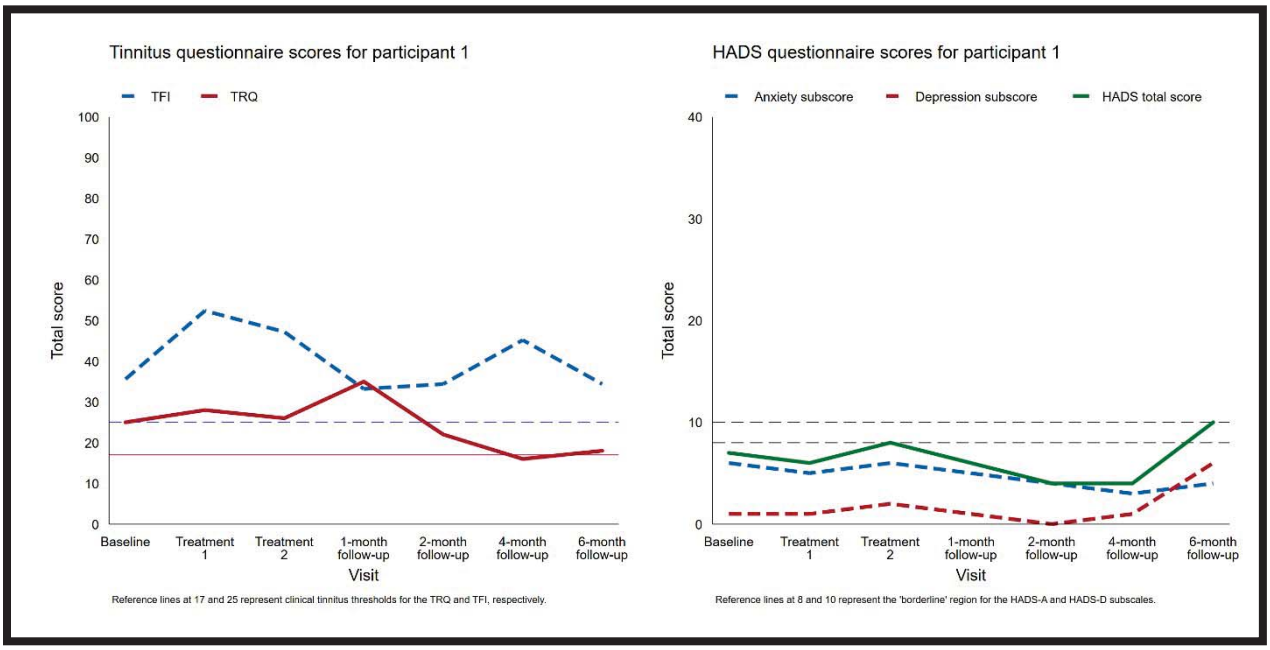
Appendix F

Individual Participant Trajectories

Participant 1

Male, 32, Active duty	Baseline	Treatment 1	Treatment 2	1-month Follow-up	2-month Follow-up	4-month follow-up	6-month Follow-up
Medication	Loratadine, sumatriptan	Loratadine	Loratadine	Loratadine	Loratadine	Loratadine	Loratadine
Therapy	Sound masking, audiology counseling, and CBT	Sound masking	--	--	--	--	--
Noise exposure	None	None	None	None	None	None	None
Health Impact	--	--	None	None	None	None	None
Tinnitus change	--	--	No change	No change	Slightly worse	Slightly worse	Slightly worse
Tinnitus interference	Yes	Yes	Yes	Yes	Yes	Yes	Yes

