ISRCTN18213400 https://doi.org/10.1186/ISRCTN18213400

Does use of the MindEar app reduce tinnitus-related distress in patients awaiting tinnitus therapy?

Submission date
13/01/2026

Recruitment status
No longer recruiting

Registration date
21/01/2026

Overall study status
Completed

Last Edited
20/01/2026

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
Research has shown that cognitive behavioural therapy (CBT) is effective in reducing the amount of distress people feel related to their tinnitus. Over the past two decades, CBT delivered online has shown to be effective as well as in-person. MindEar is a mobile phone app designed to help people manage their tinnitus using the principles of CBT.
Waiting lists to see a tinnitus specialist on the NHS tend to be long, and many people with tinnitus become more anxious or distressed while they are waiting for their appointment. The aim of this study is to investigate any effects on tinnitus distress of using the MindEar app while awaiting therapy. This study is taking place in just one hospital. We hope it will help us design a larger-scale study on the same topic in future

Who can participate?
Patients aged 18 years and over who have been referred to the Royal National Ear Nose and Throat Hospital in London because of tinnitus, had a medical assessment with an Ear Nose and Throat doctor and been referred to the Hearing Therapy department for help with their tinnitus.

What does the study involve?
Participants are put into one of two groups. One group is given free access to the MindEar app and instructions to use it regularly (between 5 and 10 minutes every day) for at least eight weeks while waiting for a tinnitus therapy appointment. There are a variety of activities in the app, such as challenging your negative thoughts, listening to nature sounds and learning relaxation exercises. The other group won't be given access to the app and should not download it.
People in both groups need to fill in a set of questionnaires about their tinnitus and how they are feeling when they join the study, and again 2-3 months later. Those patients who did not get access to the app will be able to download it for free at the end of the study (after they have attended their first hearing therapy appointment).

What are the possible benefits and risks of participating?
Using the MindEar app might help people manage tinnitus better and feel less distressed before

attending tinnitus therapy.
It is possible that using the app or filling in the questionnaires might make people think about tinnitus at times when they might not otherwise be thinking about it. Sometimes, people find answering questions about their mental health upsetting.

Where is the study run from?
The study is run from the Royal National Ear Nose and Throat Hospital, which is part of University College London Hospitals NHS Trust (UCLH) (UK)

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

Who is funding the study?
ENT UK

Who is the main contact?
Dr Lucy Handscomb, l.handscomb@ucl.ac.uk

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Dr Lucy Handscomb

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Additional identifiers

Study information

Scientific Title
Does use of the MindEar app reduce tinnitus-related distress in patients awaiting tinnitus therapy?

Acronym
STOP-T

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/08/2024, Wales Research Ethics Committee 5 (Health and Care Research Wales Castlebridge 4 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)2920 230457; Wales.REC5@wales.nhs.uk), ref: 317132

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Dose comparison

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Tinnitus

Interventions
The digital therapeutic called MindEar- delivered through a mobile app - provides therapies using the principles of Cognitive Behavioural Therapy (CBT), mindfulness, psycho-education and sound therapy.

All participants will be allocated to either an intervention or a control group. For the intervention group, MindEar will be offered after referral (by an audiological physician, ENT surgeon or audiologist) for a tinnitus appointment with a hearing therapist. The control group will simply wait for their appointment with a hearing therapist as usual and will be given the possibility to use MindEar afterwards. All participants will be asked to fill in a set of questionnaires at three timepoints. Anonymised data about app usage will be collected automatically. Participants will be involved for approximately 16 weeks.

Intervention Type
Behavioural

Primary outcome(s)
1. Tinnitus distress measured using Tinnitus Functional Index at baseline, 8 weeks, 16 weeks

Key secondary outcome(s)

Completion date
15/07/2025

Eligibility

Key inclusion criteria
1. Having prolonged spontaneous tinnitus
2. Having been referred for a hearing therapy appointment at the Royal National Ear, Nose and Throat Hospital, London for tinnitus support
3. Owning and using a smartphone with an internet connection

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
76

Key exclusion criteria
1. Unable to understand written English
2. Low vision making it impossible to read text on an app
3. Very high tinnitus distress requiring urgent referral
4. Already undergoing tinnitus therapy

Date of first enrolment
04/11/2024

Date of final enrolment
15/04/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal National Throat, Nose & Ear Hospital
330 Gray's Inn Road
London
England
WC1X 8DA

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type

Funder Name
ENT UK

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available