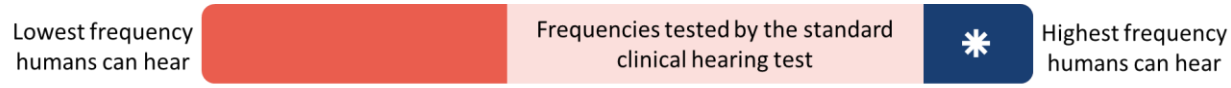
Extended High-Frequency Hearing Study

Participant Information Sheet (PIS)

You are invited to take part in a research study. The study is looking at whether a test of extended high-frequency hearing can predict how well people with mild or moderate hearing loss hear when they use hearing aids. The "extended high frequencies" are sounds that are very high in pitch. As shown in the picture below, the extended high frequencies are not usually tested in in everyday clinical hearing assessments.



✱ The "extended high frequencies"

The study forms part of a PhD project. Before you decide whether or not 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.

Why are we doing this research study?

When people with mild or moderate hearing loss first visit hearing care services, it can be hard to know if hearing aids will help them.

If clinicians could tell in advance whether someone is likely to benefit from hearing aids, it would be helpful because:

1) Clinicians could explain to patients what to expect from hearing aids. This would help the patient make decisions about their future care.
2) Clinicians could identify patients who may need extra support when learning to use hearing aids.

A test of extended high-frequency hearing might predict how well someone with mild or moderate hearing loss will hear speech in background noise when using hearing aids.

This is useful to know because it helps us decide if the test should be included in standard hearing assessment appointments.

Can I take part?

We are looking for people with a range of backgrounds and experiences to get involved. Does the following describe you:

- aged 18 years or older;
- a native English speaker;

- think (or know) you have a mild or moderate hearing loss in both ears;
- no current ear disease or disorder?

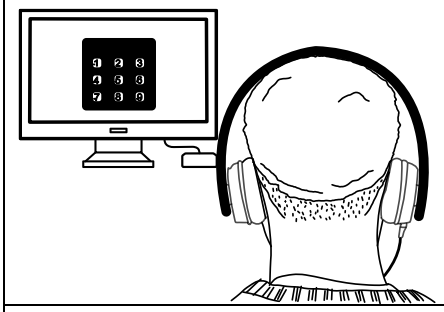
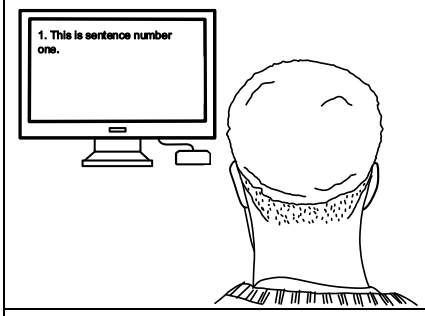
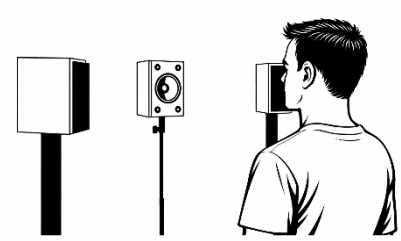
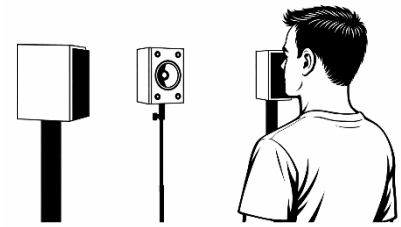
If so, you may be able to take part.

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

You will be asked to attend a single test session in one of the hearing research labs, located in the Ellen Wilkinson Building at The University of Manchester. The test session may last **up to three hours**, which includes a planned 10-min break, and up to 15 minutes of extra rest time should you need it. The test session will involve the following tests/procedures:

1. 	<u>Asking you questions about your current/previous health, particularly ear health.</u> **5 mins**
2. 	<u>Looking in your ears with a magnifying torch ("otoscope").</u> If you have earwax, we will offer to remove it for you. Any of three wax removal techniques will be used: • manual extraction with a lighted curette (a handheld plastic tool with a lightsource); • irrigation (flushing the wax out with a fine jet of warm water); • suction (hoovering the wax up through a narrow tube). It is entirely up to you whether you would like us to remove the earwax. However, if you decline, this will unfortunately prevent you from participating in the rest of the study. **2-20 mins**
3. 	<u>A routine clinical test of middle ear function ("tympanometry").</u> This test involves fitting a rubber ear tip snugly into your ear. You will feel a small change in pressure and hear a buzzing sound for approximately 10 seconds. **5 mins**

4. 	<u>A standard clinical hearing test ("pure-tone audiometry").</u> You will sit in a soundproof booth and be asked to press a button every time you hear a tone through a pair of earphones/headphones. This test measures the quietest sounds you can hear. **20-30 mins**
5. 	<u>"Extended high-frequency audiometry."</u> This is the same as the standard clinical hearing test, except the tones you will be asked to respond to will be higher in frequency (i.e., they will sound higher in pitch). **10-15 mins**
Test procedures 1-5 will confirm whether you are eligible to complete the remaining study procedures. If the test results suggest you have a problem with your ears or hearing that you were not previously aware of, the researcher will explain the results to you and give you a letter to take to your GP.	
10-minute break **During this time, you will be offered a drink and the opportunity to stretch your legs.**	
6. 	<u>A test to find the highest frequency you can hear at a set level ("Fixed level frequency threshold").</u> For this test, you will wear headphones and sit in front of a computer screen. You will see three boxes on the screen light up in turn. At the same time as one of the boxes lights up, you will be played a tone at a comfortable level. You will be asked to select on the screen which box lit up with the tone. This task will be repeated with tones of different frequency. The test will be done in each ear in turn. **20 mins**
7. 	<u>Questions about how you found Test procedure 6.</u> You will be asked four questions about how comfortable/acceptable you found the previous test (the Fixed level frequency threshold test). **5 mins**

8. 	<u>A speech-in-noise test with headphones.</u> You will wear headphones and be sat in front of a computer screen. You will hear someone say sequences of three different digits. You will be asked to select which three digits you hear from a "keypad" on the computer screen. At the same time as the voice, you will also hear a noise at a comfortable level. **5 mins**
9. 	<u>A test of your short-term memory.</u> You will be asked to read a series of sentences (presented one after another) on a computer screen. After the presentation of each sentence, you will be asked a question about its content. After you have answered a series of questions, there will be a recall exercise. **15 mins**
10. 	<u>A speech-in-noise test with speakers (unaided).</u> You will be sat on a chair a short distance away from some speakers. Over the speakers, you will hear someone say sequences of three different digits. You will be asked to repeat back the digits you hear. At the same time as the voice telling you the digits, you will hear people speaking in the background at a varying but comfortable level (volume). **10 mins**
11. 	<u>You will be fitted with a pair of hearing aids.</u> A standard clinical hearing aid fitting process will be followed. Sounds will be played from a speaker in front of you whilst the level (volume) of the sound is measured in your ear. The sound is measured using a thin, flexible tube that is placed in your ear at a safe distance from your eardrum. Measurements are taken first without the hearing aids in, and then with the hearing aids in your ears. The volume of the hearing aids will then be adjusted to match a prescription based on your hearing test results. **10 mins**
12. 	<u>A speech-in-noise test with speakers (aided).</u> Test procedure 10 will be repeated but with you wearing the hearing aids. **10 mins**

After your test session has ended, we will give you a link to (or post you) a short online form 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 study funder – 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 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.

What are the risks of doing these tests?

Overall, the risks of doing these tests are low. Some of the tests may feel tiring, but they should not cause pain, injury, or discomfort. You can ask to stop or take a break at any time. Please tell the researcher if you feel unhappy or uncomfortable.

For some tests, the researcher will need to place things in your ears. For example, when they look inside your ears or fit the hearing aids. There is a small chance that this could cause minor damage to the skin inside your ear or to your eardrum. These procedures are carried out routinely in hearing clinics. The researcher is a qualified audiologist and will follow clinical guidelines to reduce the risk of injury.

Most people will not need earwax removal. However, if earwax removal is needed, there are some uncommon risks, including:

- damage to the skin inside the ear or to the eardrum
- an ear infection after the procedure
- temporary hearing changes
- permanent hearing loss
- temporary dizziness and, rarely, feeling sick or faint
- new tinnitus (ringing, or other noises, in the ears) or temporary worsening of existing tinnitus
- temporary throat irritation, especially if your throat is already dry or sensitive

These risks vary depending on your ears, your general health, the type of earwax, and the method used to remove it. If earwax removal is needed, the researcher will explain the risks that apply to you before the procedure.

Will I be compensated for taking part?

You will receive a £25 Love2Shop gift card if you complete the screening procedures but are not eligible to participate in the rest of the study. You will receive a £45 Love2Shop gift card if you attend the full three-hour test session.

Other benefits of taking part include having your earwax removed (if required) and a hearing test performed by a qualified audiologist. If you are eligible to complete all study procedures, you will also get the opportunity to experience listening with hearing aids, although you will not be able to keep the hearing aids beyond the study visit.

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, please complete the rest of the online form, or get in touch with us directly (see Contact Details at the end of this information sheet), and we will instruct you how to arrange the test session. If, after this contact, we do not hear from you, we may attempt to contact you a maximum of two times. When you attend the

test session, you 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 after the study visit has completed. This does not affect your data protection rights. If you decide to withdraw from the study you would not need to do anything further.

If you do not wish to take part after reading this information sheet, you do not need to do anything. If you have already opened the online form, simply close the webpage.

Who will carry out the research study?

Melanie Lough, a registered audiologist and PhD student in the Division of Psychology, Communication and Human Neuroscience at The University of Manchester, will conduct the research. Dr Garreth Prendergast and Prof Chris Plack will supervise the research.

Will the findings of the research be published?

The results obtained from this research study will form part of a PhD thesis and may be published in a peer-reviewed journal. Portions of the work may be presented at academic conferences, or adapted for sharing with the public (e.g., through a blog). If you participate in the study and agree to it, we will send you a summary of the findings once the study has completed.

Who has reviewed the research study?

The research study has been reviewed by The University of Manchester Research Ethics Committee 3 [UREC reference 25185].

Who is funding the research project?

This research is funded by the NIHR Manchester Biomedical Research Centre (reference NIHR203308).

Data Protection and Confidentiality

What information will you collect about me?

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

- Your name and contact details. This is so we can arrange the test session with you, and (if you have provided consent for it) send you a summary of the study findings.
- As part of the test session, we will collect: your age and sex; information about current/previous health conditions; and, the results of your hearing tests.
- Your signature and name will be collected as record of your consent.
- Your signature and name will be recorded on a sheet as confirmation you have received reimbursement for your participation.

Please note: data from the optional survey of protected characteristics (e.g., age, gender etc) will be anonymously collected, and as such, is not classed as personal identifiable information.

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.

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:

- The paper records of your consent to participate and study reimbursement will be kept in a locked filing cabinet in an office with controlled access for at least two and five years, respectively.
- All data we collect about you during the test session will be assigned an ID number known only to the research team (i.e., the data will be "pseudonymised").
- A document linking your name and contact details with your assigned ID number will be stored separately and will be password-protected. It will only be accessible to the researcher. Once we have completed all testing, the document will be destroyed and your test data will be anonymised.
- If you gave your consent to receiving a study summary, your contact details will be stored separately in a password-protected file only accessible to the researcher. This file will be destroyed once a summary of the study findings has been disseminated.
- The data collected during the optional equality, diversity and inclusion monitoring survey may, in future, be used for secondary analysis in combined anonymised form. This means that your data is gathered together with everyone else's, with all personal identifiers removed to ensure your privacy and confidentiality. This work could support further research projects or educational activities (including training and capacity building), conducted by our research team or by others who have received our permission to use the data for their projects.
- At the end of the study, we will save a fully anonymised dataset in an open-access online data store (at www.osf.io) where it will be permanently retained. Researchers at other institutions and others can access the anonymised data directly from the online data store ("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?

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

Dr Garreth Prendergast. Email: garreth.prendergast@manchester.ac.uk. Telephone: 0161 275 3174

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.

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researcher, **Melanie Lough (email: melanie.lough@postgrad.manchester.ac.uk).**