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Investigating the benefit of hearing aids in adults with tinnitus and mild hearing loss

Submission date
16/12/2020

Recruitment status
No longer recruiting

Registration date
02/06/2021

Overall study status
Stopped

Last Edited
21/11/2022

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
The aim of this study is to provide information on whether hearing aids help people with both tinnitus and mild hearing loss to manage their tinnitus more effectively. Hearing loss and tinnitus are very common conditions in the UK, both of which can have significant impact on quality of life and mental health. Current practice by health professionals in the NHS is to offer hearing aid/s to patients with both hearing loss and tinnitus, which is bothersome for them. However, there is no guidance for professionals working with patients with mild hearing loss and tinnitus. This knowledge is important for clinicians to offer the best care to this group of patients. From a public point of view this knowledge will enable them to make the best evidence-based care choices for themselves.

Who can participate?
Patients aged 18 or over with a clinical diagnosis of tinnitus with mild hearing loss in one or both ears

What does the study involve?
Participants will be randomly allocated to have a hearing aid with amplification or without amplification. Participants will not know which hearing aid they receive. Participants will be expected to wear the hearing aid/s every day for a 6-month period. They will be asked to complete four questionnaires at the beginning of the trial, at an 8-week follow up and again at 6 months. Participants will also be asked about hearing aid usage at the 8-week and 6-month follow-up stages.

What are the possible benefits and risks of participating?
By joining in this study participants may see improvements in their tinnitus awareness. The information provided by participants to this study may also help to improve treatment for people with tinnitus and mild hearing loss in the future. As the study is using a low-risk intervention which is routinely offered in the NHS the study team do not anticipate any risks to the participants. Any risk or burden associated with the use of the hearing aid without amplification and/or the possibility of the burden of wearing the hearing aid/s for at least 7 hours will be carried out with the participant's full and informed consent.

Where is the study run from?
Betsi Cadwaladr University Health Board (UK)

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

Who is funding the study?
Health and Care Research Wales (UK)

Who is the main contact?
Mrs Joanne Goss
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
290270

Study information

Scientific Title
A randomized controlled trial assessing the effectiveness of hearing aids (intervention setting) compared to hearing aids (placebo setting) in reducing tinnitus for adults with mild hearing loss

Acronym
HEaring Aids foR tinnITus and mild hearing loss (HEAR IT)

Study objectives

Hearing aids are a management option for alleviating tinnitus symptoms in people who also have a mild hearing loss.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/03/2021, North Wales Research Ethics Committee (Central and East) (Wales REC 3, Health and Care Research Support Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)29 2078 5736; Wales.REC3@wales.nhs.uk), REC ref: 21/WA/0038

Primary study design
Interventional

Study design
Multicentre interventional double-blinded randomized controlled trial

Study type(s)
Treatment

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

Interventions
Randomisation treatment allocation will be on a 1:1 basis using a sequentially randomised dynamic adaptive algorithm via a secure database.

One group of participants will receive a hearing aid set with amplification (intervention hearing aid/s) and the other group will receive a hearing aid fitted in the same way but without amplification (placebo hearing aid/s).

Participants will be expected to wear the hearing aid/s every day for a 6-month period. They will be asked to complete questionnaires, at the beginning of the trial, at an 8-week follow up and again at 6 months.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
The effects of tinnitus measured using the tinnitus functional index (TFI) at baseline, 8 weeks and 6 months post hearing aid fitting

Key secondary outcome(s)
1. Mental and emotional health disorders screened using the PHQ-9 at baseline, 8 weeks and 6 months post hearing aid fitting
2. Generalised anxiety disorder and severity of anxiety screened using the GAD-7 at baseline, 8 weeks and 6 months post hearing aid fitting

3. General quality of life measured using the ED-5L-3D at baseline, 8 weeks and 6 months post hearing aid fitting
4. Hearing aid usage data collected at 8 weeks and 6 months post hearing aid fitting

Completion date
31/05/2022

Reason abandoned (if study stopped)
Funder closed the trial early

Eligibility

Key inclusion criteria
1. Age 18 years or over with a clinical diagnosis of tinnitus with mild sensorineural hearing loss* unilaterally or bilaterally, hearing level (4FA) measured no more than 6 months prior to tinnitus assessment appointment
2. Willing to trial hearing aid/s only as a tinnitus management option
3. Capable of providing written informed consent
4. Ability to communicate in English
5. Ability to understand and complete the English versions of the questionnaires

*For the purposes of this trial, mild hearing loss is defined as hearing threshold between 26 and 40dBHL when averaged at the four frequencies of 0.5, 1, 2 and 4kHz as per the World Health Organisation definition (2019) and other studies (Donahue et al, 2010; Ferguson et al, 2017; Mathers et al, 2000). This measure is referred to in this protocol as “4FA”

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
16

Key exclusion criteria
1. Tinnitus of a medically treatable origin
2. Hearing loss of a medically treatable origin
3. Unilateral tinnitus reported in the ear with normal hearing
4. Hearing loss (4FA) of 41dB or greater unilaterally
5. Those requiring other tinnitus management options

6. Previous use of a hearing aid, combination device or behind the ear sound generator
7. GAD-7 score of 8 or more and/or PHQ-9 score of 10 or more, suggesting more complex mental health needs

Date of first enrolment
19/04/2021

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Glan Clwyd Hospital
Betsi Cadwaladr University Health Board
Audiology Department
Sarn Lane
Bodelwyddan
United Kingdom
LL18 5UJ

Study participating centre
Royal Gwent Hospital
Aneurin Bevan University Health Board
Audiology Department
Hearing & Balance Unit
Cardiff Road
Newport
United Kingdom
NP20 2UB

Study participating centre
University Hospital of Wales
Cardiff and Vale University Health Board
Audiology Clinic
Clinic 9, Outpatients Department
Heath Park Way
Cardiff
United Kingdom
CF14 4XW

Sponsor information

Organisation
Betsi Cadwaladr University Health Board

Funder(s)

Funder type
Government

Funder Name
Health and Care Research Wales

Alternative Name(s)
Health & Care Research Wales, Health Care Research Wales, Ymchwil lechyd a Gofal Cymru, HCRW

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication. Participant level data will be shared with the North Wales Organisation for randomised trials in Health for statistical analysis.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version v1.1		02/06/2021	No	Yes