

Hearing aids, mild hearing loss and tinnitus

Submission date 24/11/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/01/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/05/2017	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
Dr Nick Thyer

Contact details
School of Healthcare, Faculty of Medicine & Health
Baines Wing
University of Leeds
Leeds
United Kingdom
LS2 9UT
+44 (0)113 343 1238
N.J.Thyer@leeds.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

Tinnitus Functional Index (TFI) before intervention and 6 weeks post intervention

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

Study participating centre

University of Leeds

Leeds

United Kingdom

LS2 9UT

Sponsor information**Organisation**

University of Leeds (UK)

ROR

<https://ror.org/024mrx33>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (UK)

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes