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EXPLORING THE FEASIBILITY AND ACCEPTABILITY OF A NON-INVASIVE SOUND THERAPY DEVICE IN REDUCING SYMPTOMS OF TINNITUS IN MILITARY VETERANS

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Abstract

Introduction: The prevalence of tinnitus in veterans is higher than in the general population and can profoundly affect daily life. Tinnitus has been associated with psychological difficulties and may result in functional impairment. Currently, no sound therapy has been widely validated as an effective option for tinnitus management. Given the profound impact of tinnitus, and its economic burden and treatment barriers, it is important to explore new approaches. Sound therapy technologies are readily accepted due to their simplicity and non-invasiveness, but there is limited research exploring sound therapy in veterans. Here we explore the feasibility and acceptability of a non-invasive management option.

Material and methods: This feasibility and acceptability study included 20 UK military veterans who trialled a non-invasive device, TinniSoothe, for 1 or 2 months. The device is a small sound-generating module designed to be worn on a lanyard or clip during the day and placed in a docking station at night. It allows users to adjust both frequency and volume according to personal preferences, and while docked at night it continues to emit sound into the nearby environment. Participants were instructed to complete a pre-intervention, post-intervention, and 2-month follow-up questionnaire which included measures of tinnitus, mental health, and physical health.

Results: All participants (20 veterans, mean age = 51.3, *SD* = 7.7, 80% male) used the device for the 1-month intervention period, with no dropouts or serious adverse events. The majority (75%) elected to keep the device after 1 month, and 80% said they would recommend it to friends and family. However, at 2 months, just 13 participants reported ongoing device use. From baseline to post-intervention and follow-up, participants reported significant reductions in tinnitus symptoms. Although there was a significant overall effect of time on sleep disturbances, pairwise comparisons did not show significant changes between specific timepoints. No significant differences were observed in the remaining outcomes.

Conclusions: This study indicates that the TinniSoothe device shows a degree of feasibility and acceptability for tinnitus management in veterans and there is some evidence supporting its efficacy. However, after 2 months 65% of the participants were still active users, indicating that further research exploring its effectiveness is necessary.

Keywords: tinnitus • wearable technology • sound therapy

BADANIE MOŻLIWOŚCI ZASTOSOWANIA I AKCEPTOWALNOŚCI NIEINWAZYJNEGO URZĄDZENIA DO TERAPII DŹWIĘKIEM W ZMNIEJSZANIU OBJAWÓW SZUMÓW USZNYCH U WETERANÓW WOJSKOWYCH

Streszczenie

Wprowadzenie: Częstość występowania szumów usznych u weteranów wojskowych jest wyższa niż w populacji ogólnej i może mieć głęboki wpływ na codzienne życie. Szumy uszne mogą skutkować trudnościami psychologicznymi i negatywnie wpływać na codzienne funkcjonowanie. Obecnie żadna terapia dźwiękowa nie została powszechnie uznana za skuteczną metodę leczenia szumów usznych. Biorąc pod uwagę głęboki wpływ szumów usznych, ich koszty ekonomiczne oraz trudności w leczeniu, ważne jest poszukiwanie nowych skutecznych metod. Technologie stosowane w terapii dźwiękiem są chętnie akceptowane ze względu na swoją prostotę i nieinwazyjność, jednak istnieje ograniczona liczba badań dotyczących terapii dźwiękiem u weteranów. W niniejszym artykule badamy możliwości zastosowania i akceptowalność nieinwazyjnej metody leczenia.

Materiał i metody: W badaniu wzięło udział 20 brytyjskich weteranów wojskowych, którzy przez 1 lub 2 miesiące testowali nieinwazyjne urządzenie TinniSoothe. Urządzenie to jest niewielkim modułem generującym dźwięk, zaprojektowanym tak, aby można było nosić je na

smyczy lub klipsie w ciągu dnia, a na noc umieszczać w stacji dokującej. Umożliwia ono użytkownikom dostosowanie częstotliwości dźwięku i jego głośności zgodnie z osobistymi preferencjami, a urządzenie podczas dokowania w nocy nadal emituje dźwięk. Uczestnicy zostali poproszeni o wypełnienie kwestionariusza do oceny szumów usznych, zdrowia psychicznego i fizycznego przed interwencją, po interwencji oraz po 2 miesiącach.

Wyniki: Wszyscy uczestnicy (20 weteranów, średnia wieku = 51,3, *SD* = 7,7, 80% mężczyzn) korzystali z urządzenia przez okres interwencji trwający 1 miesiąc, bez żadnych przypadków rezygnacji lub poważnych zdarzeń niepożądanych. Większość (75%) zdecydowała się zatrzymać urządzenie po upływie miesiąca, a 80% stwierdziło, że poleciłoby je znajomym i rodzinie. Po 2 miesiącach chęć dalszego korzystania z urządzenia zgłosiło tylko 13 uczestników. Od momentu rozpoczęcia badania do zakończenia interwencji i obserwacji uczestnicy zgłaszali znaczne zmniejszenie objawów szumów usznych. Chociaż ogólnie czas miał znaczący wpływ w przypadku zaburzeń snu, porównania parami nie wykazały znaczących zmian między poszczególnymi punktami czasowymi. Nie zaobserwowano znaczących różnic w pozostałych wynikach.

Wnioski: Badanie wykazało, że możliwość zastosowania urządzenie TinniSoothe oraz jego akceptowalność w leczeniu szumów usznych u weteranów wojskowych są ograniczone, choć istnieją pewne dowody potwierdzające jego skuteczność. Jednak po 2 miesiącach 65% uczestników nadal aktywnie korzystało z urządzenia, co wskazuje na konieczność przeprowadzenia dalszych badań nad jego skutecznością.

Słowa kluczowe: szumy uszne • technologie ubieralne • terapia dźwiękiem

Key to abbreviations	
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition
GCSE	General Certificate of Secondary Education
GHQ-12	General Health Questionnaire-12
ISI	Insomnia Severity Index
NHS	National Health Service (UK)
Short form PCL-5	PTSD Checklist for DSM-IV short version
PHQ-15	Patient Health Questionnaire-15
PTSD	post-traumatic stress disorder
SWLS	Satisfaction with Life Scale
TFI	Tinnitus Functional Index
TRT	Tinnitus Retraining Therapy

Introduction

Tinnitus is the perception of noise without any external sound stimulation [1] and is most commonly associated with sound trauma, ageing, head injury, or damage to the ear structures [2]. Though there are inconsistencies in prevalence rates, tinnitus is more frequent in military veterans compared to the general population [3,4]. Tinnitus is often associated with loud noise exposure, which military personnel often experience during military service in addition to other hazards such as ototoxicity and trauma exposure [5]. Although the exact causes of tinnitus remain unclear, ample evidence highlights the profound impact of tinnitus on the lives of military personnel and veterans [6–8]. In service members and veterans, tinnitus has been associated with psychological difficulties including depression and anxiety, sleep difficulties, reduced job performance [6], and poorer general physical health [5]. Additionally, tinnitus treatment is estimated to cost the NHS approximately £750 million annually [9] and many individuals experience significant difficulties in accessing tinnitus treatment [10]. To our knowledge, there is no sound therapy intervention that offers a universally effective solution to tinnitus management [1,11–13] and many options are poorly researched [3,14]. Given the profound economic costs and barriers to treatment, the significant impact of tinnitus on the lives of military personnel and veterans, and the current lack of effective intervention, it is important to explore the feasibility of new interventions.

There are numerous tinnitus management strategies which include psychotherapies (e.g., cognitive behavioural therapy, acceptance and commitment therapy), sound-based interventions (e.g., Tinnitus Retraining Therapy – TRT), hearing devices (e.g., hearing aids and cochlear implants), neurofeedback and neuromodulation techniques, pharmacological and physical therapies, as well as emerging virtual and digital technologies (e.g., virtual reality) [15]. Expanding on sound therapy, a scoping review exploring various sound-based tinnitus interventions highlighted their potential in suppressing tinnitus symptoms [1]. Notably, this same review illuminated the need for further research evaluating the effectiveness of different sound therapy techniques [1].

Though there are differences in sound-based interventions, potential benefits include masking (i.e., reducing the perceived noise of the tinnitus), distraction (diverting one's attention away from the tinnitus), relaxation (stress reduction), sound enrichment (adding external sound to lessen the impact of tinnitus), and habituation (gradually reducing the perceptual salience of tinnitus) [16,17]. Sound interventions are widely used and generally well-accepted by patients, likely due to their simplicity and non-invasive nature [1]. Supporting their effectiveness, a network meta-analysis illustrated how sound stimulation alone performed better than medication alone, educational intervention alone, and no treatment [18]. Interestingly, combination therapy (e.g., sound stimulation and educational consultation) resulted in significantly better outcomes in reducing tinnitus symptoms in comparison to individual treatments [18].

Figure 1. TinniSoothe device worn around the neck during the day (**left**) and beside the bed at night (**right**). Photos courtesy TinniSoothe

There are various methods of sound-based tinnitus interventions such as TRT, which combines both sound stimulation with structured counselling to promote habituation [1,11]. Tinnitus Retraining Therapy involves structured counselling that is typically delivered over a period of 6 to 18 months [19]. The Habituation Theory [20] proposes that the negative interpretation of tinnitus leads to dysfunctional cognitive processing and distress. It proposes that to function effectively, the brain needs to select which stimulus to attend to and which to ignore. Thus, if the tinnitus is subjective, the development of tinnitus tolerance is the process of habituation. Interestingly, the US Department of Veterans affairs recommend a stepped-care model for tinnitus management, namely Progressive Tinnitus Management [21]. Similar to Tinnitus Retraining Therapy, Progressive Tinnitus Management integrates sound therapy with counselling and aims to reduce tinnitus-related distress. As both require counselling over multiple sessions, there is a need to explore potential sound-based interventions that do not require counselling.

The current project aims to explore the feasibility and acceptability of a non-invasive sound therapy, a wearable white-noise device that may be a promising alternative approach –Tinnisoothe [22]. This device is designed to deliver comfortable, discreet relief from tinnitus symptoms, and may offer more immediate support compared to other tinnitus interventions. This non-invasive device, shown in **Figure 1**, aims to reduce the perception of tinnitus and the attention directed towards it, thus providing relief [22]. TinniSoothe produces gentle, highly configurable white noise and can be used continuously for 24 hours without requiring anything in or around the ear. This device is a small module, designed to be worn on a lanyard or clip during the day and in a docking station at night, where it recharges while continuing to emit sound through its speaker, facilitating 24/7 use. The frequency and volume of the module can be adjusted according to personal preferences for daytime and nighttime use. The device is designed to combine two approaches: (a) distraction, by using external sounds to shift attention away from tinnitus, and (b) habituation, which gradually helps the brain reclassify tinnitus as an insignificant sound.

The device is patented with the UK Intellectual Property Office and is certified by the UK Medicines and Healthcare products Regulatory Authority, and may provide accessible and functional relief of tinnitus symptoms. To date, there has been no specific research into its feasibility or acceptability.

Material and methods

Participation in the current study was subject to providing written informed consent. The study was subject to approval by the University of Bath ethics committee (# 6783-10218).

Trial objectives and study design

The aim of the trial was to investigate the feasibility and acceptability of a non-invasive sound device for tinnitus in a sample of 20 UK military veterans. The device is called TinniSoothe [22]. The study was a single arm, within-participants exploratory design, taking place between November 2024 and July 2025. Recruitment for the trial took 16 days.

Sample size

This study was an acceptability, feasibility, and safety trial. Our target sample size of 20 allowed us to explore feasibility outcomes such as whether the sample can be recruited and participant retention. A power calculation was not justified as this was an acceptability and feasibility trial.

Recruitment

Participants were recruited through convenience sampling methods. This involved social media posts on LinkedIn, Facebook, and Instagram by Combat Stress, a national UK veterans mental health charity. The charity offers clinical mental health services to UK veterans.

Table 1. Inclusion and exclusion criteria

Inclusion criteria	
1	Above the age of 18
2	Fluent in speaking and reading English
3	UK Armed Forces veteran
4	Persistent tinnitus for at least 3 months (participants had to confirm constant ringing or buzzing, bilateral or unilateral, lasting longer than 3 months)
5	Able to receive the device to their registered address
6	Able to follow study instructions
7	Sign the written consent form prior to any study-related procedures being performed
Exclusion criteria	
1	Below 18 years of age
2	Individuals who have already habituated to tinnitus, defined as those who report that their tinnitus is no longer bothersome or intrusive in daily life
3	Veterans receiving concurrent treatment for tinnitus (e.g., other wearable devices or ongoing audiological therapies)
4	Active self-harm or suicidal ideation
5	Severe psychotic disorder, dissociative identity disorder, or other severe mental health difficulty
6	Current alcohol or drug-use disorder or dependency requiring further support or treatment that would significantly impact treatment engagement
7	Unwilling and/or unable to provide informed consent

Screening and assessment

Interested participants completed a brief pre-screening questionnaire on SurveyMonkey that confirmed they had experienced tinnitus for at least 3 months. If an interested participant did not conform with the inclusion criteria at pre-screening, the veteran was thanked for their interest and given resources to support services. Eligible participants who met the pre-screening criteria were emailed the participant information sheet. As part of the consent procedure, participants were asked to accept a telephone call from the research assistant in which they were taken through the participant information sheet and given the opportunity to ask questions. During this call, the research assistant assessed and confirmed the participant's suitability based on their current goals. If the participant was eligible and interested, the participant was emailed a link to the baseline questionnaire via SurveyMonkey which included the consent form.

Inclusion and exclusion criteria

The initial screening questionnaire confirmed that veterans had experienced a constant ringing or buzzing (bilateral or unilateral) lasting longer than 3 months. The full inclusion and exclusion criteria are set out in **Table 1**.

Preparatory phase

The baseline survey incorporated questions assessing demographics (e.g., age, gender), in addition to the following measures: Tinnitus Functional Index (TFI) [23]; PTSD Checklist for DSM-IV Short Version (Short form PCL-5) [24]; Insomnia Severity Index (ISI) [25]; Patient Health Questionnaire-15 (PHQ-15) [26]; Satisfaction with Life Scale (SWLS) [27]; and the General Health Questionnaire-12 (GHQ-12) [28]. Additionally, hearing loss in each ear was assessed via a self-report question where participants were asked "If you are aware of your hearing loss and this has been assessed by an audiologist, at what level is your hearing loss in each ear? Please note: If you have not been assessed by an audiologist or are unsure, please tick 'Unsure.'" Participants were provided with guidance based on the British Society of Audiology definitions of hearing loss, with decibel hearing level ranges for each category as follows: Mild (21–40 dB), Moderate (41–70 dB), Severe (71–96 dB), and Profound (95+ dB). Participants were also asked if they have hearing aids and if so, in which ears.

After eligible participants completed the baseline questionnaire and consent form, the tinnitus device was sent to their address. This meant that the location of the feasibility trial was in the participant's usual environment. The package sent included: (a) the TinniSoothe module, (b) user instruction manual, (c) docking station, (d) lanyard, and (e) clothing pin. The research assistant scheduled a one-on-one phone call with each participant upon receiving the device, providing guidance on its setup and usage. The veteran was instructed to use the device for a period of 1 month (i.e., wear the device around their neck during the day and dock the device to the docking station at night). The research team was available throughout the trial period if any assistance was required.

Table 2. Measures administered at baseline, 1-month post-intervention, and 2-months follow-up

Measure	Baseline	1-month post-intervention questionnaire	2-month follow-up questionnaire
Demographics (e.g., age, sex, gender, employment status, military branch)	X		
TFI	X	X	X
Short form PCL-5	X	X	X
ISI	X	X	X
PHQ-15	X	X	X
SWLS	X	X	X
GHQ-12	X	X	X
Qualitative questionnaire assessing the TinniSoothe		X	

