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TinnSpire: Personalised vagus nerve & sound stimulation for the treatment of tinnitus

Submission date
09/04/2026

Recruitment status
No longer recruiting

Registration date
15/04/2026

Overall study status
Completed

Last Edited
15/04/2026

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Tinnitus is the experience of hearing sounds such as ringing or buzzing when there is no external sound. It is common and can be very upsetting. Many people find that current treatments do not help enough. This study tests a new combined approach called TinnSpire. It brings together gentle electrical stimulation of the ear, sound therapy, and slow breathing exercises. The main aim is to find out if this combined approach is safe, practical, and acceptable for people with long lasting tinnitus. The results will be used to plan a larger study in the future.

Who can participate?
Adults aged 18 years or over can take part if they have had tinnitus for 6 months or more and their symptoms are moderate in severity. Participants need to understand English. Some people cannot take part, for example those with certain ear problems, severe hearing loss, some heart or neurological conditions, implanted medical devices, or people who are pregnant.

What does the study involve?
Each participant takes part for about 18 weeks. There are two in person assessment visits at the start, which include hearing tests and questionnaires. Participants then attend eight treatment sessions at a clinic over 4 weeks. Each session lasts about 40 to 50 minutes. During these sessions, participants receive mild electrical stimulation on the ear, listen to personalised sound therapy through headphones, and follow guided slow breathing exercises. Participants also complete questionnaires at home at several time points before treatment, after treatment, and at follow up.

What are the possible benefits and risks of participating?
Some participants may notice improvements in their tinnitus or stress levels, but this cannot be guaranteed. The risks are low. Possible side effects include temporary discomfort or tingling around the ear, mild dizziness during breathing exercises, or temporary changes in tinnitus or mood. Participants can stop a session or leave the study at any time.

Where is the study run from?
The study is run by Brighton and Sussex Medical School in partnership with University Hospitals Sussex NHS Foundation Trust. Study visits take place in Brighton and Worthing in England.

When is the study starting and how long is it expected to run for?
August 2024 to January 2025

Who is funding the study?
National Institute for Health and Care Research (UK).

Who is the main contact?
Dr Alan Sanderson, a.sanderson@bsms.ac.uk

Contact information

Type(s)
Principal investigator

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Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
336506

Central Portfolio Management System (CPMS)
61735

Study information

Scientific Title
TinnSpire: open-label, single arm, non-randomised, feasibility study of bimodal transcutaneous auricular vagus nerve stimulation & broadband shaped-noise sound therapy with slow resonant breathing for the treatment of tinnitus

Acronym
TinnSpire

Study objectives
Primary
Feasibility of combining bimodal stimulation of taVNS and (BSN) sound therapy with slow diaphragmatic breathing relaxation training course:
1. Safety
2. Feasibility of recruitment
3. Retention
4. Protocol Adherence

Secondary
Feasibility of collecting quantitative outcome data using the 4 measures proposed for future RCT.

Secondary objectives are to evaluate the feasibility of collecting patient outcome measures of tinnitus symptoms, psychological stress and physiological status.
The Tinnitus Functional Index (TFI) and Perceived Stress Scale (PSS) will be administered together, on-line or on paper at home/remotely at 5 timepoints before and after the 8 stimulation sessions and then at 6 and 12-weeks post stimulation sessions.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/05/2024, East of England - Cambridge South Research Ethics Committee (Equinox House City Link, Nottingham, NG2 4LA, United Kingdom; +44 207 104 8109; cambridgeeast.rec@hra.nhs.uk), ref: 24/EE/0069

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment

Single

Purpose
feasibility of intervention (transcutaneous auricular vagus nerve stimulation in combination with sound therapy and slow breathing) and study procedures.

Study type(s)

Health condition(s) or problem(s) studied
Chronic tinnitus

Interventions
The TinnSpire stimulation sessions have five elements. Firstly, participants will be asked to rate their tinnitus loudness on a VAS at the start of the session. Physiological data will then be collected using a medical grade 'Nexus 10' device, with finger photoplethysmography (PPG) and an abdominal respiration sensor. Five minutes and 15 seconds of data will be recorded.

Transcutaneous vagus nerve stimulation
The taVNS electrodes will be placed on the cymba concha of both ears using conductive gel, with headphones placed over the top. The taVNS parameter settings are consistent with the majority of other taVNS tinnitus studies, with a frequency of 25 Hz and a pulse width of 200 μs. Stimulation will be delivered using a commercially available TENS device, EM-6300A TENS/EMS (Med-Fit UK Ltd), CE 2460. To set the taVNS amplitude, a standard Parametric Estimation by Sequential Testing (PEST) method will be used to determine the individual's perceptual threshold, defined as the minimum current required to elicit a perceived sensation.

Broadband shaped-noise sound therapy
Auditory stimulation will be presented to each participant during the approximately 30 minute TinnSpire stimulation sessions. The stimuli will consist of a broadband signal of approximately 200 Hz to 8 kHz, with frequency-specific level adjustments matched to the participant's hearing threshold levels (HTL). Participants will be asked to select from different sound types, ranging from static unmodulated sounds such as white noise to natural modulated sounds such as ocean sounds, to avoid undesirable sound quality. Stimuli will be delivered using supra-aural headphones. The sound level will be adjusted by the participant to an audible and comfortable level.

