ISRCTN69465849 https://doi.org/10.1186/ISRCTN69465849

# Hearing aids, mild hearing loss and tinnitus

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 24/11/2012 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 14/01/2013 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 23/05/2017 | Ear, Nose and Throat | [_] Record updated in last year |

## Plain English summary of protocol

Background and study aims
Hearing aid technology has changed dramatically over the last decade with the use of miniaturised computer chips and improved plastics engineering. Both the structural design and the sound processing have seen major changes. It is suggested that the rules previously used to guide the selection of hearing aids for hearing losses and the minimum hearing loss are not relevant when considering the modern hearing instrument. In particular, for those patients with a mild hearing loss and also suffering from tinnitus (the perception of noise in one ear, both ears or the head), new open fit digital hearing aids are thought to be helpful with mild hearing losses where traditional hearing aids would not have been fitted. The aim of this study is to inform the clinical practice of audiologists who see patients with distressing tinnitus associated with a mild hearing loss; in particular whether these patients should be offered amplification with digital hearing instruments using open fit technology. A secondary aim would be to stimulate further research on a larger scale, possibly using multiple centres. A larger scale, longer term and more robust study with higher numbers of patients involved would serve to support the findings of this smaller study.

Who can participate?
Patients with tinnitus aged between 18 and 80

What does the study involve?
Each participant has their tinnitus severity measured before treatment and six weeks after treatment to measure any changes. The measurement tool to be used is the Tinnitus Functional Index, which is sensitive to change over time. Treatment consists of an open-fit hearing aid fitting verified by Real Ear Measurement.

What are the possible benefits and risks of participating?
The possible benefits of participating are a reduction of tinnitus distress and improved hearing. There are no risks to the participants. The proposed treatment is identical to current clinical practice over the past 3 years.

Where is the study run from?
Rotherham Community Health Centre (UK)

When is the study starting and how long is it expected to run for?
January 2013 to September 2013

Who is funding the study?
The study does not require any funding as the participants undergo the same interventions currently carried out in clinic.

Who is the main contact?
Peter Byrom
peter.byrom@rothgen.nhs.uk

# Contact information

### Type(s)
Scientific

### Contact name
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

### Scientific Title
Does amplification alleviate the distress caused by tinnitus in patients with mild hearing loss?

### Study objectives
Amplification provided by digital hearing instruments using open fit technology combined with counselling, giving advice and information alleviates the tinnitus distress measured by the Tinnitus Mini Questionnaire in patients with a mild hearing loss.

**Ethics approval required**
Old ethics approval format

**Ethics approval(s)**
Leeds West, 05/03/2013, ref: 13/YH/0033

**Study design**
Single-centre quasi-experimental before and after design

**Primary study design**
Interventional

**Secondary study design**
Non randomised study

**Study setting(s)**
GP practice

**Study type(s)**
Treatment

**Participant information sheet**
Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**
Tinnitus/mild hearing loss

**Interventions**
Before and after - no control

Prior to treatment, the Tinnitus Functional Index (TFI) is completed by each participant. They are then fitted with 'open-fit' hearing aids using real ear measurements as a verification to National Acoustic Laboratories - Non Linear 2 (NAL-NL2) algorithm. After 6 weeks the TFI is completed again to measure relief from tinnitus provided by the hearing aids.

**Intervention Type**
Other

**Phase**
Not Applicable

**Primary outcome measure**
Tinnitus Functional Index (TFI) before intervention and 6 weeks post intervention

**Secondary outcome measures**
No secondary outcome measures

**Overall study start date**
01/01/2013

### Completion date
01/09/2013

## Eligibility

### Key inclusion criteria
1. Referred to Audiology for tinnitus management by general practitioner (GP), audiologist or ENT
2. A Tinnitus Functional Index higher than 24
3. Any hearing threshold >20dB in either ear
4. Aged between 18 and 80 years, either sex
5. Voluntary informed consent given
6. Psychosocially, mentally and physically able to fully comply with the protocol including adhering to follow-up schedules and requirements and filling out forms

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
40

### Key exclusion criteria
Does not meet inclusion criteria

### Date of first enrolment
01/01/2013

### Date of final enrolment
01/09/2013

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre

**University of Leeds**
Leeds
United Kingdom
LS2 9UT

# Sponsor information

**Organisation**
University of Leeds (UK)

**Sponsor details**
Faculty Research Ethics and Governance Administrator
Faculty Research Office, Room 10.110, Level 10
Worsley Building
Clarendon Way
Leeds
England
United Kingdom
LS2 9NL

**Sponsor type**
University/education

**Website**
http://www.leeds.ac.uk/

**ROR**
https://ror.org/024mrxd33

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded (UK)

# Results and Publications

**Publication and dissemination plan**
Publication plans are unknown at this stage.

## Intention to publish date

## Individual participant data (IPD) sharing plan
The current 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? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |