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Study Title: Speech test reliability in adult cochlear implant users

PARTICIPANT INFORMATION SHEET

Research Ethics Reference: 445-1912
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We would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. One of our team will go through the information sheet with you and answer any questions you have. Please take time to read this carefully and discuss it with others if you wish. Ask us anything that is not clear.

What is the purpose of the research?

In March 2019, the National Institute for Health and Care Excellence (NICE) changed its guidance for the NHS about which adults should be offered a cochlear implant (CI). Part of the assessment for CI includes deciding if adults can hear well enough with their hearing aids. This used to be done by asking people to repeat words from whole sentences (the 'BKB Sentence test'). Now, it is measured by asking adults to repeat single words played one at a time. This test is called the 'AB word test'.

Now that the test that is used to make decisions about who should receive a CI has changed, it is very important for us to understand how reliable this test is. In other words, if the test is done twice and the patient's hearing has not changed, how likely is it that the test will give the same score? The specific questions we would like to answer in this study are:

1. How reliable are scores from the test?
2. Is the test more or less reliable if the words are played at different volumes?
3. Are scores from the test affected by who administers the test, and if so by how much?

Why have I been invited to take part?

You may have read about this study on a website or social media channel, or in the newsletter of the NIHR Nottingham Biomedical Research Centre. You may also have been approached to take part because you previously joined our research participant database and agreed to be informed of future hearing research studies that you may be interested in.

You are eligible to take part if you:

- are aged 18 or over
- have received one cochlear implant (unilateral cochlear implantation)
- have used a cochlear implant for at least 6 months
- are able and willing to take part in all study assessments

If you are not sure if you are eligible, please contact us and we can discuss this with you.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you decide to take part, you will have the chance to ask questions about anything on this information sheet and the study itself. You will then be asked to sign a consent form to confirm that you understand what is involved.

If you decide to take part, you are free to leave the study at any time without giving a reason.

If you withdraw, please note that it will not be possible to destroy any data already collected. Unless you object, we may still include any information and measurements obtained prior to your withdrawal in our final analyses.

What will happen to me if I take part?

If you are eligible to take part in the study, you will be invited to attend a research appointment at the Nottingham Biomedical Research Centre, part of the School of Medicine in the University of Nottingham. This will last approximately 1 hour.

When you arrive, you will have an opportunity to ask us any questions you have about the study. You will then undertake the following:

- Sign a consent form telling us that you understand the information and that you are happy to take part in the study. You will be given a copy of this information sheet and the signed consent form to keep.
- A hearing test to measure the softest sounds that you can hear with your CI.
- A few questions about you and your CI use, e.g. what kind of implant you have and how long you have used it for.
- Speech tests: You will be asked to listen to pre-recorded lists of spoken words and sentences. We will ask you to repeat what you hear. You will complete the tests twice with a break before you complete the tests a second time. We will present the words at different volumes, but always at a comfortable level.

While you take part in the speech tests, we will make an audio-visual recording of you repeating the words using a digital camera and a microphone. This recording is made only so that we can check whether other members of the research team would give you the same scores if they watched and listened to your responses. This video would only be seen by the research team and not shared with anyone else, and only used to understand if scores on the speech tests change based on who is assessing your responses.

Are there any risks in taking part?

There are no risks or side-effects associated with any of the tests used in this study. All sounds will be presented at a comfortable level, and we will provide breaks during the testing session.

Are there any benefits in taking part?

There are no direct benefits to you for taking part, but the information we get could help us to improve the lives of adults with hearing loss, by helping to improve decision making around who should be offered a cochlear implant. The results of the study could also help us to design better research studies in the future by understanding more about how reliable speech tests are.

Will my time/travel costs be reimbursed?

Participants will receive an inconvenience allowance to participate in the study (£7.50/hour). Travel expenses will be offered for any visits incurred as a result of participation, up to a total of £15.

What happens to the data provided?

The **research data** will be stored confidentially by assigning you a volunteer study identification number (for example P01 for participant number 1). This number will be used instead of your name. We will save all the recordings and research data using that volunteer study identification number so that none of the data will have your real name or other individual identifiers associated with them. Your name and any information about you will not be disclosed outside the study centre.

Personal data, including the audio-video recordings, will be stored confidentially using the secure digital file storage systems provided and maintained by the University of Nottingham. Any paper records containing personal data (e.g. informed consent forms) will be stored in locked filing cabinets in locked offices at the University of Nottingham.

Only members of the research team will have access to research and personal data, under the supervision of the Chief Investigator, Dr Padraig Kitterick.

All research data and records will be stored for a minimum of 7 years after publication or public release of the work of the research.

We would like your permission to use anonymised data in future studies, and to share our research data (e.g. in online databases) with other researchers in other Universities and organisations both inside and outside the European Union. This would be used for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. All personal information that could identify you will be removed or changed before information is shared with other researchers or results are made public.

What will happen if I don't want to carry on with the study?

Even after you have signed the consent form, you are free to withdraw from the study at any time without giving any reason and without your legal rights being affected. Any personal data (including audio-visual recordings) will be destroyed.

If you withdraw we will no longer collect any information about you or from you but we will keep the anonymous research data that has already been collected and stored as we are not allowed to tamper with study records. This information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Who will know that I am taking part in this research?

All information collected about you during this research would be handled in confidence. All such data are kept on password-protected databases sitting on a restricted access computer system and any paper information (such as your consent form, contact details and any research questionnaires) would be stored safely in lockable cabinets in a swipe-card secured building and would only be accessed by the research team.

Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx/

Designated individuals of the University of Nottingham may be given access to data for monitoring and/or audit of the study to ensure we are complying with guidelines.

What will happen to the results of the research?

The results of the study may be published in scientific journals and presented at scientific meetings. In all such cases, data will be presented anonymously so that it is not possible to identify you or the other volunteers. The video recordings will never be shown to anyone outside of the research team.

Who has reviewed this study?

All research involving people is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Faculty of Medicine and Health Sciences Research Ethics Committee (Reference number: FMHS 445-1912).

Who is organising and funding the research?

The research is organised by the Severe to Profound Hearing Loss team, part of the Hearing Sciences research group in the School of Medicine at the University of Nottingham.
The research is funded by the Nottingham Biomedical Research Centre.

What if there is a problem?

If you have a concern about any aspect of this project, please speak to the lead researcher Dr Robert Pierzycki or the Principal Investigator Dr Padraig Kitterick, who will do their best to answer your query. The researcher should acknowledge your concern within 10 working days and give you an indication of how he/she intends to deal with it. If you remain unhappy and wish to complain formally, you can do this by contacting the FMHS Research Ethics Committee Administrator, Faculty Hub, Medicine and Health Sciences, E41, E Floor, Medical School, Queen's Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG7 2UH or via E-mail: FMHS-ResearchEthics@nottingham.ac.uk.

Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

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