



# Evaluating a tinnitus device for reducing tinnitus symptoms and mental health difficulties in veterans: waitlist-controlled trial protocol

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## Abstract

The prevalence of tinnitus in veterans is notably higher than in the general population and can significantly disrupt daily life. Given the impact of tinnitus, along with the lack of effective interventions, exploring new approaches is warranted. Wearable sound technologies offer a non-invasive and easily accessible approach. However, limited research has explored the effectiveness of sound therapy in UK veterans. A prior study supported the feasibility and acceptability of a non-invasive wearable device (i.e., TinniSoothe) in a sample of veterans. However, a waitlist-controlled trial is needed to investigate the effectiveness of the device. This waitlist-controlled trial aims to explore the effectiveness of a wearable device in reducing tinnitus symptoms in a sample of UK veterans. Veterans will be randomly allocated to one of two conditions: (1) the immediate intervention condition, which receives the device post-randomisation, or (2) the waitlist control group, which receives the device one-month post-randomisation. The trial will be conducted in veterans ( $n = 20$ ) who have experienced tinnitus. Participants will be asked to use the device for one month. The immediate intervention group will be compared to the waitlist control group. The primary outcome is change in tinnitus severity (Tinnitus Functional Index, TFI) and mental health (General Health Questionnaire-12, GHQ-12) from baseline to one-month post-randomisation. Primary and secondary outcomes will be assessed at all timepoints (baseline, one-month post-randomisation, and two-month post-randomisation), while predictor variables will only be assessed at baseline to reduce participant burden. Recruitment will begin in October 2025. The study is expected to take 12 months, with results published in 2027. This study explores whether a wearable device is efficacious in reducing self-reported symptoms of tinnitus in comparison to a waitlist control group. This innovative approach, if successful, could offer a practical option for reducing tinnitus distress. The trial is registered on [clinicaltrials.gov](https://clinicaltrials.gov), identifier: NCT06905158.



## Keywords

sound device, tinnitus, veterans, wearable technology

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## Introduction

Tinnitus is the perception of sound with no external sound source [1] and is more common in the veteran population compared to the general population [2, 3]. Tinnitus can manifest as various sounds such as buzzing, hissing, ringing, or tonal noises. Though the exact causes of tinnitus are unknown, tinnitus is often associated with noise exposure, which military personnel may experience during their military service, in addition to other hazards, including trauma exposure and ototoxicity [4]. For example, tinnitus is the most prevalent in-service disability in US veterans [5, 6], and individuals with past military service are estimated to be about double the risk of experiencing tinnitus compared to their civilian counterparts [7, 8]. Prior evidence highlights the profound impact tinnitus can have on the lives of military personnel and veterans, as tinnitus has been significantly associated with depression, anxiety, sleep difficulties, and job performance [9], in addition to poorer general physical health [4]. As such, tinnitus can have a profound impact on one's quality of life [10]. For example, in the US, veterans diagnosed with tinnitus are twice as likely as veterans without tinnitus to be diagnosed with mental health or behavioural disorders such as substance use disorders, PTSD, depression, and anxiety [11]. However, there is still no treatment or intervention that has been found to be consistently effective for most people [12]. Further, many individuals report barriers and challenges in accessing tinnitus treatment [13]. As such, there is a need to explore the effectiveness of alternative approaches.

Examples of approaches for tinnitus management include psychotherapies such as acceptance and commitment therapy, sound-based therapies, neurofeedback, neuromodulation techniques, hearing devices such as cochlear implants, pharmacotherapy, and emerging digital solutions [14]. As sound-based interventions are non-invasive and easily acceptable, they may provide a promising avenue for tinnitus management [1]. Though prior research has supported the potential use of sound-based interventions in managing symptoms of tinnitus, there has been limited research in the veteran population [15]. As such, there is a need to investigate the potential efficacy of sound-based therapies in the veteran population.

A prior study supported the feasibility and acceptability of a small, non-invasive wearable technological device (i.e., TinniSoothe) in a sample of veterans. This device is designed to provide comfortable and discreet relief of tinnitus symptoms by using sound therapy [16]. In this trial, all participants used the device for a one-month intervention period, with no dropouts or serious adverse events (submitted Journal of Hearing Science-under review). The majority of participants elected to keep the device and reported they would recommend it to friends and family. This non-invasive device attempts to reduce the perception of tinnitus and attention paid to it, thereby providing relief [16]. This white noise device produces highly configurable volume and frequency settings, tailored to personal preferences, and can be used continuously, day or night, without the need for anything in or on the ear [16]. This device is designed to be effective with two mechanisms: (1) distraction, using external white noise sound to shift an individual's attention away from tinnitus, and (2) habituation, helping the brain reclassify the tinnitus as not significant, thereby reducing distress. The device is patented with the UK Intellectual Property Office and is certified by the UK Medicines and Healthcare products Regulatory Authority. Though the device has been supported as feasible and acceptable (submitted Journal of Hearing Science-under review), there is a need to conduct a waitlist-controlled trial to determine the efficacy of the device.

The aim of this exploratory waitlist-controlled trial is to assess the efficacy of a non-invasive sound intervention in reducing self-reported symptoms of tinnitus between baseline and the one-month post-randomisation (day 28) among UK veterans who experience tinnitus.

## Materials

### Trial objectives and design

This waitlist-controlled trial aims to explore the efficacy of a non-invasive wearable tinnitus device in reducing tinnitus symptoms in UK military veterans compared to a waitlist control group. This device is named TinniSoothe v1.0, Wearable Module & Docking Cradle, made in Britain. The manufacturer is TinniSoothe Limited. This waitlist-controlled trial will take place between October 2025 and October 2026. Our target sample is UK military veterans ( $n = 20$ ) who have experienced tinnitus for at least three months prior to enrolment. Our primary objective is to evaluate the effectiveness of the non-invasive tinnitus device versus the waitlist control group in reducing the symptoms of tinnitus and mental health difficulties in UK veterans. The secondary objective is to explore whether improvements in tinnitus symptoms and mental health difficulties are maintained at later follow-ups for the immediate intervention group. Additionally, this study will explore whether the waitlist control group, once they receive the device, will experience similar or different rates of improvement compared to the immediate intervention group.

### Sample size

A power calculation is typically used to determine the sample needed to detect an effect of a given size with a certain degree of confidence. However, since this is a pilot exploratory study, no sample size calculation has been performed. Following a pragmatic approach and building on prior studies of tinnitus (e.g., [17, 18]), we aim to recruit 10 veterans per group (total sample = 20). This sample size will allow us to address our research question.

## Procedure

### Recruitment

Eligible veterans will be recruited from a sample of participants who previously completed a qualitative survey on their experience with tinnitus (submitted Journal of Hearing Science-under review) and elected to be contacted for future research on veterans. In the prior study (submitted Journal of Hearing Science-under review), recruitment was conducted through convenience sampling methods (social media feeds of a UK national veterans' mental health charity called Combat Stress). In the current study, potential participants will be incrementally emailed by the research assistant, asking if they would like to participate. A maximum of 20 participants (the target sample of this study) will be emailed at a time to ensure no participant is invited to participate and then denied participation. This approach may introduce selection bias, as participants who elected to be contacted about future tinnitus research in the veteran population may differ systematically from those who did not consent to be contacted. To mitigate this, we will document all participant demographic characteristics and compare them to the broader veteran population. As this is an exploratory study, findings may inform feasibility and the design of future trials, which may incorporate broader recruitment strategies.

### Screening and assessment

Potential participants will complete a brief screening survey in SurveyMonkey to confirm their interest in the trial and their contact details (i.e., telephone number and preferred time of contact). In this screening survey, participants are asked to confirm an experience of constant ringing or buzzing (bilateral or unilateral) lasting longer than three months. After completing the screening survey, eligible participants will receive the participant information sheet via email, followed by an individual phone call from the research assistant. During this call, each participant will be guided through the participant information sheet and given the opportunity to ask any questions. The research assistant will assess and confirm the potential participant's suitability for this trial based on their current situation and their goals. If the research assistant decides the participant's goals do not align with the current trial (e.g., they are not willing to use a noise device for a one-month period), the veteran will be thanked for their interest and given information about other potential support services. Eligible participants will be sent the baseline survey.

### Inclusion and exclusion criteria

The full inclusion and exclusion criteria are described in [Table 1](#).

**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 three months [participants with tinnitus had to confirm experience of constant ringing or buzzing (bilateral or unilateral) lasting longer than three months].
5	Able to receive the device at 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	Significant, severe, or profound hearing loss.
3	Individuals who have already habituated to tinnitus.
4	Veterans receiving concurrent treatment for tinnitus (e.g., other wearable devices or ongoing audiological therapies).
5	Active self-harm or suicidal ideation.
6	Severe psychotic disorder, dissociative identity disorder, or other severe mental health difficulty.
7	Current alcohol or drug-use disorder or dependency requiring further support or treatment that would significantly impact treatment engagement, as assessed clinician.
8	Unwilling and/or unable to provide informed consent.

### Assignment of interventions: allocation and blinding

After eligible participants complete the consent form and baseline questionnaire on SurveyMonkey, participants will be randomly allocated to one of the two conditions: (1) the immediate intervention, or (2) the waitlist control. The asymptotic maximal procedure will be employed to randomly allocate participants [19], and randomised lists will be generated using an online tool (<https://ctrandomization.cancer.gov/tool/>). The outcome of the randomisation will be emailed to each veteran.

### Interventions

Veterans randomised to the immediate intervention will be sent the device to their allocated address immediately, while those allocated to the waitlist control group will receive the device one-month post-randomisation.

At their scheduled time points, veterans will be sent the device to their registered address. As such, the location of this feasibility trial is in the participants' usual environment. The package sent to their address includes the following: (a) user instruction manual, (b) module, (c) docking station, (d) necklace, and (e) clothing pin. The research assistant will personally call each participant to guide them through the setup and usage of the device. Participants will be asked to use the device for a continuous period of one month (i.e., wear the device around their neck during the day and dock the device to the docking station at night). The research assistant will be available throughout the trial period in case the participant requires any assistance with the device.

### Questionnaires

Participants will be asked to complete a one-month post-randomisation questionnaire (i.e., 28 days post-randomisation) and a two-month post-randomisation questionnaire (i.e., 56 days post-randomisation). Though the baseline questionnaire will incorporate all measures (predictor and outcome measures), the one-month and two-month questionnaires will only include primary and secondary outcome measures (not predictor measures) to reduce participant burden. Specifically, the baseline questionnaire will include questions on demographics (e.g., age, gender), the Tinnitus Functional Index (TFI) [20], General Health

Questionnaire-12 (GHQ-12) [21], Insomnia Severity Index (ISI) [22], Satisfaction with Life Scale (SWLS) [23], PTSD Checklist for DSM-5 short version (PCL-5 short version) [24], as well as the Patient Health Questionnaire-15 (PHQ-15) [25]. However, the one-month post-randomisation and two-month post-randomisation will only include the TFI [20], GHQ-12 [21], ISI [22], and the SWLS [23]. All measures are fully described below. Participants will be asked to complete a questionnaire assessing the device (e.g., the comfort level, how often they used the device) after they use the device for a one-month period (one-month post-randomisation for the immediate intervention group and two-month post-randomisation for the waitlist control group). Participants will be instructed that survey completion is voluntary, and all responses will remain anonymous. All surveys will be completed on SurveyMonkey, and participants will be contacted by the research assistant to ask them to complete the surveys. Consent will be reaffirmed at all questionnaire timepoints via SurveyMonkey. Participants in both arms will be free to withdraw from the trial at any point for no reason. Notably, participants may withdraw data at any point up to two weeks after the final questionnaire, after which data will be anonymised.

Outcome measures

An overview of the outcome measures collected throughout the study is illustrated in Table 2. The primary outcomes of the study include the TFI [20] and the GHQ-12 [21]. The TFI [20] is a 25-item measure of tinnitus symptoms that has been supported as a reliable and valid measure in assessing the severity and functional impact of tinnitus [26, 27]. Secondly, the GHQ-12 [21] is a 12-item measure of potential mental health issues, including depression and anxiety, and has demonstrated robust reliability and validity across populations [28, 29]. The GHQ-12 is included to capture the broader mental health difficulties that may co-occur with tinnitus symptoms. Additionally, secondary outcomes include the SWLS [23], a 5-item measure of life satisfaction, and the ISI [22], a 7-item measure of current sleep problems. Thirdly, predictor measures (collected at baseline) include the PCL-5 short version [24], a brief 4-item measure of the presence of PTSD symptoms according to the DSM-IV, and the PHQ-15 [25], a 15-item measure of physical health and somatic symptoms. All of the secondary measures and predictor measures have shown positive psychometric properties [22–24, 30].

Table 2. Measures administered at baseline, one-month post-randomisation, and two-month post-randomisation.

Measure	Baseline	One-month post-randomisation	Two-month post-randomisation
Socio-demographics (i.e., age, marital status, service branch, years of service, reason for leaving service, etc.)	X		
PCL-5 short version	X		
PHQ-15	X		
TFI	X	X	X
GHQ-12	X	X	X
SWLS	X	X	X
ISI	X	X	X
Qualitative questionnaire assessing the non-invasive device		X (immediate intervention only)	X (waitlist control only)

X: represents the time points when each questionnaire was sent to participants; GHQ-12: General Health Questionnaire-12; ISI: Insomnia Severity Index; PCL-5 short version: PTSD Checklist for DSM-5 short version; PHQ-15: Patient Health Questionnaire-15; SWLS: Satisfaction with Life Scale; TFI: Tinnitus Functional Index.

Finally, the acceptability of the device will be assessed through a qualitative questionnaire administered post-intervention. This incorporates multiple dimensions of user experience, including the frequency of device use, satisfaction with various aspects of the device (e.g., volume, weight, instructions, usefulness, usability), and potential adverse effects. Participants will be asked about the integration of the device into their daily life, such as whether it helped them return to previously avoided activities, in addition to whether family and friends can hear the device, and if it bothers them. Further, participants will be invited to provide feedback, including the potential addition of alternative sounds (e.g., pink noise) as

well as other recommendations and general comments on what they most like about the device. Finally, participants will be asked whether they would recommend the device to others and whether they would use it in the future. As such, this post-intervention survey will provide insight into user satisfaction, perceived effectiveness, and practical considerations. Responses will be a mixture of multiple choice and free text.

## Expected results

### Planned statistical analyses

RStudio will be used to analyse the data. Descriptive statistics will be calculated for baseline, one-month post-randomisation, and two-month post-randomisation. Additionally, the effectiveness of the device will be assessed by examining changes in primary and secondary outcomes from baseline to one-month post-randomisation and two-month post-randomisation. Paired *t*-tests will be used to assess within-group changes from baseline to follow-up, and between-group differences will be assessed using independent *t*-tests. If the normality assumption for the Student's *t*-test is not met based on the Shapiro-Wilk test, testing will be conducted with the Wilcoxon signed-rank test. For achieving superiority, the observed *p*-value must be  $< 0.025$  for a one-sided hypothesis. Regression analyses will examine whether baseline predictor scores are associated with outcomes at one- and two-month post-randomisation. The qualitative results will be analysed using thematic analysis.

### Adverse events reporting

Protocols for managing any risk or safeguarding concerns will be followed, and potential adverse events will be recorded and monitored in accordance with the study's adverse-events protocol and Combat Stress standard operating procedures. Potential adverse events will be recorded and monitored by senior authors, and serious adverse events will be reported to the clinical lead within the organisation where recruitment is being conducted.

This study protocol describes the design of a waitlist-controlled trial which aims to assess the effectiveness of a non-invasive sound intervention in reducing self-reported symptoms of tinnitus between baseline and the one-month post-randomisation (day 28) among UK veterans who experience tinnitus. Findings from the proposed study will provide critical information on the effectiveness of this device in this population. As such, the current trial may provide a means to support an easily accessible, low-cost option for reducing tinnitus distress. Though this study will provide novel findings, limitations should be considered when interpreting the findings. Firstly, the convenience sample recruitment method could potentially introduce a sampling bias as the sample was selected from a prior study on tinnitus. Though this was an exploratory study, given the small sample of veterans, the representativeness is limited, reducing generalisability to the broader veteran population. Finally, the short follow-up period in this study limits the ability to evaluate the long-term effects of the intervention.

### Ethics and dissemination

Participation in this study is subject to providing written informed consent. This study was reviewed and approved by the local ethics committee of King's College London (LRS/RGO-24/25-48840). Throughout the trial, participants' personal information will be password-protected, with access limited to the Combat Stress study team. Each participant will be allocated a unique ID number, which will be used for data storage and references. All personally identifiable information will only be seen by the Combat Stress research team, and data will be anonymised prior to analysis.

A manuscript describing the results of the study will be submitted to a peer-reviewed journal. Any published materials will be checked for potentially identifiable information.



## Abbreviations

GHQ-12: General Health Questionnaire-12

ISI: Insomnia Severity Index

PCL-5 short version: PTSD Checklist for DSM-5 short version

PHQ-15: Patient Health Questionnaire-15

SWLS: Satisfaction with Life Scale

TFI: Tinnitus Functional Index

## Declarations

### Acknowledgments

While no direct funding was provided for the makers of the TinniSoothe device to support this project, we would like to acknowledge their generous support in discounting the TinniSoothe devices to the study team. We extend our deepest gratitude to all the veterans who participated in this research.

### Author contributions

PH: Conceptualization, Investigation, Writing—original draft, Writing—review & editing. DM: Conceptualization, Supervision, Writing—review & editing. Both authors read and approved the final submitted version.

### Conflicts of interest

The authors declare that they have no conflicts of interest. The authors confirm that the makers of the TinniSoothe device mentioned in the Acknowledgments have no conflicts of interest with the authors, and had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

### Ethical approval

The study in this protocol was reviewed and approved by the local ethics committee of King's College London (LRS/RGO-24/25-48840) and was registered as a clinical trial (registration number: NCT06905158). This study complies with the 2024 Declaration of Helsinki.

### Consent to participate

Informed consent to participate in the study will be obtained from all participants.

### Consent to publication

Not applicable.

### Availability of data and materials

The data that will support the findings of this study are not yet available as the study is ongoing. Upon completion, the data will be made available by the corresponding author upon reasonable request.

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