Slow diaphragmatic resonant breathing
Once the taVNS amplitude and audio volume have been established, participants will be asked to sit still and breathe at six breaths per minute while watching a visual respiration pacer on a laptop. Participants will be instructed to breathe in as the graphic bar and line move up, and to breathe out as they move down. They will receive instruction in diaphragmatic breathing, slowly but not deeply. Slow breathing will be performed for five minutes, followed by a five minute rest period, and repeated twice more. This will result in three five minute trials of slow breathing during the approximately 30 minute stimulation period. Participants will be monitored by a member of the research team throughout the session.

Heart rate variability and respiration will be recorded during stimulation and for five minutes post-stimulation. Following this, the post-stimulus tinnitus loudness VAS will be administered. The participant will then be debriefed and the next session will be scheduled.

The session will last approximately 40 minutes. Participants will be asked to attend two sessions per week for four weeks. Where possible, participants will be asked to attend on the same days each week, for example Mondays and Thursdays, Tuesdays and Fridays, or Wednesdays and Saturdays.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
EM-6300A TENS/EMS (Med-Fit UK Ltd) CE 2460

Primary outcome(s)
1. Safety feasibility measure measured using Description statistics (count) at Week 1 session1, Week 1 Session 2, Week 2 Session 2, Week 2 Session 2, Week 3 Session 1, Week 3 Session 2, Week 4 Session 1, Week 4 Session 2, +6weeks, +12 weeks

2. Recruitment feasibility measure measured using Description statistics (proportion) at Week 1 session1, Week 1 Session 2, Week 2 Session 2, Week 2 Session 2, Week 3 Session 1, Week 3 Session 2, Week 4 Session 1, Week 4 Session 2, +6weeks, +12 weeks

3. Retention feasibility measure measured using Description statistics (proportion) at Week 1 session1, Week 1 Session 2, Week 2 Session 2, Week 2 Session 2, Week 3 Session 1, Week 3 Session 2, Week 4 Session 1, Week 4 Session 2, +6weeks, +12 weeks

4. Protocol adherence feasibility measure measured using Descriptive statistics (proportion) at Study completion

Key secondary outcome(s))
1. Tinnitus Functional Index measured using Questionnaire - Score mean at Week 1 session1, Week 1 Session 2, Week 2 Session 2, Week 2 Session 2, Week 3 Session 1, Week 3 Session 2, Week 4 Session 1, Week 4 Session 2.

2. Perceived Stress Scale measured using Questionnaire - Score mean at Week 1 session1, Week 1 Session 2, Week 2 Session 2, Week 2 Session 2, Week 3 Session 1, Week 3 Session 2, Week 4 Session 1, Week 4 Session 2.

3. Visual Analogue Scale (VAS) - tinnitus loudness measured using VAS - Score mean at Week 1 session1, Week 1 Session 2, Week 2 Session 2, Week 2 Session 2, Week 3 Session 1, Week 3 Session 2, Week 4 Session 1, Week 4 Session 2.

4. Heart Rate Variability measured using HRV SD2 at Week 1 session1, Week 1 Session 2, Week 2 Session 2, Week 2 Session 2, Week 3 Session 1, Week 3 Session 2, Week 4 Session 1, Week 4 Session 2.

Completion date
09/01/2025

Eligibility

Key inclusion criteria
1. Chronic subjective tinnitus (defined as tinnitus duration 6 months or more)
2. English speaking
3. Male and Female
4. ≥ 18 years
5. > 17 Tinnitus Functional Index Score

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
13

Key exclusion criteria
1. Active care in audiology for tinnitus
2. Objective tinnitus
3. Acute tinnitus
4. Pulsatile tinnitus
5. Conductive hearing loss
6. Active middle ear pathology (defined by audiological assessment)
7. Severe-to-profound sensori-neural hearing loss (defined by audiological assessment)
8. Ménière’s disease
9. Skin lesions or piercing or extensive tattooing of the concha or skin disease: infection or eczema of the ears
10. Active implant, e.g. ICD, pacemaker, neurostimulator, cochlear implant, and VP shunt
11. Ongoing vagal nerve stimulation or s.p. vagotomy
12. Progressive neurological disease (e.g. Parkinson’s, epilepsy, multiple sclerosis)
13. Relevant cardiac disease, e.g. bradycardic arrhythmia, insufficiency, and s.p. infarction
14. Severe psychiatric disease (e.g. schizophrenia)
15. Pregnant
16. Breathing-related difficulties (e.g. COPD, emphysema, or asthma)
17. Raynaud's disease
18. Beta blockers
19. Involvement in any clinical study within the last 28 days

Date of first enrolment

14/08/2024

Date of final enrolment
04/09/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Worthing Hospital
Lyndhurst Road
Worthing
England
BN11 2DH

Study participating centre
University of Sussex
Sussex House
Falmer
Southern Ring Road
Brighton
Sussex
England
BN1 9RH

Sponsor information

Organisation
University of Sussex

ROR
https://ror.org/00ayhx656

Funder(s)

Funder type

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available