Note: X marks the time points when each questionnaire was sent to participants

Questionnaires

Participants were asked to complete a post-intervention questionnaire (i.e., 28 days post baseline) and a 2-month follow-up questionnaire. After completing the 28-day intervention period, veterans were given the option to keep or return the device. All participants, irrespective of device retention, were asked to complete the 2-month follow-up questionnaire in order to assess post-intervention outcomes following the 1-month exposure. While the 2-month follow-up provided information on continued device use, this was intended to observe patterns of engagement rather than assess longer-term effectiveness. Both questionnaires included the following measures: TFI [23], Short form PCL-5 [24], ISI [25], PHQ-15 [26], SWLS [27], and the GHQ-12 [28]. These questionnaires are listed in **Table 2** and outcome measures described below. Participants were asked to complete another questionnaire which comprised of qualitative questions assessing the device (e.g., the comfort level, how often they used the device etc.) at post-intervention. All instructions confirmed that the questionnaires were voluntary. All surveys were completed on SurveyMonkey, and participants were contacted via email asking them to complete the surveys. Consent was reaffirmed at all questionnaire timepoints via SurveyMonkey. Participants were able to withdraw data at any point up to 2 weeks after the final questionnaire was completed. From 2 weeks after the final survey, withdrawal was no longer possible due to data having then been anonymised.

Outcomes

An overview of the outcome measures collected throughout the study is set out in **Table 2**.

Feasibility

Feasibility was explored by assessing the ability to recruit the target sample of 20 participants (i.e., yes if the sample was recruited and no if it was not) and by participant retention (i.e., the proportion of participants who completed the study out of the total number of participants).

Acceptability

The device acceptability was assessed through the post-intervention qualitative questionnaire. This questionnaire included questions exploring participants' experience of the device (e.g., rating satisfaction of the usefulness of the device during the day and at night). Participants were asked whether they experienced any adverse effects and potential recommendations. Responses were a mixture of multiple choice and free text.

Primary Outcome Measure

TFI [23]: A 25-item measure assessing the severity and impact of tinnitus symptoms, with higher scores indicating greater tinnitus-related distress and functional impairment. Though the TFI includes 8 subscales, the present study only focused on the overall TFI score.

Secondary Outcome Measures

1. Short form PCL-5 [24]: A four-item measure assessing the presence of PTSD symptoms according to the DSM-IV criteria, with higher scores indicating greater symptom severity.
2. ISI [25]: A 7-item measure assessing current sleep difficulties, with higher scores indicating more severe insomnia symptoms.
3. PHQ-15 [26]: A 15-item measure assessing physical health and somatic symptoms, with higher scores indicating greater somatic symptoms.
4. SWLS [27]: A 5-item measure assessing life satisfaction, with higher scores indicating greater life satisfaction.
5. GHQ-12 [28]: A 12-item measure of potential mental health issues, primarily focusing on depression or anxiety, with higher scores indicating worse mental health. The GHQ-12 was assessed using a Likert scale (0, 1, 2, 3).

Statistical analyses

Analyses were conducted using RStudio version 4.4.3 (2025-02-28). The feasibility outcomes of the study were firstly reported as descriptive statistics. To assess the

Table 3. Sociodemographic characteristics of the sample ($n = 20$)

Variable	*n* (%)
Age	*M* = 51.3, *SD* = 7.7
Sex	
Male	16 (80%)
Female	4 (20%)
Education level	
School until 16 years / GCSE	3 (15%)
Further education (e.g., college, vocational training)	7 (35%)
Higher education (undergraduate degree)	5 (25%)
Master's degree	5 (25%)
Doctoral degree (PhD, MD, etc.)	
Ethnicity	
White British	20 (100%)
Employment status	
Employed full-time	11 (55%)
Employed part-time	2 (10%)
Self-employed/freelance	4 (20%)
Not working, looking after the home	1 (5%)
Not working, seeking employment	1 (5%)
Voluntary work	1 (5%)
Relationship status	
Married or living with a partner	15 (72%)
Single	2 (10%)
Divorced	2 (10%)
Widowed	1 (5%)
Military branch	
Army	12 (60%)
Royal Navy	6 (30%)
Royal Airforce	2 (10%)

primary and secondary outcomes of the study, scores at baseline were compared to the scores at 1-month post-intervention and at 2-month follow-up. Normality of each outcome measure at each timepoint was assessed using the Shapiro–Wilk test. For outcomes that met the normality assumption, repeated-measures ANOVA was conducted to evaluate changes across baseline, post-intervention, and follow-up. For outcomes that violated the normality assumption, the non-parametric Friedman test was used. Where the repeated-measures ANOVA indicated a significant main effect of time, pairwise comparisons were conducted with Bonferroni correction. For outcomes analysed with the Friedman test, post hoc pairwise comparisons using Wilcoxon signed-rank tests were performed when appropriate. All tests were performed at a significance level (α) of 0.05. All measures required complete item responses; thus, no item-level missing data were present. Participants who did not complete a questionnaire at a given timepoint were excluded from the corresponding repeated-measures analyses (complete-case analysis).