-- = not asked at visit; **NR =** no response from participant



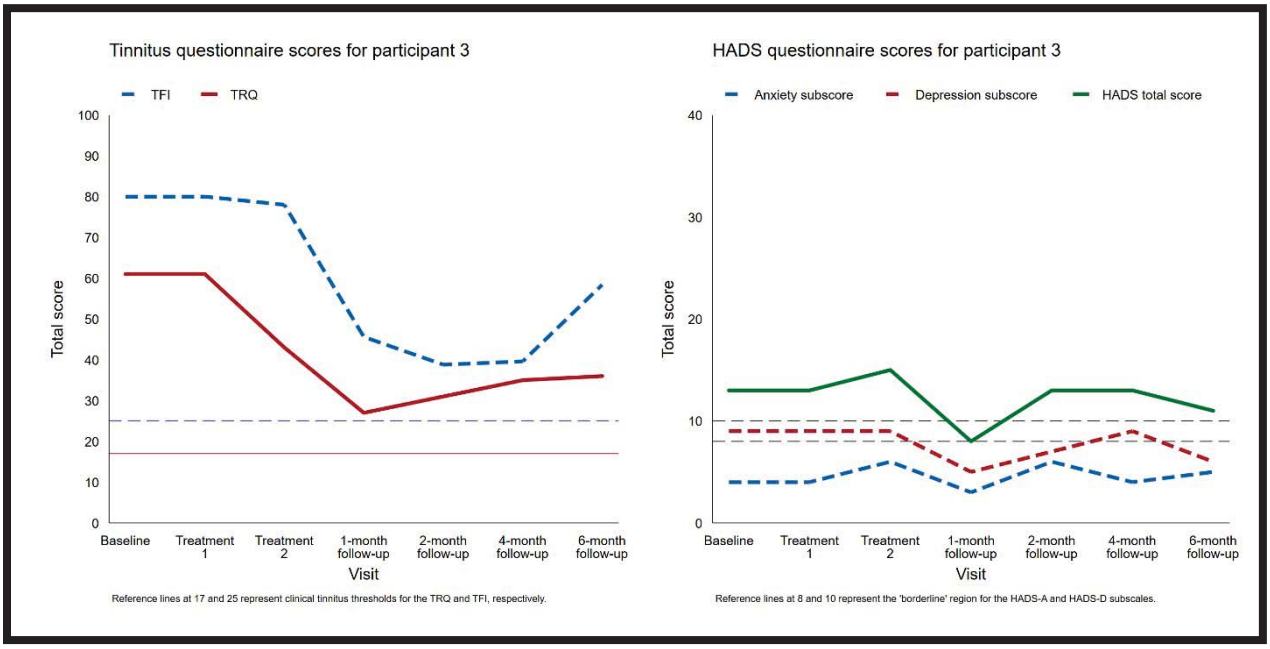
TFI subscale scores by visit

Participant 1	Baseline	Treatment 1	Treatment 2	1-month follow-up	2-month follow-up	4-month follow-up	6-month follow-up
TFI total	35.6	52.4	47.2	33.2	34.4	45.2	34.4
TFIi	46.7	70.0	63.3	33.3	33.3	40.0	46.7
TFIsc	43.3	60.0	63.3	33.3	40.0	66.7	53.3
TFIc	30.0	53.3	66.7	43.3	36.7	40.0	40.0
TFIsl	56.7	50.0	36.7	23.3	50.0	46.7	30.0
TFIa	40.0	70.0	53.3	80.0	43.3	56.7	50.0
TFIr	40.0	50.0	53.3	36.7	30.0	70.0	40.0
TFIq	30.0	47.5	32.5	20.0	30.0	30.0	20.0
TFIe	0.0	20.0	13.3	0.0	13.3	16.7	0.0

Participant 3

Male, 56, Retired	Baseline	Treatment 1	Treatment 2	1-month Follow-up	2-month Follow-up	4-month follow-up	6-month Follow-up
Medication	Atorvastatin, multi-vitamin, aspirin	Atorvastatin, multi-vitamin, aspirin	Atorvastatin, multi-vitamin, aspirin	Atorvastatin, multi-vitamin, aspirin	Atorvastatin, multi-vitamin, aspirin	Atorvastatin, multi-vitamin, aspirin	Atorvastatin, multi-vitamin, aspirin
Therapy	Sound masking, PTM class	Sound masking, PTM class, CPAP	--	--	--	--	--
Noise exposure	None	NR	None	None	None	None	None
Health Impact	--	--	Yes	None	Yes	None	None
Tinnitus change	--	--	Slightly improved	Slightly improved	Slightly worse	No change	Slightly improved
Tinnitus interference	Yes	Yes	Yes	Yes	Yes	Yes	Yes

