**HE**aring **A**ids fo**R** tinn**IT**us and mild hearing loss **(HEAR IT)** study

**Participant Information Sheet**

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it will involve for you. Please read the following information carefully and take time to decide whether you wish to take part or not. At your face-to-face appointment, one of our team will also go through the information sheet with you and answer any questions you have. You are also encouraged to talk to others about the study if you wish.

**What is the purpose of the study?**

This research project aims to find out whether hearing aids help people with both tinnitus and mild hearing loss.

**Am I eligible to take part?**

This study is open to anyone who has recently undertaken a tinnitus assessment with the Audiology Departments in Betsi Cadwaladr University Health Board, Aneurin Bevan University Health Board or Cardiff and Vale University Health Board. You must be 18 years or older, and have been diagnosed with both tinnitus and a mild hearing loss. You must be able to read and understand English, as the questionnaires that we will ask you to complete are only available in English.

**Do I have to take part?**

It is up to you to decide whether to participate in this research study. We will describe the study and go through this information sheet. Your future care will not be affected whatever you decide. If you agree to take part, we will then ask you to sign a consent form and you will be given a copy of this information sheet. You are free to withdraw at any time without prejudice and without giving a reason. This will not affect the standard of care you receive.

**What will happen to me if I take part?**

Sometimes we do not know which way of treating certain conditions is best. We put people into groups and give each group a different treatment. The results are compared to see if one is better than the other. To try to make sure that the groups are the same to start with, each participant is randomly allocated to the following treatment options. In this study you will be allocated either a hearing aid with amplification (interventional setting) or a hearing aid without amplification (placebo setting). There is a 50:50 chance of you receiving either hearing aid.

This is a blinded trial, which means that you will not know which hearing aid you receive. The Audiologist who fits your hearing aid will be aware of which treatment group you are in. However, another Audiologist who completes the follow up appointment will not be aware of your treatment group.

With your permission your GP will be informed by letter if you decide to take part in this study.

**What will I have to do?**

If you choose to participate in the trial, you will be expected to complete questionnaires about your tinnitus, mental health and quality of life at the start of the trial, again at the 8 week follow up and finally again at the 6 month follow up. You will also be asked questions about your tinnitus, hearing and medical history. If there are any significant changes to your mental health, the clinician will contact your GP.

You will be asked to attend all appointments arranged; these may be via video/telephone call or a face-to-face appointment at your local Audiology Department. These appointments will arranged at a time which is convenient for you. A plan of the appointments is provided below:

**Assessment appointment**

45 minutes video/telephone appointment with a clinician from your Local Audiology Department

* You will be asked about your tinnitus, hearing ability and your medical history.
* The clinician will explain the study subject to your eligibility to be included into the study
* You be posted some questionnaires which ask how you are feeling, these are to be completed, scores discussed via this remote appointment and handed back to the clinician at your face to face appointment
* The clinician will book a face to face appointment at a convenient day and time at your local Audiology department.

**Testing and hearing aid fitting appointment**

1 hour 45 minutes appointment which will be face to face at your Local Audiology Department

* The clinician will look in your ears, test your hearing and carry out a simple test to measure the function and movement of the eardrum and middle ear
* The hearing test results will be explained to you and if eligible for the study the clinician will explain the study to you.
* If you are happy to join the study you will be asked to sign a consent form
* You will be randomly allocated to a treatment group (hearing aid with or without amplification) and this device will be fitted for you
* An explanation on how to use the hearing aid/s and how to care for them will be provided to you by the clinician.

**8 week follow up appointment after hearing aid fitting**

30 minutes appointment, which will be via Video/telephone consultation

* We will ask you how you are getting on with your hearing aid/s
* We will repeat the questionnaires about your tinnitus, mental health and quality of life

**6 month follow up after hearing aid fitting**

You will be contacted either via email or post (whichever is most convenient)

* We will repeat the questionnaires about your tinnitus, mental health and quality of life
* We will you advise you on long term care of your hearing aid/s and how to access your local service

You will be expected to wear the hearing aid or hearing aids provided for at least 7 hours every day for the 6 month study period. If you do not feel that you will be able to do this, please discuss this at the face-to-face appointment.