Results

Participants

Overall, 20 participants (mean age = 51.3; *SD* = 7.7) completed the study. The majority were male (80%) and had served in the army (60%); all participants were White British. The sample sociodemographic characteristics are presented in **Table 3**, and the specific hearing-related characteristics are shown in **Table 4**. All participants reported having experienced tinnitus for 12 months or more. None of the 20 participants who enrolled in the study dropped out of using TinniSoothe in the first month. At the end of the intervention period, 5 participants elected to return the device. There were 2 participants who were lost to the 2-month follow-up.

Table 4. Hearing characteristics of the sample ($n = 20$)

Variable	*n* (%)
Right hearing loss	
No	5 (25%)
Mild	2 (10%)
Moderate	4 (20%)
Unsure/have not been assessed by an audiologist	9 (45%)
Left hearing loss	
No	5 (25%)
Mild	3 (15%)
Moderate	4 (20%)
Unsure/have not been assessed by an audiologist	8 (40%)
Hearing aids	
Yes: both ears	6 (30%)
Yes: right ear (only)	2 (10%)
Yes: left ear (only)	0 (0%)
No	12 (60%)

Table 5. Device usability at 1-month post-intervention ($n = 20$)

Please answer the following by rating how satisfied/dissatisfied you were with the device in these different aspects	Dissatisfied/neutral *n* (%)	Satisfied *n* (%)
Usefulness of the device during the day	4 (20%)	16 (80%)
Usefulness of the device at night	11 (55%)	9 (45%)
Volume of the device	6 (30%)	14 (70%)
Weight of the device	0 (0%)	20 (100%)
Usability of the device	2 (10%)	18 (90%)
The process to set the device to your personal level	6 (30%)	14 (70%)
Instructions to use the device	1 (5%)	19 (95%)

At the 1-month post-intervention, 8 participants (40%) reported they used the device *most of the time* (20–23 hours per day), followed by *all of the time* (24/7 as instructed; 25%), *frequently* (16–19 hours per day; 20%), and *occasionally* (8–15 hours per day; 15%). At this timepoint, participants reported high satisfaction across multiple usability domains (**Table 5**). Satisfaction was highest for the weight of the device, with all participants rating it as *satisfied*. Similarly, 95% of participants reported being *satisfied* with the instructions for using the device, while 90% reported being *satisfied* with its usability. Notably, the usefulness of the device at night indicated more mixed feedback, with 55% reporting *some dissatisfaction/ neutral feelings,* and 45% expressing *satisfaction*. Other domains such as the process to set the device to your personal level and volume of the device indicated a broader spread but trended towards satisfaction, with the majority rating them as *satisfied*.

At 1-month post-intervention, 17 reported that others could hear the tinnitus device, and of those, 10 mentioned that others were bothered by it. The majority of participants (80%) reported that the tinnitus device did not help them return to activities, although there were 4 reports that the device did help. The majority of participants (80%) would recommend the device to friends and family. Additionally, most participants (90%) reported no adverse events. One participant reported a migraine, and another reported that they were more aware of their tinnitus because of the device. Of the 20 participants, 15 elected to keep using the device after the 1-month post-intervention period (5 elected to give the device back as they did not wish to continue using it). At the 2-month follow-up, 18 participants completed the questionnaire, even though 5 of them had elected to return the device after completion of the 28-day intervention period and therefore had not used it during the second month. Among the 13 who retained the device, usage

Table 6. Outcomes at baseline, 1-month post-intervention ($n = 20$, third column), and 2-month follow-up ($n = 18$, final column). Note that in the final column, 5 participants had already returned the device and thus did not use it during the second month; these 5 were retained in the analysis to reflect post-intervention outcomes following the initial intervention, which was the primary aim of the study

Variable	Baseline *M* (*SD*)	1-month post-intervention *M* (*SD*)	2-month follow-up *M* (*SD*)
TFI	58.72 (13.87)	45.66 (17.51)	40.51 (16.38)
Short form PCL-5	2.85 (3.01)	3.00 (3.32)	3.22 (3.45)
ISI	13.15 (5.00)	10.85 (5.82)	9.17 (6.46)
PHQ-15	6.75 (4.33)	6.45 (4.94)	5.83 (4.67)
SWLS	22.35 (6.67)	22.35 (8.13)	23.94 (7.53)
GHQ-12	13.75 (6.09)	11.35 (5.54)	11.22 (6.21)

during the follow-up varied: 3 used it *all of the time* (24/7 as instructed), 1 *most of the time* (20–23 hours per day), 3 *frequently* (16–19 hours per day), 3 *occasionally* (8–15 hours per day), and 3 used it *rarely* (1–7 hours per day). Two participants were lost to follow-up.

The mean changes for each of the primary outcomes are presented in **Table 6**. As the TFI and ISI scores met the assumption of normality, repeated-measures ANOVAs were conducted. For measures that violated the assumption of normality, including the SWLS, PHQ-15, GHQ-12, and the Short form PCL-5, the non-parametric Friedman test was used to compare scores across timepoints. Participants showed significant improvements in tinnitus symptoms (TFI) across the three time points, as indicated by a repeated-measures ANOVA (sphericity violated, Greenhouse–Geisser corrected), $F = 9.37$, $p = 0.003$. Post hoc paired *t*-tests with Bonferroni correction revealed that TFI scores decreased significantly from baseline to post-intervention ($p = 0.020$) and from baseline to 2-month follow-up ($p = 0.014$), with no significant change between post-intervention and follow-up ($p = 0.303$). Participants showed a significant overall effect of time on sleep disturbances (ISI) across the three time points, as indicated by a repeated-measures ANOVA (sphericity violated, Greenhouse–Geisser corrected, $F = 5.24$, $p = 0.020$). However, post hoc paired *t*-tests with Bonferroni correction revealed no statistically significant changes between neighbouring time points. No significant changes were observed across time in life satisfaction (SWLS; $\chi^2 = 2.58$, $p = 0.276$), somatic symptoms (PHQ-15; $\chi^2 = 0.95$, $p = 0.621$), general mental health difficulties (GHQ-12; $\chi^2 = 4.03$, $p = 0.133$), or post-traumatic stress symptoms (Short form PCL-5; $\chi^2 = 1.68$, $p = 0.431$).

Discussion

This study has explored the feasibility and acceptability of a new non-invasive sound therapy white noise device. There appeared to be evidence of acceptability and feasibility with all participants using the device for the 1-month period, with no dropouts or serious adverse events (two minor adverse events). Additionally, 15 participants (75%) elected to continue using the device after the 1-month trial ended and 16 participants (80%) reported they would recommend the device to friends and family. On the other hand, long-term usage of the device is unknown, with just 13 of the 20 participants continuing beyond the first month (5 gave it back and 2 were lost to follow-up); 3 of those 13 said they used the device rarely (1–7 hours per day). That is, at the final point of contact, there were just 13 active users remaining out of the original 20, so further investigation of efficacy is needed.

This study addresses a key gap by exploring the feasibility and acceptability of a non-invasive sound therapy device in a UK veteran population. Prior research involving trauma-focused treatment trials for military personnel and veterans highlights how treatment dropout is often higher than in trials among the general population [29,30]. Though the current sample was not trauma-focused, a veteran sample may have predicted similar attrition. Veterans may dropout for various reasons such as work conflicts, perceived treatment ineffectiveness, concerns with confidentiality, and stigma-related concerns [30]. However, all participants completed the one-month intervention period with no dropouts. This highlights the feasibility and acceptability of this non-invasive device in this population. Since there were no serious adverse events reported, this illustrates how this non-invasive device is unlikely to cause harm. At the 2-month follow-up, continued use of the device declined relative to the intervention period. There were 5 participants who elected to return the device at the end of the 28-day intervention and 2 were lost to follow-up, leaving 13 remaining active users.