-- = not asked at visit; **NR =** no response from participant

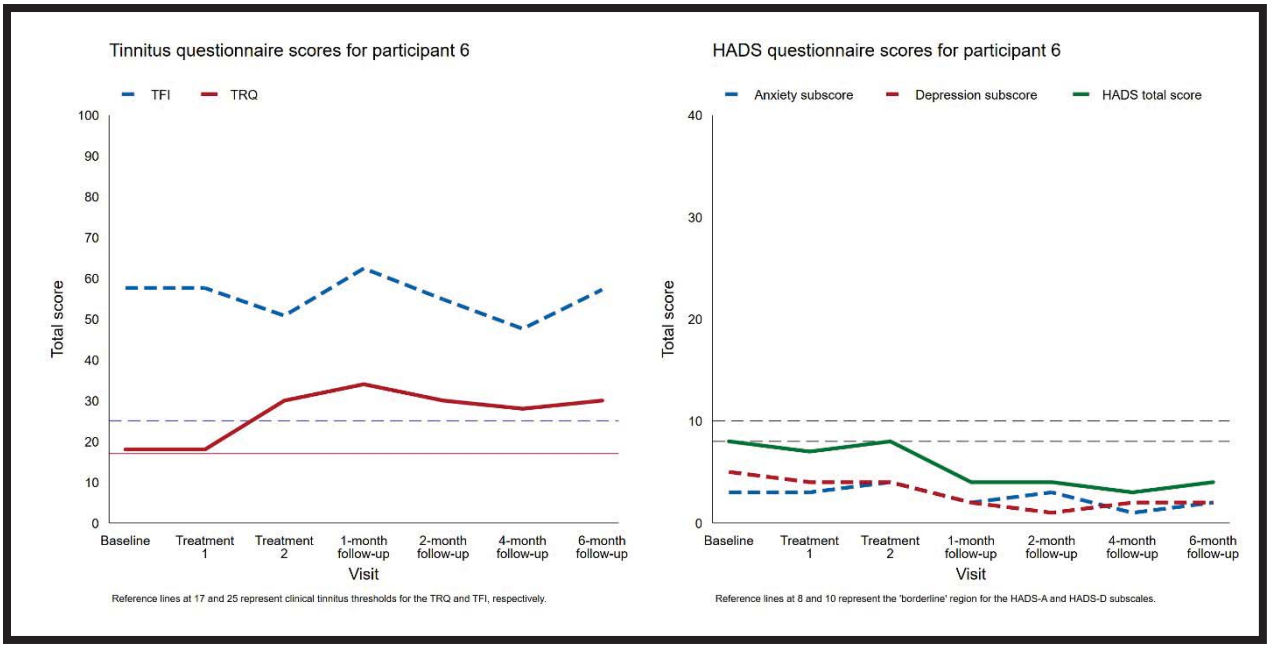


TFI subscale scores by visit

Participant 3	Baseline	Treatment 1	Treatment 2	1-month follow-up	2-month follow-up	4-month follow-up	6-month follow-up
TFI total	80.0	80.0	78.0	45.6	38.8	39.6	58.4
TFIi	90.0	90.0	86.7	70.0	76.7	43.3	80.0
TFIsc	86.7	86.7	83.3	30.0	30.0	40.0	50.0
TFIc	76.7	76.7	83.3	40.0	30.0	36.7	60.0
TFIsl	76.7	76.7	86.7	50.0	30.0	50.0	56.7
TFIa	76.7	76.7	76.7	63.3	53.3	46.7	70.0
TFIr	90.0	90.0	76.7	50.0	40.0	50.0	70.0
TFIq	87.5	87.5	75.0	45.0	40.0	40.0	57.5
TFIe	53.3	53.3	56.7	16.7	10.0	10.0	23.3

Participant 6	Baseline	Treatment 1	Treatment 2	1-month Follow-up	2-month Follow-up	4-month follow-up	6-month Follow-up
Medication	Lisinopril	Lisinopril	Lisinopril	Lisinopril	Lisinopril	Lisinopril	Lisinopril
Therapy	Sound masking and OTC supplements	Sound masking, OTC supplements, relaxation training	--	--	--	--	--
Noise exposure	None	None	None	None	None	None	Yes
Health Impact	--	--	None	None	None	None	None
Tinnitus change	--	--	No change	No change	No change	No change	No change
Tinnitus interference	Yes	Yes	Yes	Yes	Yes	Yes	Yes

