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Digital thErapy For Improved tiNnitus carE Study (DEFINE)

Submission date
23/05/2023

Recruitment status
No longer recruiting

Registration date
21/07/2023

Overall study status
Completed

Last Edited
18/03/2025

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
Tinnitus is a common condition, affecting about 15% of UK adults. It is usually perceived as a buzzing or ringing in the ears, without a stimulus in the outside world. There is currently no cure, but cognitive behavioural therapy (CBT) has been shown to be effective in reducing self-reported distress and illness severity. Unfortunately, access to CBT is limited, with significant healthcare costs associated with provision and additional costs to people with tinnitus including time away from work, travel and lost productivity.
The Oto Tinnitus Programme is a digital approach to tinnitus management, delivered as a self-paced smartphone app. It is based on CBT but also includes education, mindfulness and physical therapy. The main aim of this study is to assess whether Oto's digital tinnitus programme is as effective at reducing self-reported tinnitus severity as therapist-delivered CBT.

Who can participate?
Adults aged 18 years and over with tinnitus that has persisted for at least 3 months and is self-assessed as impacting their quality of life. Participants must not have previously undergone tinnitus therapy (TRT or CBT by any delivery method).

What does the study involve?
All enrolment (pre-screening, informed consent, eligibility review, and collection of baseline data) and follow-up procedures will be conducted remotely via telephone/video calls and online questionnaires. Eligible participants will be randomly allocated to either the control group, where they will receive one-to-one therapist-delivered tinnitus therapy from an audiologist /hearing therapist, or the intervention group, where they will receive the Oto tinnitus programme (smartphone app-delivered CBT). Participants will be asked to complete online questionnaires at months 1, 3, 6 and 12 to assess the primary and secondary outcome measures.

What are the possible benefits and risks of participating?
Taking part in this study will allow participants to receive treatment for tinnitus without a significant wait. Participants in the control CBT group will receive rapid access to CBT, rather than typical waiting times of more than 12 months from GP referral. While participants in the intervention group will receive immediate access to therapies through the Oto app. The Oto App and therapist-delivered CBT are free of charge.

There are minor potential risks associated with the trial. For example, some participants may find it difficult to access online surveys and/or the Oto App. Access to a smartphone is an inclusion criteria and at the consenting interview the Lindus Health team will go through the process of downloading the App.

Where is the study run from?
Lindus Health (UK)

When is the study starting and how long is it expected to run for?
April 2023 to December 2024

Who is funding the study?
1. Innovate UK (UKRI) (UK)
2. Oto Health (UK)

Who is the main contact?
Dr Matt Smith, m.e.smith@doctors.org.uk

Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
328487

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 328487, CPMS 56997

Study information

Scientific Title
Digital thErapy For Improved tiNnitus carE Study (DEFINE)

Acronym
DEFINE

Study objectives
Primary Objective:
To assess whether Oto’s digital tinnitus programme is as effective at reducing self-reported tinnitus severity as therapist-delivered CBT.

Secondary Objectives:
1. To assess whether Oto’s digital tinnitus programme is superior to therapist-delivered CBT in reducing self-reported tinnitus severity.
2. To assess the self-reported impact of Oto’s digital tinnitus programme on aspects of participants' tinnitus experience, and on the overall health-related quality of life of Oto’s digital programme and human-delivered CBT.
3. To assess the usability of the Oto digital programme.
4. To explore participants' views of the impact and usability of Oto’s digital programme.
5. To understand the health economic consequences of using a digital therapeutic for tinnitus.
6. To assess the number of adverse events between the groups.
7. To assess intervention adherence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/07/2023, West Midlands - Black Country Research Ethics Committee (2 Redman Place, Stratford, E20 1JQ, UK; +44 (0)207 104 8210; blackcountry.rec@hra.nhs.uk), ref: 23/WM /0146

Study design
Open-label prospective parallel-design randomized controlled study

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

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

Interventions
Participants will be randomised using the 'Sealed Envelope' randomisation service to one of two arms, intervention or control.

Intervention Group
The Oto Tinnitus Programme is a digital therapeutic combining CBT with mindfulness, patient education and physical therapy (physical stretches/exercises). Oto's programme offers a series of daily therapy sessions, where the user listens to recorded audio content that takes them through education, cognitive exercise or a tinnitus-specific meditation, and optional 1-1 chat support. Users work their way through progressive modules using a spiral curriculum, where the sessions build on techniques and exercises learned in previous sessions. The programme lasts approximately 6 weeks, using the app 4-5 times per week, which evidence suggests is sufficient time for a therapeutic difference. Users can personalise their therapy by listening to additional modules and sounds from the sound library. Participants are expected to have completed the intervention in approximately 6
weeks.

Control Group
Those allocated to the control arm of the study will undertake one-to-one tinnitus therapy from a trained Audiologist/Hearing Therapist/Psychologist via video calls. This is not a direct mirror of NHS practice as patients will have rapid access to therapy, rather than typical long waiting times from GP referral. Participants in the control group will agree to not use Oto or an alternative tinnitus app for the duration of the study.

This control intervention will consist of a minimum of one tinnitus therapy session, with further sessions at the discretion of the participant and therapist up to a maximum of six.

Therapy will begin within 1 week of randomisation. There will be a panel of therapists selected to deliver the therapy. The therapy will include several elements of current standard care formulated into a personal management plan:
1. Assessment of participant needs
2. Participant education
3. CBT
4. Relaxation therapy
5. Signposting to hearing aid fitting and other support

Intervention Type
Behavioural

Primary outcome(s)
Self-reported tinnitus severity measured using the Total Tinnitus Functional Index (TFI) score 6 months from starting therapy

Key secondary outcome(s))
1. Self-reported tinnitus severity measured using the total TFI and TFI subscale scores at 1, 3 and 12 months
2. Participant health-related quality of life measured using the EuroQol EQ-5D-5L and the Health Utilities Index Mark 3 (HUI3) responses and summary scores at 3, 6 and 12 months follow-up from starting therapy
3. Adverse events measured using participant-reported side effects or medical events while participating in the DEFINE study from randomisation to 3 months
4. OTO digital app programme usability measured using the System Usability Scale scores at 3 months
5. Qualitative feedback from focus groups and semi-structured interviews at 3, 6 and 12 months
6. Cost-utility analysis synthesising costs and quality-adjusted life years (QALYs) over the trial period
7. Intervention adherence assessed using electronic case report form data at 3 and 6 months

Completion date
04/12/2024

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Experienced tinnitus symptoms for at least 3 months and self-assessed as having a significant impact on quality of life
3. Have access to a smartphone
4. Able and willing to give consent for the study prior to participation
5. Able to speak and read English to a sufficient level

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
210

Key exclusion criteria
1. Tinnitus with potential “red flag” symptoms i.e. unilateral or pulsatile tinnitus (assessed via a red flag checklist during the screening call)
2. Significant mental health problems e.g. history of suicidal ideation or requirement for

psychiatric/psychological support beyond primary care level
3. Have required hospitalisation for depression or taking antipsychotic drug
4. Currently taking part in another clinical trial for hearing/tinnitus
5. Awaiting surgical intervention for hearing/tinnitus
6. Previously undergone tinnitus therapy of any type e.g. CBT or TRT
7. Pregnant and breastfeeding women

Date of first enrolment
28/06/2023

Date of final enrolment
30/11/2023

Locations

Countries of recruitment
United Kingdom

Study participating centre
Not provided at time of registration
United Kingdom
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Sponsor information

Organisation
Oto Health Ltd

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
Technology Strategy Board

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Oto Health

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		05/01/2024	08/01/2024	Yes	No
Protocol file	version 2.0	07/07/2023	04/09/2023	No	No
Statistical Analysis Plan	version 1.0	21/07/2023	04/09/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes