Testing hearing using Auditory Steady State Response (ASSR)

Participant Information Sheet (PIS)

This participant information sheet should be read in conjunction with the University's research privacy notice (http://documents.manchester.ac.uk/display.aspx?DocID=37095).

We have also supplied an Easy Read version of this form.

We invite you to take part in a research study

Joining the study is entirely up to you, but before you decide we would like you to understand why the research is being done and what it would involve for you.

Please take the time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Do ask if there is anything that is not clear or if you would like more information.

How to contact us

If you have any questions about this study, please contact Christy Davidson or Siobhan Brennan by emailing Christy.Davidson@postgrad.manchester.ac.uk or Siobhan.Brennan@manchester.ac.uk.

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1. Who will conduct the research?

The study will be carried out by Christy Davidson, a final year master's student in Advanced Audiology, under the supervision of Dr Siobhan Brennan in the Division of Human Communication, Development & Hearing at the University of Manchester.

This project has been reviewed and approved by The University of Manchester Research Ethics Committee (Project Reference: 2026-25461-47207).

2. What is the purpose of the research?

We would like to assess your hearing using a test called the Auditory Steady State Response (ASSR).

This test is used routinely in NHS Audiology clinics in the UK; however, we are hoping to find out if there are any differences in the results in adults with Down's syndrome, compared to adults without Down's syndrome. This knowledge will help us to understand how to best use this test for different groups of people.

We would also like to ask you about your experience of participating in the study, so that future research looking into this topic can be designed in the best way.

3. Who can take part?

You will be considered for this research study if you fit the below inclusion criteria:

- Adults with or without Down's syndrome aged 18-50 years
- Adults of any gender
- Adults of any ethnic background
- Hearing that falls withing the satisfactory to moderate range (your hearing will be screened as part of the study so if you are unsure, please still enquire)

You may be excluded from the study if:

- You are unable to provide consent for yourself
- You have too much wax in your ears for us to safely perform the hearing tests
- You are unable to complete the screening hearing test, or if this shows your hearing loss is too great for the requirements of our study
- You are a wheelchair user or you have reduced mobility which means you are unable to climb several steps as unfortunately this is necessary to access our mobile research van

4. What would I need to do to take part?

If you agree to take part in the study, we will take some personal details from you which we will keep secure until we no longer need them. This will include contact details so we can discuss what will happen in the session and how you might need to prepare. There is more information regarding this in section 5 below.

We will then arrange for you to attend one in-person session at our mobile research van. This will be arranged at a time and a place which is convenient to you. The session should be no more than one hour long, and you can bring someone with you if you like.

1. We will check that you understand what will happen during the session and we will ask you to sign a formal consent form so we can continue with the session. There is an option to provide verbal informed consent if you are unable to or uncomfortable providing written informed consent, however this must be witnessed by someone independent of the researchers, i.e. you must bring someone with you who can verify this.
2. We will ask you some general questions about your ears so that we are happy to proceed safely with the hearing test.
3. We will look in your ears and perform a basic hearing test where you will be asked to tell us when you hear a sound (this may be pressing a button or playing a game). If you are unable to complete this part of the testing, or if this test shows that your

hearing loss is greater than moderate it may affect your ability to continue in the study.

4. We will lightly rub the top of your head and behind your ears with a paste, and attach some sticky pads to your head which will measure your brain's response to sounds. We will ask you to relax in a comfy chair. We may ask you to read a book or watch videos on a tablet computer. We will then play some sounds into your ears which you don't have to listen to. Some will be louder than others but none of them should be uncomfortable.

After the tests have been completed, we will ask you some simple questions about your experience of taking part in the study. We would like you to be honest as this may affect how we conduct future research into this topic. Questions might include:

- How did you feel about the testing happening in the van?
- Did the tests take too long or was the length of the session ok?
- Did any of the testing make you feel uncomfortable?
- Did you enjoy the session?

Additional comments and perspectives are welcomed but not mandatory.

Once the session is complete, we will answer any questions you may have and in the unusual event that anything unexpected has been picked up during testing we will let you know so that you can speak to your GP about it. You will then be free to leave. You do not need to have any further contact with the research team unless you would like a summary of the study outcome or if any questions arise following the session.

5. What information will be collected 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:

- Your name
- Your date of birth so we can ensure you fit the inclusion criteria
- Your email and/or telephone number so we can contact you to arrange the session
- Your address or general location so we can set up an appropriate meeting point
- Your GP or care provider information (if applicable) in case we need to inform them of anything that is disclosed during the session that may be considered a safeguarding issue
- Your consent that you have read and understood this PIS and you are happy to participate in the study.

We will collect most of this personal information by email/telephone prior to the session, once you have emailed the research team to confirm you have read and understood this PIS and are willing to take part in the study. You will receive a standard reply informing you that it will be inferred that you are happy for the researchers to store your personal identifiable information for screening purposes. You can 'opt out' at this point if you are not comfortable with this and all your identifiable information will be deleted. We will store all

your personal information securely in accordance with UK data protection law which protects your rights. We will not share it with anyone else.

We will also complete a formal consent form at the start of the session. Your results from the testing will be stored anonymously after the session has concluded and it will not be possible to identify you from the data.

6. What are the risks and benefits of taking part?

Your safety and comfort will be taken very seriously during the study, and we will do as much as we can to protect this.

The tests are performed in a quiet (sound treated) room which can be a strange experience for some people, especially those who have not been in this kind of environment before. It is possible that you could become upset or agitated during the session. We will discuss any reasonable adjustments prior to the session to reduce this possibility, including having an accompanying adult with you for reassurance if needed.

Occasionally, people with tinnitus (noises in their ears) can find that quiet rooms or hearing tests can temporarily exacerbate their tinnitus noise. The risk of this happening during the session will be minimal and any changes in tinnitus should resolve quickly once you return to an environment with normal amounts of background noise. Also, we will not be testing to levels which would be excessively loud; however, if you do have tinnitus please let us know prior to the session and we will proceed cautiously.

We will follow national recommended procedures for all tests performed. We will pause or discontinue the session if this is necessary. You are also free to leave the session at any time if you do not feel comfortable.

We understand that people have different communication needs, and we will plan the session so that you are able to participate fully. We will provide information in different formats including Easy Read etc. as appropriate. Please tell us about any adjustments we can make to help you participate in the study.

There are no long-term risks to your hearing or your general health by partaking in this research study, and if you are a patient of an NHS or private Audiology clinic this will not affect your ongoing management. You will not require any further contact with the researchers following the session.

There are no health-related benefits from partaking in this research study as we are only recording your responses to sound stimulation, we are not providing you with any treatment.

Upon successful completion of the study, you will be given a shopping voucher worth £10 to thank you for participating. We will also try to make participation as convenient as possible by using our mobile research van, so there should be no significant travel expenses for you if you live outside of Manchester.

7. Can I change my mind?

It is up to you to decide whether or not to take part. If you want to take part, you can contact the research team using the email details supplied on the front page of this information sheet.

If you do 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 (once your data has been transferred to the secure server following the session) 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.

8. What will happen to my personal information?

For more information about how we will keep your personal information confidential and secure, including how we comply with UK GDPR legislation, please refer to the Data Protection and Confidentiality section of the Supplementary PIS.

9. Will my information be kept confidential?

If, during the study, we have concerns about your safety or the safety of others, we will need to inform your GP/care team.

Please 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 information. All individuals involved in auditing and monitoring the study will have a strict duty of confidence to you as a research participant.

So that we can provide the shopping voucher as a thank you for your time, your full name and email address will be shared with our Finance department who will send the voucher to you. Your full name and email address will be securely retained by Finance for a period of up to 7 years for audit purposes only and then destroyed. It will not be used by them for any other purpose.

10. What if I want to make a complaint?

If you have a complaint that you wish to direct towards members of the research team, please contact Siobhan Brennan: Siobhan.Brennan@manchester.ac.uk.

If you are not satisfied with the response you receive or your wish to make a formal complaint to someone independent of the research team, please contact The Research Ethics Manager by emailing research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

How to contact us

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

Christy Davidson: Christy.Davidson@postgrad.manchester.ac.uk.

Siobhan Brennan: Siobhan.Brennan@manchester.ac.uk.

Thank you for taking the time to read this information sheet.

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Supplementary Information

This supplementary information should be read in conjunction with the information provided in the Participant Information Sheet.

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A. Maintaining Confidentiality

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. Your data will be looked after in the following way:

- Your personal identifiable information will be stored on the University of Manchester's secure server in a password protected file that is only accessible to the research team.
- Test results will be transferred to the University of Manchester's secure server and will only be available to the research team. This process will be done by Christy Davidson.
- All participant data will be provided with anonymous identifiers as soon as the data is transferred and all identifying information (names, date of birth etc.) will be removed.
- Identifiable information (names, date of birth etc.) will be anonymised in the reported data so it will not be possible to identify you in the study results.

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 (available at https://documents.manchester.ac.uk/display.aspx?DocID=37095).

B. Storage, Retention and Archiving

Consent forms and anonymised test results will be stored for 1 year and will then be deleted. Unless a report of the study's outcomes is requested, participant email correspondence and contact details will be deleted once the sessions are finished. We will not retain any personal information for any other reasons, such as for invitations to future studies.

The results of this study may be published in future, if so, all data will be fully anonymised so it will not be possible to identify you from the study results.

The results of this study may be shared with other organisations such as the Down's Syndrome Association, or national Audiology professional bodies such as the British Society of Audiology and the British Academy of Audiology to help inform policy. Again, all data will be fully anonymised so it will not be possible to identify you from the study results.

C. Disclosure and Barring (DBS) Check

Both members of the research team (Christy Davidson and Siobhan Brennan) have undergone an enhanced DBS check as part of the requirements of their clinical work within the NHS.