-- = not asked at visit; **NR =** no response from participant

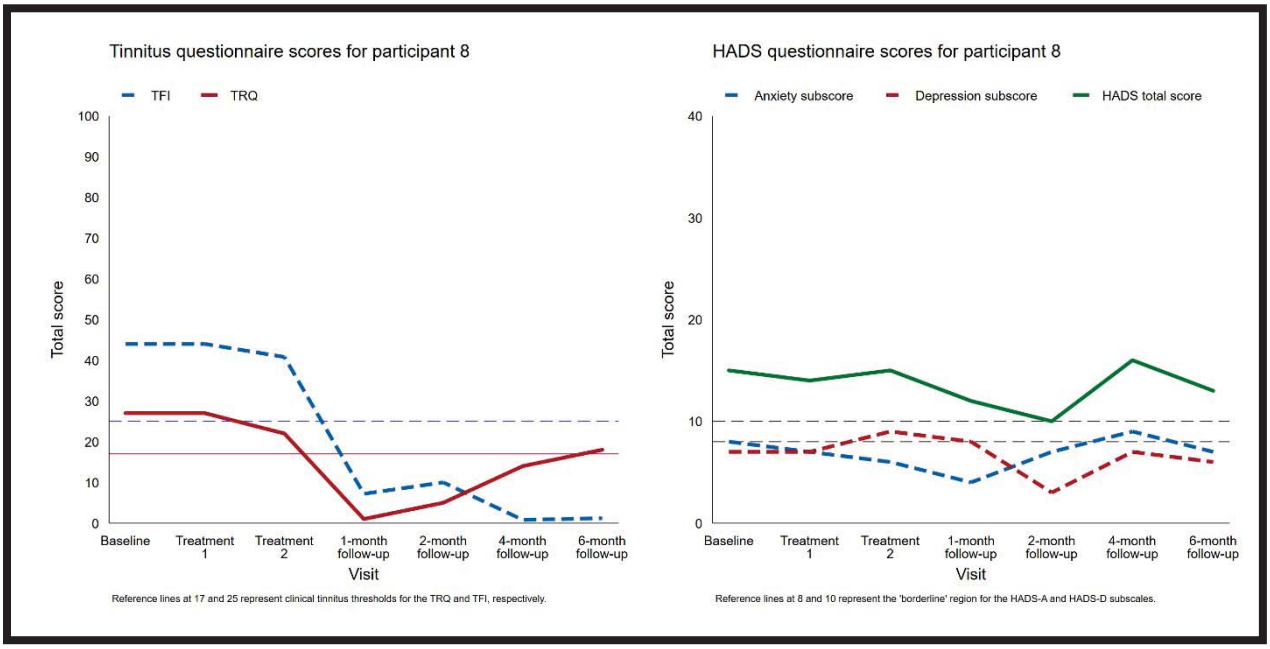


TFI subscale scores by visit

Participant 6	Baseline	Treatment 1	Treatment 2	1-month follow-up	2-month follow-up	4-month follow-up	6-month follow-up
TFI total	57.6	57.6	50.8	62.4	54.8	47.6	57.2
TFIi	76.7	76.7	73.3	90.0	80.0	66.7	73.3
TFIsc	70.0	70.0	76.7	86.7	66.7	63.3	73.3
TFIc	36.7	36.7	16.7	53.3	33.3	33.3	36.7
TFIsl	90.0	90.0	80.0	100.0	100.0	100.0	100.0
TFIa	63.3	63.3	56.7	53.3	40.0	33.3	60.0
TFIr	86.7	86.7	86.7	93.3	100.0	83.3	96.7
TFIq	37.5	37.5	17.5	15.0	2.5	7.5	7.5
TFIe	6.7	6.7	10.0	23.3	33.3	6.7	26.7

Participant 8	Baseline	Treatment 1	Treatment 2	1-month Follow-up	2-month Follow-up	4-month follow-up	6-month Follow-up
Medication	Celecoxcib	Celecoxcib	Celecoxcib	Celecoxcib	Celecoxcib	None	None
Therapy	None	None	--	--	**Received hearing aids*	--	--
Noise exposure	None	None	None	None	None	None	None
Health Impact	--	--	None	None	Yes	None	None
Tinnitus change	--	--	Slightly improved	Much improved	Moderately improved	Much improved	Much improved
Tinnitus interference	Yes	Yes	Yes	Yes	Yes	Yes	Yes

-- = not asked at visit; **NR =** no response from participant

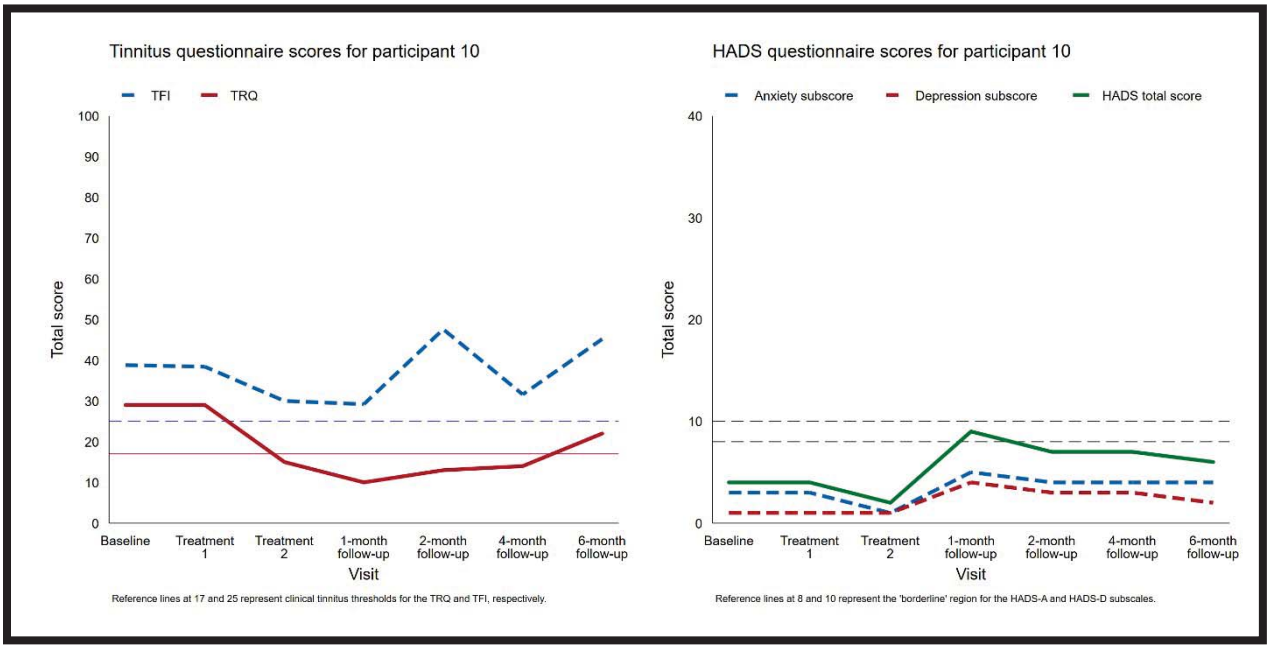


TFI subscale scores by visit

Participant 8	Baseline	Treatment 1	Treatment 2	1-month follow-up	2-month follow-up	4-month follow-up	6-month follow-up
TFI total	44.0	44.0	40.8	7.2	10.0	0.8	1.2
TFIi	63.3	63.3	53.3	23.3	43.3	6.7	0.0
TFIsc	70.0	70.0	20.0	0.0	0.0	0.0	0.0
TFIc	80.0	80.0	60.0	0.0	0.0	0.0	0.0
TFIsl	0.0	0.0	0.0	0.0	0.0	0.0	0.0
TFIa	63.3	63.3	70.0	30.0	40.0	0.0	10.0
TFIr	50.0	50.0	40.0	0.0	0.0	0.0	0.0
TFIq	15.0	15.0	47.5	5.0	0.0	0.0	0.0
TFIe	20.0	20.0	33.3	0.0	0.0	0.0	0.0

Participant 10	Baseline	Treatment 1	Treatment 2	1-month Follow-up	2-month Follow-up	4-month follow-up	6-month Follow-up
Medication	Loratadine, zolmitriptan	Loratadine, zolmitriptan	Loratadine, zolmitriptan	Loratadine, zolmitriptan	Loratadine, zolmitriptan	Loratadine, zolmitriptan	Loratadine, zolmitriptan
Therapy	Sound maskers, hearing aids/ear-level maskers	Sound maskers, hearing aids/ear-level maskers	--	--	--	--	--
Noise exposure	None	None	None	None	Yes	None	None
Health Impact	--	--	None	None	None	None	None
Tinnitus change	--	--	Slightly improved	Moderately improved	Slightly worse	No change	No change
Tinnitus interference	Yes	Yes	None	Yes	Yes	Yes	None

