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Sound therapy for tinnitus relief for adult cochlear-implant users

Submission date
11/10/2019

Recruitment status
No longer recruiting

Registration date
14/10/2019

Overall study status
Completed

Last Edited
19/10/2022

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Tinnitus is the perception of a sound in the absence of a sound source. 70% of adults who wear a cochlear implant have tinnitus, with approximately 13% describing tinnitus as a serious concern. It is not fully understood why or how tinnitus occurs, but recently it has been suggested that tinnitus may occur in the process that the brain uses to form perceptions about the world. The brain makes predictions about what is happening in the environment, and for hearing, the default prediction is silence. However, tinnitus can transform into the default prediction instead. There are certain sounds known to change the predictions of the brain (sounds with a certain temporal pattern) which may reduce tinnitus loudness, or even suppress tinnitus.

Who can participate?
Adult cochlear-implant users recruited from the Emmeline Centre for Hearing Implants (Cambridge)

What does the study involve?
We will explore the effect of specially designed sounds in adult cochlear-implant users recruited from the Emmeline Centre for Hearing Implants (Cambridge). We will also determine whether there are any objective markers of tinnitus in the responses of the brain to sound or in the size of the eye pupil during a listening activity (which is a measure of listening effort). Objective markers of tinnitus would be helpful to understand why and how tinnitus occurs. We will compare brain responses to sound across two groups of adult cochlear-implant users, one with tinnitus and another one without tinnitus (Part A) and we will measure the effect of using special sounds (sound textures) on the reduction of tinnitus loudness/annoyance and on the brain responses (Part B). We will also explore the relationship between tinnitus and listening effort.

What are the possible benefits and risks of participating?
Identified benefits: In general, taking part in research can help participants to better understand their condition. No specific benefits were identified for Part A, but participants in Part B could find that one or more sounds used in the study help them to relieve tinnitus.
Identified risks: In general, participants may get tired if sessions are long. Breaks and refreshments have been included in planning in order to reduce this burden as much as possible.

For participants in Part A, focusing on tinnitus in order to reply to the questionnaires could make the volunteer more aware of their tinnitus. This means that their tinnitus may appear louder or they may notice it more frequently. This effect does not occur for most people, and when it does, it is usually temporary.
Additionally, sounds used to relieve tinnitus can sometimes increase tinnitus loudness, but this is more frequent when sounds are loud (as similarly, it is common for tinnitus to be worse after being in noisy places). We will check with the participant the loudness level of any sounds presented to them to make sure that no loud/uncomfortable sounds are presented during the study. Participants will be made aware that they can ask us to interrupt what we are doing any time if they feel uncomfortable.

Where is the study run from?
Cambridge University Hospitals NHS Foundation Trust, UK

When is the study starting and how long is it expected to run for?
November 2019 to June 2020

Who is funding the study?
Addenbrooke's Charitable Trust, Cambridge University Hospitals NHS Foundation Trust, UK

Who is the main contact?
Dr Marina Salorio-Corbetto
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
265044

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS Project ID 265044

Study information

Scientific Title
Functional impact of tinnitus in post-lingual users of cochlear implants and short-term effects of sound therapy

Study objectives
Main question: In cases of moderate or severe tinnitus, do 'sound textures' reduce tinnitus loudness/annoyance for adult cochlear-implant users?
Secondary questions:
1. Are there any differences in the electrophysiological or pupillometry findings between the tinnitus group and the no-tinnitus group? This will be addressed in Part A. If found, these can be used as objective markers of tinnitus
2. What are the functional impact and characteristics of tinnitus are in adult users of cochlear implants? This is a secondary question that will be addressed in Part A
3. In cases of moderate or severe tinnitus (Part B):
3.1. Do the auditory evoked responses and/or the pupillary responses change after stimulation with sound textures compared to white noise filtered to match their long-term spectrum?
3.2. Are any changes in the objective measures (evoked potentials and electrophysiology) correlated with the reduction of tinnitus loudness/annoyance?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, NHS East of England - Cambridgeshire and Hertfordshire Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; +44 (0)207 1048106; nrescommittee.eastofengland-cambsandherts@nhs.net)

Study design
Cross-over randomised-controlled study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
While Part A of the study seeks to explore objective measures of tinnitus, Part B seeks to assess the effect of sound therapy on tinnitus.

In Part B, participants will be asked to come to the research centre for two sessions, each lasting between 2 h 15 min and 2 h 45 min. Breaks will be spaced as needed during the session and tea and refreshments will be provided. If any of the event-related auditory evoked potentials used in Part A is significantly different across participants with and without tinnitus, the type of evoked potential with the highest sensibility and specificity will be used in Part B.

Responses will be obtained at the start of the session. Next, the participant will be presented with a five-minute duration sound texture or with a control sound, randomly chosen. During the presentation of the sound, participants will be prompted to rate the loudness and annoyance of their tinnitus several times (once per minute) using a computer interface. At the end of the stimulation, the evoked potentials will be repeated.

As this is a controlled trial, each participant gets exposed to two sounds, in random order. Therefore, after the first sound was presented, the participant comes back for a second session with the same structure, where the second sound (the sound not presented in the first part of the session) is presented

Intervention Type
Other

Primary outcome(s)
Part A:
1. Mismatch negativity: Variables are amplitude, latency, and area under the curve
2. Auditory Steady State Response and N1-P2 responses: The variable is amplitude in each case.
3. P300: The variables are amplitude and latency
For all of these outcome measures (1, 2, and 3), the method of measurement is recording event-related auditory evoked potentials
4. Pupillometry: The variable is Pupillar diameter. The method of measurement is pupillometry

Part B:
5. Tinnitus loudness ratings. Methods: Subjective ratings in a visual-analogue scale
6. Tinnitus annoyance ratings. Methods: Subjective ratings in a visual-analogue scale
7. One objective measure selected based on the outcomes of Part A. It could be 1, 2, 3, or 4. The measure with the highest sensitivity to separate between participants with tinnitus and without tinnitus will be used

Key secondary outcome(s))
Part A:
1. Variable: Tinnitus Functional Index; Method: validated questionnaire
2. Variable: Qualitative data describing each participant's tinnitus. Method: Tinnitus Cochlear Implant Questionnaire, non validated questionnaire
3. Variable: Tinnitus Loudness Ratings; Methods: Subjective ratings in a visual-analogue scale

Completion date
30/06/2020

Eligibility

Key inclusion criteria
Part A:
1. Adult (aged 18+ years, with no upper limit)
2. Users of unilateral cochlear implants
3. Fluent in English
4. Attend the Emmeline Centre for Auditory Implants
5. Had their cochlear implants switched on for at least one year

Part B:
1. Adult (aged 18+ years)
2. Users of unilateral cochlear implants
3. Attend the Emmeline Centre for Auditory Implants
4. Had their cochlear implants switched on for at least one year
5. Have tinnitus even when their cochlear implant is switched on
6. Scored 32 or higher in the Tinnitus Functional Index questionnaire

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Part A and B:
1. Bilateral cochlear implantation
2. Aged less than 18 years
3. Severe visual impairment
4. Severe mental-health condition
5. Severe general-health condition
6. Currently having medication that affects tinnitus or the recording of evoked potentials

Additionally, for Part B:
7. Currently receiving other treatments for tinnitus apart from tinnitus management therapy

Date of first enrolment
01/12/2019

Date of final enrolment
31/05/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Hills Road
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Sponsor information

Organisation
Jointly sponsored by the University of Cambridge and Cambridge University NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Addenbrooke's Charitable Trust, Cambridge University Hospitals

Alternative Name(s)
Addenbrooke's Charitable Trust, Cambridge University Hospitals NHS Foundation Trust, ACT

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2	16/03/2022	19/10/2022	No	No