That looks noisy!

Participant Information Sheet (PIS)

You are being invited to take part in a research study investigating a new hearing health questionnaire. 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?

Prof Gabrielle Saunders, Dr Samuel Couth, Dr Michael Loughran, Dr Emanuele Perugia, Gemma Perfect and Helen Whiston are the researchers. All of them are based at Manchester Centre for Audiology and Deafness (ManCAD); Division of Psychology, Communication and Human Neuroscience; School of Health Sciences, at the University of Manchester.

## What is the purpose of the research?

The purpose of the research is to find out whether a new hearing health questionnaire that uses pictures instead of words, is reliable and useful for understanding hearing loss. We are looking to recruit people with normal hearing and people with hearing loss (mild, moderate, severe) from a variety of backgrounds. We hope to recruit up to 120 participants.

## Am I suitable to take part?

We’d like you to consider taking part if you are:

* At least 18 years old
* Able to understand simple test instructions written in English

## Will the outcomes of the research be published?

The findings from the research may be presented in scientific conferences, published in peer-reviewed journals, and in scientific or hearing-related magazines that are published both online and in paper format. Your individual responses will not be identifiable in any published research.

## Who has reviewed the research project?

This study has been reviewed by the University of Manchester Proportionate Research Ethics Committee (REF: 2024-19601-34540).

## Who is funding the research project?

This project has been funded by the National Institute of Health and Care Research (NIHR) Manchester Biomedical Research Centre (BRC)

# What would my involvement be?

## What will I be asked to do if I took part?

If you agree to take part, you will be asked for your consent to be given online using a computer or tablet, and you will then be asked to complete a questionnaire that asks some general questions about you. You will then be asked to complete some short online hearing health questionnaires at home on two occasions using a computer or tablet, and you will make one hour-long research visit to the Manchester Centre for Audiology and Deafness (ManCAD), at the University of Manchester. During that visit you will do some hearing tests and complete some other questionnaires.

Hearing Health Questionnaires completed at home on two occasions: You will be asked to fill in three questionnaires via Qualtrics, an online survey platform. One is a new questionnaire and two are questionnaires already in use clinically. If you use hearing aids you will be asked to complete each questionnaire twice - once for how you hear without your hearing aids and once for how you hear with your hearing aids. The new questionnaire uses photographs instead of words to show common situations in which you might find yourself wanting to hear. For each questionnaire you will be asked to rate how well you think you would hear in that situation. The questionnaires will take a total of 15 - 20 minutes to complete. You will fill in the questionnaires two weeks before your research visit to the University of Manchester, and then a day or so before your research visit.

Research visit to the Manchester Centre for Audiology and Deafness (ManCAD), University of Manchester arranged to suit your schedule: Your hearing will be tested using standard audiology tests, as follows: (a) We will look into your ears using an otoscope to check ear health and for the presence of wax that may prevent participation. (b) We will do a routine hearing test that consists of playing quiet beeps to find out what are the quietest sounds you can hear. (c) We will do a quick pressure test of each ear to check the function of your middle ear (ear drum) (d) You will do a listening task that involves identifying spoken digits (numbers) presented in some background noise. This appointment will last about 1 hour.

At the very end of the research visit, we will provide you with a link to an additional short questionnaire to collect information about your age, gender, occupation and other protected characteristics. This form and the data will be stored separately from the data collected during the rest of the study. 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 it or not.

## What are the risks if I take part?

Aside from being bored or tired during the testing there are no risks to taking part in the study. It is possible that the hearing tests will show that you have a hearing loss, wax in your ears, or some other sort of ear issue. If this is the case the researcher will give you a letter that will advise you to book an appointment to see your GP for further assessment of your ear health. This information sheet will be attached to the letter.

## Will I be compensated for taking part?

To thank you for completing all parts of this study, you will be compensated with £30 cash once the research visit has been completed.

## What happens if I don’t want to take part or change my mind?

It is up to you to decide whether or not to take part. If you do not want to take part you should simply not press the link to begin the online part of the study. Regardless of whether or not you decide to take part you can download this information sheet to keep. Once you have read this sheet you will be asked to tick a box to confirm that you consent to take part. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself, and you are free to provide as much or as little information as you wish in the questionnaires. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

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.

# 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
* Email
* Age
* Gender
* Education
* Ethnicity
* Use of English language
* Your hearing status
* Use of hearing aids/cochlear implants

## 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 that 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).

## 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 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:

* All data will be pseudonymised. Data will be recorded electronically against a participant number (or "ID"). Only the research team will be able to see this information, which will be saved electronically and will be password-protected. This document will be deleted 1 year after the entry.
* Processed, de-identified, data will also be stored and backed up using the University of Manchester Research Data Storage service, and will additionally be deposited in an online, open-access repository (e.g. the Open Science Framework, https://osf.io/).
* Data will be stored for 5 years

## Potential Disclosures

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 want to make a complaint?

Contact details for complaints

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

Email: gabrielle.saunders@manchester.ac.uk

Tel: 0161 275 3386

**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 researcher in the first instance then please contact**

TheResearch 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](https://ico.org.uk/concerns) 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 researchers:

**MICHAEL LOUGHRAN**: michael.loughran@manchester.ac.uk

**Gabrielle Saunders**: gabrielle.saunders@manchester.ac.uk

**Samuel Couth**: samuel.couth@manchester.ac.uk

**HELEN WHISTON**: helen.whiston@manchetser.ac.uk

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