**What are the possible benefits of participating in this study?**

By participating in this study you may see improvements in your tinnitus awareness. Your participation and the information you provide to this study may also help to improve treatment for people with tinnitus and mild hearing loss in the future.

**Will I get paid to participate?**

Participation in the study is voluntary and no payment is offered.

**What happens when the research study stops?**

At the end of the study you will be contacted by telephone and the clinician will tell you which treatment group you were allocated to. They will ask you whether you would like to keep the hearing aid or hearing aids on loan. If you have been provided hearing aid/s with the placebo setting we will ask you whether you would like a face to face appointment with a clinician to retune your hearing aid or hearing aids. You will also be offered a face to face appointment if you need more support with your tinnitus. Once the study is complete, you will be supported by your local Audiology Department and this provision will be discussed with you.

**What will happen to the results of the study?**

The results of this study will be published and reported to other professionals within Audiology. You are welcome to receive a copy of the results of the study following completion.

**Confidentiality**

All information which is collected about you during the course of the research will be kept strictly confidential. Any data used in publications or reports will not include your name or any other personal information so that you cannot be identified.

**Who is organising or funding the research?**

This study has been organised by Joanne Goss (Advanced Practitioner Audiologist, Betsi Cadwaladr University Health Board, Audiology service) and sponsored by Betsi Cadwaladr University Health Board.

Support is provided by colleagues in the BCUHB Audiology Department, BCUHB Research and Development department, North Wales Organisation for Randomised Trials in Health (NWORTH), ABUHB Audiology Department and Cardiff and Vale Audiology Department.

The research is being funded by Research for Patient and Public funding (RfPPB) from Health and Care Research Wales.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your interests. This study has been reviewed by the Wales REC 3 committee, Ethics Committee Reference: 21/WA/0038

**How will we use information about you?**

We will need to use information from you and from your medical records for this research project.

This information will include usual questions asked by audiologist plus some additional information for the research study including you’re:

* Initials and Name
* NHS number
* Contact details
* Gender
* Ethnic group
* First language
* Employment status
* If you live alone
* Medical history
* Hearing history and assessments
* Mental health and Quality of Life questionnaires
* How much you use your hearing aid

This information will be collected by your NHS audiology team who are working on this research study at your hospital. Your information will be identified by a unique code and shared with the researchers at NWORTH, the North Wales Organisation for Randomised Trials in Health, based in Bangor, North Wales. The NWORTH researchers are supporting the trial data management and analysis and will not be able to see your name or contact details.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**What are your choices about how your information is used?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information:

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* at www.hra.nhs.uk/patientdataandresearch/
* by asking one of the research team
* by contacting the Sponsor’s Information Governance Department 01978 727689.
* By sending an email to the Sponsor’s Data Protection Officer and you can contact them at bcu.dpo@wales.nhs.uk

**Any questions?**

Please ask us if you have any questions. Here are the contact details of all investigators in this study.

Your local Principle investigator at your hospital is:

**[Insert local details]**

Or please contact:

Joanne Goss, Chief Investigator (BCUHB, Audiology Department) joanne.goss@wales.nhs.uk

Laura Longshaw, Trial manager (BCUHB, R&D Department) laura.longshaw@wales.nhs.uk

If you have any general questions regarding taking part in this, or any other research study, you can contact Involving People (Email: involving.people@wales.nhs.uk. Telephone: 02120 196806. Address: NISCHR CHC, 3rd Floor, 12 Cathedral Road, Cardiff, CF11 9LJ. Website: [www.involvingpeople.org.uk](http://www.involvingpeople.org.uk)) or your local concerns team here:

**[Insert local Concerns Team or PALS details]**

**What do I need to do now?**

If you are willing to participate you will need to complete the consent form provided to you by the clinician.

**Thank you.**