While the overall satisfaction for the device was high, limitations of the device should be noted. Firstly, the usefulness of the device at night received relatively mixed feedback, with 55% of participants reporting dissatisfaction. Further, some participants reported the device could be heard by others, and in 59% of these participants, this caused some disturbance, indicating a potential limitation of this device in social environments. As such, though the device was generally acceptable, improvements in night-time functionality and sound masking may enhance its adoption.

Nonetheless, the results suggest tentative evidence of efficacy with respect to the primary outcome and potential secondary outcomes. Specifically, participants showed

statistically significant improvements in tinnitus symptoms across the three time points, with scores significantly improving from baseline to post-intervention and from baseline to follow-up.

For sleep disturbances, although there was a significant overall effect of time, pairwise comparisons between timepoints were not statistically significant. This improvement may reflect the proposed mechanism of action, whereby the non-invasive device attempts to facilitate both distraction and habituation. By introducing a consistent white noise sound, participants may have experienced reduced attentional focus on the tinnitus and thus a gradual reduction in tinnitus salience. While the data suggests potential improvements in outcomes, since there is no comparator group in the current study, results should be interpreted with caution and seen as tentative evidence on the potential effectiveness of the device.

Interestingly, prior research has indicated the benefit of sound therapy in suppressing tinnitus symptoms [1,18,31–33] and thus, further research is needed to explore the effectiveness of the TinniSoothe device. Additionally, there is currently limited consensus on the effectiveness of sound therapy in tinnitus management [34], further highlighting the need for more research.

In respect to the remaining secondary outcomes, the results indicated no significant change. This is unsurprising, given that the non-invasive device aims to reduce symptoms of tinnitus rather than targeting secondary outcomes. Notably, as participants reported varying levels of device use during the month following the intervention, follow-up findings should be interpreted with caution. It was outside the scope of this feasibility trial to explore the matter further. Additionally, the above findings should be interpreted cautiously as the design of the study (no comparator group) means that the efficacy of the device could not be assessed.

Limitations

The study included male and female veterans and implemented a range of questionnaires to assess both their experiences using the device and their mental health and wellbeing outcomes, providing comprehensive insight into their perspectives. However, there were several limitations. Firstly, the convenience sample recruitment method could potentially introduce biases as it was not randomly selected. Given the small number of veterans, the representativeness is limited which may restrict the generalisability to the broader veteran population. Further, as it was out of the scope of the study to include a comparator group, the findings do not provide insight into the effectiveness of this device. Additionally, the study did not include a screening measure to rule out tinnitus arising from temporary or secondary causes (e.g., ear infection, impacted cerumen), which may have reduced the consistency of the sample, although all participants reported experiencing tinnitus for 12 months or longer. Nonetheless, future research should incorporate screening questions to ensure tinnitus is not attributable to reversible or identifiable factors. Additionally, while all participants who completed the 2-month follow-up questionnaire ($n = 18$) were included in the analysis, 5 had returned the device after the 1-month intervention and therefore reported no device use during the follow-up period. This will affect interpretation of outcomes beyond the primary intervention period. Finally, future research should recruit a larger sample and incorporate a comparator group to explore the effectiveness of this device over a longer time-frame.

Conclusions

This study presents evidence that TinniSoothe offers a broadly acceptable, feasible, and safe intervention for tinnitus management. Patients who used the non-invasive device for 1 month reported a significant reduction in tinnitus symptoms from baseline to post-intervention and from baseline to 2-month follow-up. However, with 13 of the 20 participants reporting continued device use at the 2-month follow-up, variability in sustained engagement highlights differences in user adherence after the intervention period. A larger randomised study exploring the effectiveness of this device is necessary to explore whether TinniSoothe can be recommended.

Ethics and dissemination

Participation was subject to providing written informed consent. The study was subject to approval by the University of Bath ethics committee (#6783-10218). Throughout the trial, participants personal information was password protected, with access limited to the Combat Stress study team. Participants were allocated a unique ID, with all data stored and references made to this ID. All personally identifiable information was only seen by the Combat Stress research team and data was anonymised prior to analysis.

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Competing interests

The authors declare they have no competing interests.

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