-- = not asked at visit; **NR =** no response from participant

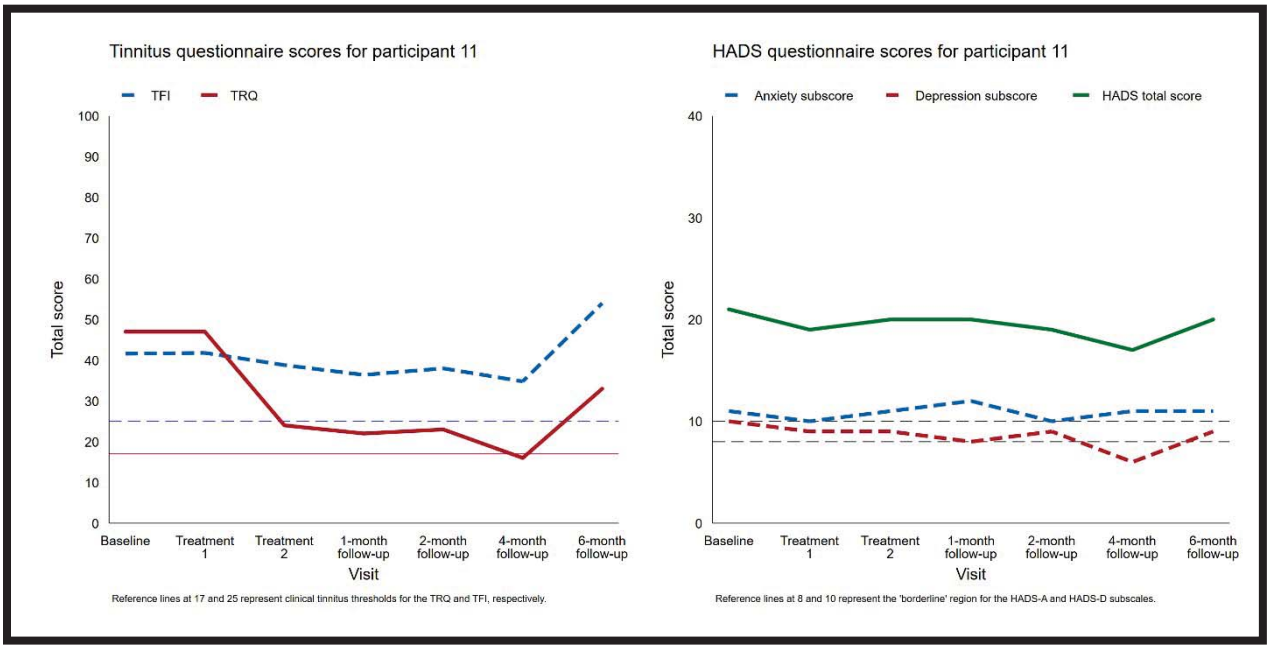


TFI subscale scores by visit

Participant 10	Baseline	Treatment 1	Treatment 2	1-month follow-up	2-month follow-up	4-month follow-up	6-month follow-up
TFI total	38.8	38.4	30.0	29.2	47.6	31.6	45.2
TFIi	50.0	50.0	43.3	23.3	96.7	60.0	63.3
TFIsc	43.3	43.3	53.3	50.0	56.7	13.3	66.7
TFIc	36.7	36.7	33.3	36.7	56.7	50.0	50.0
TFIsl	13.3	13.3	10.0	20.0	40.0	20.0	30.0
TFIa	70.0	70.0	40.0	56.7	63.3	63.3	56.7
TFIr	43.3	43.3	23.3	26.7	36.7	20.0	33.3
TFIq	22.5	20.0	17.5	12.5	27.5	20.0	40.0
TFIe	36.7	36.7	23.3	13.3	10.0	10.0	23.3

Participant 11	Baseline	Treatment 1	Treatment 2	1-month Follow-up	2-month Follow-up	4-month follow-up	6-month Follow-up
Medication	Atorvastatin	Atorvastatin	Atorvastatin	Atorvastatin	Atorvastatin	Atorvastatin	Atorvastatin
Therapy	None	None	--	--	--	--	--
Noise exposure	None	None	None	None	None	None	Yes
Health Impact	--	--	None	None	None	None	None
Tinnitus change	--	--	Slightly worse	Slightly worse	Slightly worse	Slightly worse	No change
Tinnitus interference	Yes	Yes	None	Yes	Yes	Yes	Yes

