Auditory biomarkers of healthy ageing and Alzheimer's disease (ABHAD)

Participant Information Sheet (PIS)- Controls

You are being invited to take part in a research study investigating how hearing ability changes in healthy ageing and Alzheimer's disease. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

- **Who will conduct the research?**

Dr Jenna Littlejohn- Research Fellow, Division of Psychology, Communication & Human Neuroscience, University of Manchester
Professor Chris Plack- Professor of Audiology, Division of Psychology, Communication & Human Neuroscience, University of Manchester
Dr Ross Dunne- Consultant Old Age Psychiatrist, Greater Manchester Mental Health Foundation Trust
Dr Salman Karim- Consultant Psychiatrist, Lancashire & South Cumbria NHS Foundation Trust

- **What is the purpose of the research?**

Alzheimer's disease (AD) is the most common form of dementia, which currently affects 1 in 14 people over the age 65, and 1 in 5 over the age of 80. In AD, symptoms such as memory loss are caused by a build-up of abnormal proteins in the brain, called amyloid and tau, which affect normal brain function. While there are no treatments available today which would slow the progress of the disease, early identification is important for people living with AD and their families.

Research has shown that in people with AD, amyloid and tau also gather in the hearing (auditory) system. We would expect these abnormal proteins to affect the way the auditory system responds to sounds. We want to investigate how sounds are processed along the auditory pathway in normal healthy ageing and at various stages in people living with AD. This would help us to understand whether early and measurable changes are found in people living with AD, which can be used to help us predict who is at risk of developing dementia.

You have been invited to participate in this study because you:

- Are over 55 years old
- Have no subjective memory complaints
- Happy to visit the hearing labs on Oxford Road

- **Will the outcomes of the research be published?**

Data obtained from this study may be published in academic journal articles and/or oral presentations and posters at academic conferences. All data are anonymised (i.e. your name will not

be disclosed in journals or at presentations). We will also publish a summary of the results on the BRC Hearing Health website: https://www.manchesterbrc.nihr.ac.uk/our-research/hearing-health/

- **Who has reviewed the research project?**

The London-Camberwell St Giles Research Ethics Committee has reviewed the study and agreed it may go ahead, REC reference: 24/PR/0538.

- **Who is funding the research project?**

This project has been funded by Deafness Support Network (www.dsnonline.co.uk) and the National Institute for Health Research Manchester Biomedical Research Centre (NIHR BRC).

What would my involvement be?

- **What would I be asked to do if I took part?**

If you agree to take part, you will be asked to sign the informed consent form. You will also be asked to donate a blood sample for group characterisation purposes. **This part is completely optional, you do not have to donate any blood if you do not want to.**

You will then be invited to visit our Hearing Research Laboratories (Ellen Wilkinson building, University of Manchester) for up to a 3-hour testing session, which can be split over 2 sessions if required.

During this session(s) you will answer some basic background information and undertake various tests which measure different parts of the hearing system and a series of questionnaires to assess your cognitive function (memory, thinking and reasoning skills). All tasks will be administered by a fully trained researcher, and breaks will be frequently offered. Some tasks are automatic and don't require any response from you, whereas others you will need to concentrate and respond to the best of your ability. A task may be stopped at any time if you do not wish to continue.

You may be asked to return for repeat testing in 18 months to 2 years. Again, it is up to you if you would like to take part again at this stage.

- **Blood sample**

You will be asked to provide one blood sample of about 12mls. The sample will be used to measure the abnormal proteins amyloid and tau that accumulate in the brain and cause AD. The results of these tests are not yet clinically validated and therefore will not be fed back to you by the research team.

The blood samples will be taken by a research nurse or other qualified clinician, processed in the study laboratory and frozen as whole blood, plasma, and serum for up to a year. These frozen samples will be sent to UKDRI Fluid Biomarker Laboratory for testing. All of the sample will be consumed by the analysis.

- **Hearing tests**

Just before the hearing tests are performed, your external ears will be checked by the investigator using an otoscope (which is a device for looking into the ear canal) to ensure they are clear. If excessive ear wax is found, you will be asked if you would like the wax removing. If applicable, this will be undertaken by a fully qualified clinical audiologist. If not, you will not be able to take part in the hearing tests or the research study.

Then you will proceed to do the first hearing test in which you will listen to beeps through headphones, and you will respond to these sounds by pressing a button each time (this test lasts about 20 minutes). If this test reveals your hearing is not within normal limits, we will advise you on the best course of action. Typically, this is in the form of us providing a letter which you can take to your GP in order to arrange a formal clinical assessment of your hearing.

Following this, function of your middle ear will be measured (about 5 minutes). This test is automatic and requires no response from you. It involves a soft sensor tip being placed into your ear canal to evaluate the movement of your ear drum. You will momentarily feel a little pressure in your ear.

The next two tests are measures of listening (about 30 minutes). Both involve presenting speech sounds (numbers or letters) through headphones, and you will have to identify as many of the target stimuli correctly as you can on a computer screen.

Depending on your level of hearing, if it is identified as within normal limits, we will ask you to do some further tests.

The function of your inner ear will be measured (about 10 minutes). A soft tip will be placed into your ear and a relatively soft to moderate sounds will be presented. You do not need to make any response to these sounds.

Finally, we will test the function of your hearing nerves by taping sensors to your forehead and to the bone just behind the ear. You will be presented with moderate levels of clicks through earphones inserted into the ear canal. Responses are recorded automatically so all you have to do is relax on the testing couch throughout the procedure time (about 60 minutes).

For all tests in the case of any discomfort, please let us know so that we stop the test immediately.

- **Cognitive testing**

Cognitive tests are tests of memory, thinking and reasoning skills and they are used frequently in dementia research. We will administer a series of tests to measure global cognitive function (about 10 mins) and specifically aspects of attention, language, visuospatial abilities, and memory (about 20-30 mins). This battery of tests will include answering questions verbally as well as pen and paper responses.

- **Other**

You will also be given the opportunity to complete an optional questionnaire to collect information about you such as age, gender, occupation, and other protected characteristics. The purpose of this form is to collect anonymous information about the people who consent to take part in our research studies. The NIHR BRC is committed to ensuring that its research projects are accessible to everyone regardless of race, gender, ability, religion, sexual orientation, or age. The information you give on

this form will help us comply with our policy of ensuring equality in our work. **This form is optional, and you do not have to complete all/any of the questions if you do not want to. The responses are completely anonymous, so we won't know who has completed or not.**

- **Will I be compensated for taking part?**

We will pay travel expenses. This can be for standard class rail or bus travel, or car mileage at a rate of 45p per mile for the first 100 miles (25p per mile for additional miles) plus parking costs. Alternatively, we can arrange for a taxi from your home address to and from the appointment if you are unable to travel independently.

- **Potential benefits and risks of taking part.**

Your participation in this research delivers wider benefits society and in particular to others who are at risk of AD. It may help us in the future to identify which patients are at an increased risk of developing AD, and aid in early diagnosis. You will also have comprehensive hearing assessment undertaken, and any issues will be identified to you with a letter to take to your GP.

A full risk assessment has been undertaken for the study to protect you and the research team from harm. All risks have been rated as 'low' and are adequately controlled. The risks associated with phlebotomy include minor discomfort, bruising or infection; and ear wax removal include minor discomfort, trauma to the ear canal, eardrum perforation or infection.

In the unlikely event that something does go wrong, and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester, Greater Manchester Mental Health Foundation Trust or Lancashire & South Cumbria NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

- **What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part, you do not need to do anything further.

In the unlikely event of a loss of capacity, the research team would retain tissue and personal data collected and continue to use it confidentially in connection with the purposes for which consent was originally sought.

Data Protection and Confidentiality

- **What information will you collect about me?**

In order to participate in this research project, we will need to collect information that could identify you, called "personal identifiable information". Specifically, we will need to collect:

- Name
- Age
- Gender
- Contact details
- Medical history

As mentioned above, we will also ask to collect some demographic data in order for us to monitor inclusion, equality and diversity of our participants. It is entirely optional as to whether you wish to provide the following information to us:

1. Ethnicity
2. Religion
3. Employment status
4. Educational level
5. Sexual orientation
6. Disability

➢ **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

The additional demographic data is optional for monitoring purposes and is not a requirement in order to take part in our research.

➢ **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you. Sometimes your rights may be limited if it would prevent or delay the research. If this happens you will be informed by the research team.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research. This can be found using the following link (http://documents.manchester.ac.uk/display.aspx?DocID=37095) or a hard copy can be provided should you wish.

- **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

To ensure confidentiality, as soon as possible, your study data will be pseudoanonymised, meaning your name and any other identifying information will be removed and replaced with a random ID

number. Only the research team will have access to the key that links this ID number to your personal information, and with your consent, we will also retain this and your contact details for 5 years, in order to contact you for the follow-up, provide you with a summary of the findings for this study and also to inform you about future studies that you may be interested in. After this time, data will become fully anonymised as the key-link will be destroyed. If you provide consent for this, your study data will be safely stored on UoM servers in a digital folder, only accessible to the study team and used only for the purposes described above.

Paper copies of data, including your signed informed consent forms will be retained in a locked filing cabinet for 5 years on UoM premises for audit purposes.

At the end of the study, your fully anonymised data may be shared with other dementia or hearing researchers in an open data repository where it will be permanently stored. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results. In order to do this safely and securely, the team will use national governance procedures like those created for the Dementia Platform UK (DPUK) which allows researchers access to anonymised data in a controlled environment.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant. If you would like more general information on how researchers use data about patients, please visit: www.hra.nhs.uk/information-about-patients/

What if I have a complaint?

If you have a complaint that you wish to direct to members of the research team, please contact:

DR JENNA LITTLEJOHN
Jenna.littlejohn@manchester.ac.uk
07818 032190

PROF CHRIS PLACK
chris.plack@manchester.ac.uk

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact:

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information https://ico.org.uk/make-a-complaint/

Tel 0303 123 1113

Contact Details

If you have any queries about the study or if you are interested in taking part, then please contact the researcher(s)

DR JENNA LITTLEJOHN
Jenna.littlejohn@manchester.ac.uk
07818 032190

This Project Has NHS REC and HRA Approval.