

Investigating the different types of listening difficulty in noise in individuals with normal or near-normal hearing

Participant Information Sheet (PIS)

You are being invited to take part in a research study to understand why some people have difficulty understanding speech in noise even though they have normal or near-normal hearing. 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?**

Professor Gabrielle Saunders, Professor Michael Stone and Dr Jenny Chan, who are researchers in the Division of Psychology, Communication and Human Neuroscience, University of Manchester

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

"Obscure Auditory Dysfunction" (OAD) refers to people who struggle to understand speech in noisy environments, even though their hearing seems normal when it is quiet. These difficulties can vary from person to person; and can happen in various listening situations. We want to find ways to identify different types of listening problems in people with OAD and gather evidence to help create better treatments in the future.

We are looking for anyone who has normal hearing for their age to take part whether or not you notice listening difficulties in noise. This is because we want to find out whether our measurement tools can identify people who have, or do not have, difficulty hearing in noise. We aim to recruit 180 participants in total, about half with listening difficulties and half without listening difficulties.

➤ **Am I suitable to take part?**

You can take part if you:

- (1) Are aged 18 – 50 years,
- (2) Have normal hearing in both of your ears, as measured by clinical equipment
- (3) Can concentrate on a task for up to about 10 minutes at a time
- (4) Have used English as your first language since at least since primary school age and speak English fluently now
- (5) Have good enough vision to read standard-sized print (e.g. a paperback book) while wearing glasses (if you need them)

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

We expect to report the results at scientific conferences and in peer-reviewed journals. If you wish to be contacted with the results, this option is available on the consent form.

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

The project has been reviewed by The University of Manchester Proportionate University Research Ethics Committee (UREC)

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

The Hearing Health theme of the NIHR Manchester Biomedical Research Centre (BRC)

What would my involvement be?

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

We will start by checking your ears and hearing, similar to what is done in a hospital's audiology department. This includes checking your ear canals and ear drum for any issues. If you have excessive earwax in your ears that would prevent us testing your hearing properly, we will offer to remove it for you. It is entirely up to you whether you do this. If you choose not to have us remove the wax, you will have to get it removed elsewhere before you can take part in the study.

We will remove the earwax in one of three ways:

- manual extraction (scrape the wax out with a small tool)
- irrigation (flush the wax out with a fine jet of warm water)
- suction (hoover the wax up through a narrow tube).

If wax removal is required, the risks involved with the chosen method/s will be explained to you in detail.

We will also get you to listen for very quiet sounds through headphones and pressing a button in response. After these checks, we will discuss the results with you and let you know if you can participate in the full experiment. If the hearing test revealed a possible hearing loss, we will provide you with a copy of the results and will advise you to contact your GP to arrange a formal audiological assessment. A letter addressed to your GP can be provided to you if you wish. If you pass the hearing screening test and are eligible to take part in the study, you will then complete a series of tests. Some tests involve listening tasks, including cognitive listening tasks; and others involve filling out short questionnaires. We will give you clear instructions for each activity. For the listening tasks, you will sit in a quiet room with headphones and listen to different sounds, such as nonsense syllables or speech, in quiet or noisy settings, and in one or both ears. You will respond either verbally or by using the mouse to choose your answer on the computer screen. All sounds and noises will be at comfortable and safe levels; and will not harm your hearing. You will receive a short training session before each task to help you understand what to do. For the short questionnaires, you will be completing them on a computer in the testing room. In one of them, you will be asked to look at images of

different scenes on the screen, and you will be asked to identify any hearing problem you might encounter in these different daily situations. In the second one, you will respond to the written questions on the screen.

The order of some tasks will be random; for example, different noise conditions will be presented in a random order. Each listening task will have about 20-30 presentations and will take around 8-10 minutes of concentration. You can take breaks between tasks to rest, and we encourage you to do so.

After finishing all the activities, we will also give you a link to a short online form to collect information about you such as age, gender, occupation and other protected characteristics. You can fill this form out on your computer at your own convenience. The purpose of this form is to collect fully anonymous information about the people who consent to take part in our research studies. The National Institute for Health Research Manchester Biomedical Research Centre (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 **entirely optional** and you do not have to complete all/any of the questions if you do not want to. The response process is completely anonymous so we don't even know who has completed it and who has not.

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

We will compensate you for attending the visit, which could take up to four hours spread across two sessions. If you do not pass the hearing screening, or only complete one session, we will pay you £10 in cash at the end of the visit. If you complete the full experiment in two sessions, we will pay you an additional £30 cash after the second session, as an appreciation of your commitment. Reimbursement for reasonable travel expenses (eg local bus) can also be provided.

➤ **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 wish to participate, please use the contact details for the researchers detailed below. If you do decide to take part you will be given this information sheet to keep. You will be asked to sign a consent form, and 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.

Data Protection and Confidentiality

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

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

Name

Contact details

Gender

Date of Birth

All other data collected will immediately be pseudonymised and only linkable to your personal details via a subject identifier (ID) until the full data set has been collected, at which point the link will be broken. Your data is then fully anonymised. This data set is held completely separate from, and un-linkable to, the optional online equality survey.

➤ **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”.

➤ **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.

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](http://documents.manchester.ac.uk/display.aspx?DocID=37095).

URL for Privacy Notice : <http://documents.manchester.ac.uk/display.aspx?DocID=37095>

➤ **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:

Your experimental data will be locally stored against a unique ID, ie pseudonymised, and held on encrypted laptops. A very small proportion of this pseudonymised experimental data will be stored on a commercial website to which we can gain access to read it. (1) The key for the pseudonymisation is only held in the University of Manchester; and (2) the nature of the experimental data does not contain personally-identifiable information (PII), so the chances of de-anonymisation are very small, and the personal damage from the leakage of such data is minuscule. Your personal data will only be made on a single paper record kept in a locked filing cabinet in a university office. Only the research team will have access to the key that links this ID number to your personal information. Your consent form (including your name and signature) will be retained separately for 5 years after the end of the study in a locked filing cabinet on university premises. We will also ask for your permission to keep your contact details on file and contact you about future studies that you might be interested in.

In accordance with the University of Manchester’s Research Privacy notice and with your consent, we would like to be able to share your anonymised data with other University of Manchester researchers who are doing studies similar to ours.

At the end of the project we would like to deposit a fully anonymised dataset in an open data repository where it will be permanently stored. We will use Figshare at the University of Manchester Library. 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.

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.

What if I have a complaint?

Complaints in the first instance should be made to one of the researchers, or, if you wish to direct your complaint to someone independent of the research team, this should be the Research Governance and Integrity Office, listed below.

➤ Contact details for complaints

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

Dr Jenny Chan:	Email	jenny.chan@manchester.ac.uk	Tel	0161 306 5540
Prof Michael Stone :	Email	michael.stone@manchester.ac.uk	Tel	0161 275 8563

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](#) Tel 0303 123 1113

Web address : <https://ico.org.uk/concerns/>

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 Jenny Chan:	Email	jenny.chan@manchester.ac.uk	Tel	0161 306 5540
Prof Michael Stone :	Email	michael.stone@manchester.ac.uk	Tel	0161 275 8563
Prof Gabrielle Saunders:	Email	gabrielle.saunders@manchester.ac.uk	Tel	0161 275 3386