-- = not asked at visit; **NR =** no response from participant

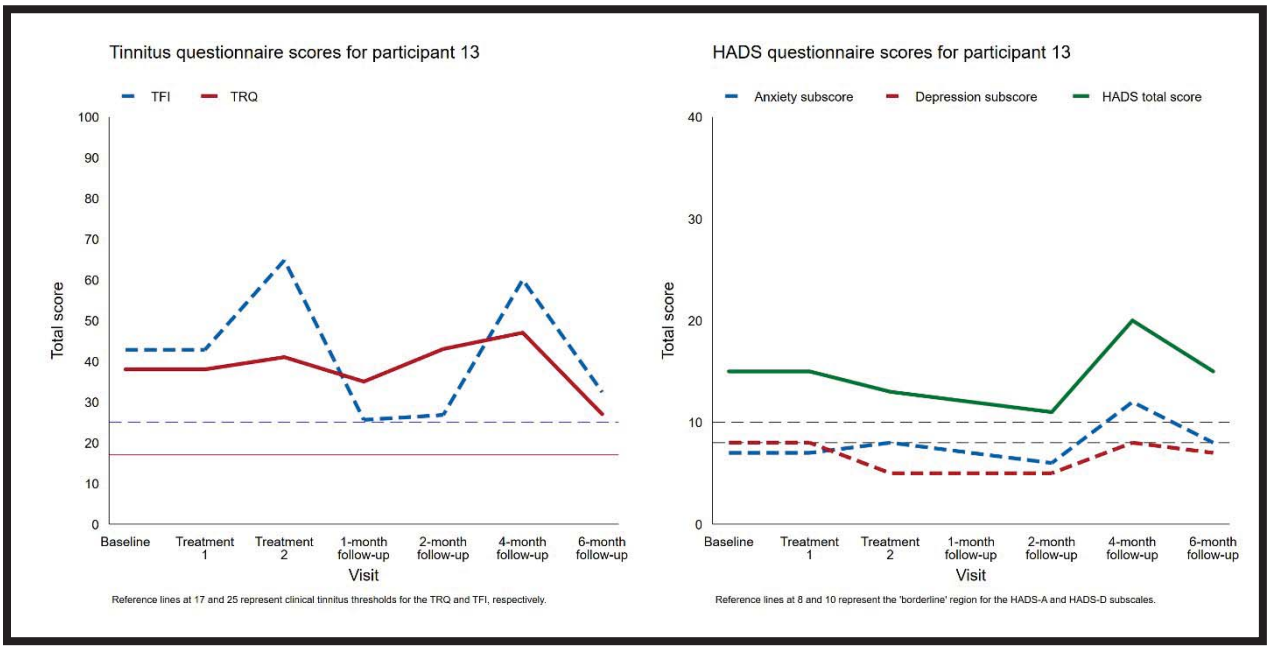


TFI subscale scores by visit

Participant 11	Baseline	Treatment 1	Treatment 2	1-month follow-up	2-month follow-up	4-month follow-up	6-month follow-up
TFI total	41.6	41.8	38.8	36.4	38.0	34.8	54.0
TFIi	40.0	40.0	50.0	56.7	43.3	53.3	70.0
TFIsc	26.7	28.3	36.7	56.7	60.0	40.0	66.7
TFIc	40.0	40.0	36.7	16.7	33.3	26.7	50.0
TFIsl	60.0	60.0	36.7	40.0	50.0	80.0	100.0
TFIa	76.7	76.7	50.0	56.7	43.3	33.3	63.3
TFIr	43.3	43.3	36.7	36.7	36.7	30.0	50.0
TFIq	27.5	27.5	32.5	20.0	30.0	12.5	22.5
TFIe	23.3	23.3	33.3	13.3	10.0	10.0	20.0

Participant 13	Baseline	Treatment 1	Treatment 2	1-month Follow-up	2-month Follow-up	4-month follow-up	6-month Follow-up
Medication	OTC supplements	OTC supplements	OTC supplements	OTC supplements	OTC supplements	OTC supplements	OTC supplements
Therapy	Sound masking	Sound masking	--	--	--	--	--
Noise exposure	None	None	None	None	None	None	None
Health Impact	--	--	None	None	None	None	None
Tinnitus change	--	--	No change	No change	Slightly worse	Moderately worse	No change
Tinnitus interference	Yes	Yes	Yes	Yes	Yes	Yes	Yes

