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Online sound therapy for chronic tinnitus using a novel type of sound

Submission date 25/07/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 21/08/2024	**Overall study status** Completed	
Last Edited 16/08/2024	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol

Background and study aims
Tinnitus, the sensation of ringing or other sounds in one or both ears, affects 10-15% of people on a long-term basis, and at present there is no established treatment to silence or suppress this sound. Researchers at Newcastle University, led by Dr William Sedley, have developed a specific type of sound intended to reduce the loudness of tinnitus when listened to regularly over a period of time. This study aims to test the effectiveness of this sound in quietening tinnitus and also to explore the feasibility of a fully online longitudinal study of this kind.

Who can participate?
Anyone over 18 years old who has subjective tinnitus, has access to a phone or a computer to download the sound files, and is able to clearly hear those sounds playing through their headphones/earphones.

What does the study involve?
1. Listening to a range of sounds in order to estimate hearing, type, and frequency of tinnitus
2. A 6-week period of listening to one type of sound (active or sham) daily, which can be done while performing other activities if preferred. Each day, participants record how long they listened to the sound, but there is no set time of required listening - it is the volunteer's choice (as a suggestion, 30-60 minutes at a time is recommended)
3. A 3-week 'washout' period with no daily listening
4. A further 6-week period of daily listening (to the other type of sound), and a further 3-week washout period
5. Completing questionnaires before and after each listening and washout period about hyperacusis (sound sensitivity), tinnitus loudness, and the impact of tinnitus at the time

What are the possible benefits and risks of participating?
Participants would be helping to advance medical science in the field of tinnitus, and working towards better treatment for the hundreds of millions of people worldwide with this condition. Furthermore, there is a chance that taking part might result in some improvement in their tinnitus. This might be difficult to tell for certain, as many factors can influence the perceived loudness of tinnitus, including naturally occurring changes over time, and also the very act itself of taking part in a study. If participants perceive a benefit from listening to the sounds used in

the study then they will be able to download or continue to access these even after they have completed the study. The researchers are unable to provide any financial incentive for taking part in the study.

Where is the study run from?
Newcastle University (UK)

When is the study starting and how long is it expected to run for?
July 2020 to April 2022

Who is funding the study?
1. Royal National Institute for Deaf People (UK)
2. Wellcome Trust (UK)
3. Masonic Charitable Foundation (UK)

Who is the main contact?
Dr Ekaterina Yukhnovich, Kate.Yukhnovich@newcastle.ac.uk

Study website
https://www.newcastletinnitus.org/

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
4574/2020, 222071/Z/20/Z

Study information

Scientific Title
Online sound therapy for chronic tinnitus using a novel cross-frequency covariance-cancelling stimulus

Study objectives
A novel type of sound modulation was created, aiming to reduce the covariance of neuronal activity in different frequency channels within and surrounding the tinnitus frequency (or frequency range). The hypothesis was that listening to sounds with a modulation applied to tones within the tinnitus frequency range of each participant would reduce the self-rated tinnitus loudness of that participant and that this loudness reduction would not occur following a 'sham' condition where the same participants listen to sounds with a modulation applied to tones far outside of their tinnitus frequency range.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/08/2020, Research, Policy, Intelligence and Ethics Team (Newcastle University, Newcastle upon Tyne, NE1 7RU, United Kingdom; +44 (0)191 208 6000; res.policy@ncl.ac.uk), ref: 4574/2020

Study design
Fully online interventional randomized blinded study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home, Internet/virtual

Study type(s)

Treatment

Participant information sheet
https://drive.google.com/file/d/1D3Dmdp_KxT1lDY_R_ZtAPFkhYEZnKvZO/view

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

Interventions
Participants are randomised to receive one of three types of modulated sound:
1. Notch degradation
2. Amplitude modulation
3. Phase modulation

Randomisation method: block randomisation. There were six blocks. The first three had the sham condition as the first listening period and the last three had the active condition as the first listening period. The first and fourth blocks were amplitude-modulated sounds, the second and fifth were notch degradation sounds, the third and sixth were phase-modulated sounds.

Within their modulation group, participants are randomly assigned to listen to either sham or active sound therapy first (a sound with a modulation within their tinnitus frequency range, or outside of it) for 6 weeks, and then, after a 3-week washout period, they cross over to the other condition for a further 6 weeks of listening and a 3-week washout period. As the difference between the conditions is not easily discernible, they do not know which condition they are in. The carrier sounds are hour-long sequences of non-overlapping 4-second broadband (spectrum 1-16 kHz) harmonic complexes. In the first condition, there is a frequency-specific notch degradation applied to the sounds. For the second and third conditions, dynamic spectral ripple modulations are applied to tinnitus or non-tinnitus sections of the sounds, with the spectral modulation rate also being constantly modulated over a one-octave range. There are two alternative implementations of this modulation, which are applied either as an amplitude modulation (range 0-2) or phase modulation (range 0 to 2 π).

Intervention Type
Other

Primary outcome measure
Tinnitus loudness measured using a numerical rating scale before the start of the listening period and after the end of the listening period

Secondary outcome measures
1. Tinnitus bothersomeness measured using the Tinnitus Handicap Inventory, just before and immediately after each 6-week listening period and immediately after the 3-week washout period
2. Tinnitus bothersomeness measured using the Tinnitus Functional Index, just before and immediately after each 6-week listening period and immediately after the 3-week washout period
3. Sound sensitivity/hyperacusis measured using the Hyperacusis Questionnaire, just before and immediately after each 6-week listening period and immediately after the 3-week washout period

Overall study start date

01/07/2020

Completion date
01/04/2022

Eligibility

Key inclusion criteria
1. At least 18 years old
2. Able to make a voluntary and informed choice about whether to take part
3. Experience tinnitus (persistent sound in one or both ears) for the MAJORITY of the time, provided that the level of background sound is not loud enough to mask it. It is not important whether you notice the tinnitus most of the time, provided it is there if you listen out for it

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25 x 3 clusters

Total final enrolment
560

Key exclusion criteria
1. Do NOT have hearing loss that is in the 'severe' or 'profound' range at the higher frequencies. Where there are such high degrees of hearing loss, it is unlikely the sounds used in the study will have any effect on the tinnitus. If you do have this level of hearing loss, but USE A HEARING AID OR COCHLEAR IMPLANT to correct this, then you CAN still take part, though we cannot guarantee that the sounds will have the same effect when used with such a device;
2. Do NOT have tinnitus that is 'PULSATILE', meaning that it gets significantly louder and quieter in time with your pulse. This type of tinnitus is usually described as a low-pitched 'whooshing' sound.

Date of first enrolment
01/10/2020

Date of final enrolment
01/02/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Newcastle Upon Tyne
Claremont Road
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NE1 7RU

Sponsor information

Organisation
Newcastle University

Sponsor details
Newcastle University
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Sponsor type
University/education

Website
http://www.ncl.ac.uk/

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
Charity

Funder Name

Royal National Institute for Deaf People

Alternative Name(s)
RNID

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Masonic Charitable Foundation

Alternative Name(s)
The Masonic Charitable Foundation, MCF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A presentation about this study was done in 2023 at the TRI conference. We plan a publication in a high-impact peer-reviewed journal.

Intention to publish date
01/09/2024

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?
Participant information sheet		25/07/2020	30/07/2024	No	Yes