-- = not asked at visit; **NR =** no response from participant

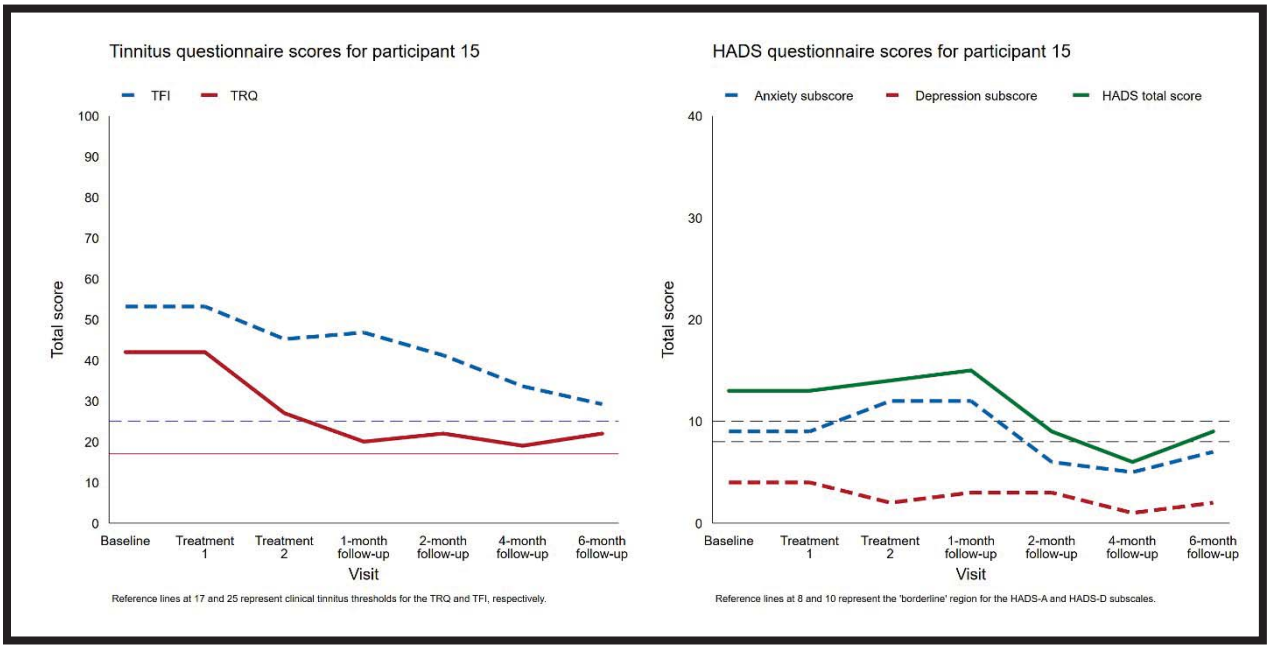


TFI subscale scores by visit

Participant 13	Baseline	Treatment 1	Treatment 2	1-month follow-up	2-month follow-up	4-month follow-up	6-month follow-up
TFI total	42.8	42.8	64.8	25.6	26.8	60.0	32.4
TFIi	86.7	86.7	86.7	36.7	50.0	56.7	36.7
TFIsc	50.0	50.0	30.0	53.3	40.0	76.7	70.0
TFIc	40.0	40.0	90.0	10.0	30.0	43.3	33.3
TFIsl	73.3	73.3	90.0	23.3	40.0	46.7	16.7
TFIa	10.0	10.0	63.3	16.7	10.0	70.0	36.7
TFIr	50.0	50.0	90.0	50.0	20.0	90.0	20.0
TFIq	25.0	25.0	57.5	12.5	17.5	40.0	32.5
TFIe	13.3	13.3	13.3	6.7	10.0	63.3	13.3

Participant 15	Baseline	Treatment 1	Treatment 2	1-month Follow-up	2-month Follow-up	4-month follow-up	6-month Follow-up
Medication	None	None	None	None	None	None	None
Therapy	Sound masking, audiology counseling	Sound masking, audiology counseling	--	--	--	--	--
Noise exposure	None	None	None	None	None	None	None
Health Impact	--	--	None	None	None	None	None
Tinnitus change	--	--	Slightly improved	Slightly improved	Slightly improved	Slightly improved	Slightly improved
Tinnitus interference	Yes	Yes	Yes	Yes	Yes	None	None

-- = not asked at visit; **NR =** no response from participant



TFI subscale scores by visit

Participant 15	Baseline	Treatment 1	Treatment 2	1-month follow-up	2-month follow-up	4-month follow-up	6-month follow-up
TFI total	53.2	53.2	45.2	46.8	41.2	33.6	29.2
TFIi	46.7	46.7	63.3	36.7	53.3	43.3	56.7
TFIsc	56.7	56.7	66.7	83.3	60.0	56.7	46.7
TFIc	80.0	80.0	63.3	43.3	76.7	43.3	36.7
TFIsl	56.7	56.7	36.7	36.7	46.7	23.3	23.3
TFIa	56.7	56.7	36.7	50.0	33.3	60.0	33.3
TFIr	83.3	83.3	63.3	73.3	40.0	40.0	33.3
TFIq	37.5	37.5	15.0	27.5	17.5	10.0	7.5
TFIe	13.3	13.3	26.7	30.0	10.0	0.0	3.3