

Participant Information Sheet For Adults

UCL Research Ethics Committee Approval ID Number: **SHaPS-2018-DV-028**

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of Study:

Using Objective Measures to Evaluate Perception in Adults with Normal Hearing or Cochlear Implants

Department:

Speech, Hearing and Phonetic Sciences

Name and Contact Details of the Researcher(s):

Dr Axelle Calcus – a.calcus@ucl.ac.uk - 020 7679 4283

Name and Contact Details of the Principal Researcher:

Dr Deborah Vickers – d.vickers@ucl.ac.uk

1. Invitation Paragraph

You are being invited 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. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.'

2. What is the project's purpose?

For many people with a hearing loss, cochlear implants are used with the intention of improving hearing. However, large variations remain in the benefit provided by a cochlear implant on an individual basis. Predicting the differences has been a challenge, but being able to do so may help to alleviate some of the problems. Recent research suggests that the lack of sound input prior to receiving a cochlear implant has an impact on brain responses and parts of the brain that should pick up sound change their behaviour and respond better to visual information. This effect is termed 'cortical re-organisation'. So far, cortical re-organisation was mostly investigated with electroencephalography (EEG) in patients with cochlear implants. The main purpose of this study is to evaluate the use of a new measures, known as functional near infrared spectroscopy (fNIRS), to look at brain patterns to sound. We hope to compare this technique to EEG, and apply it with normal hearing adults, and adults with cochlear implants. fNIRS works by shining light into the brain, and then measuring it when it bounces back out again to see how much light has been absorbed. This changes with brain activity so helps us to understand which parts of the brain are responding to sound. It is completely safe and has been widely used, even on infants. In this study, brain activity will be measured while listening to different kinds of sounds.

3. Why have I been chosen?

We are looking for participants meeting one of the following set of criteria:

- A. normal hearing adults (no age restriction)
- B. hearing impaired adult (no age restriction) using cochlear implant(s)

Exclusion criteria are the following:

- Patients with neurological diseases (e.g., epilepsy)
- Hearing impaired patients not using cochlear implants

4. Do I have to take part?

No, the decision is entirely yours. If you do decide to take part you will be given this information sheet to keep (and be asked to sign a consent form). You can withdraw at any time without giving a reason and without it affecting any benefits that you are entitled to. If you decide to withdraw you will be asked what you wish to happen to the data you have provided up to that point.

5. What will happen to me if I take part?

- You will be invited to come to our research lab at Chandler House in London for two measurement sessions. Each session will last approximately 1.5-2 hours.
- You will arrive at the research labs and be greeted by one of our researchers. Before each recording session, you will be given information about the study, giving you the chance to ask any questions. Again, you may withdraw from the study without giving any reason.
- If you do not have a cochlear implant we will test your hearing ability with a device known as an audiometer. This will involve wearing headphones through which we will present various sounds of different frequencies and you will be asked to click using a button every time you hear a sound. This will give us an indication of whether or not your hearing appears to be within the normal clinical range.
- Should your hearing be normal, we will proceed to the next stage. If at this point, your hearing is not considered normal, we will not proceed with the session. We are not audiologists so you will be advised to consult your GP for further examination.
- During the measurement session, a head cap will be placed on your head from which several optodes (light delivery and recording sensors connected to the fNIRS scanner) and/or electrodes (sensors measuring physiological activity connected to the EEG recorder) will gather brain activity as we carry out the study.
- During the recording session, you will be asked to listen to sound sequences or watch someone on a screen or read a book while we make recordings. We might then ask you to listen to the sounds and play a game to see which ones you can hear apart or to do a quick speech test where you say what words you hear.
- If you don't have an implant the sound sequences will be presented to you via insert earphones to minimise the effects of external noise created by the fNIRS/EEG machines. These consist of small tubes contained in ear plugs which you will insert into your own ears. The experimenter will look into your ears using an otoscope to ensure that they are relative clear of wax. If there is a lot of wax in your ears, you may not be able to use the insert earphones, and hence not participate any further. For cochlear implant users the sound will be played through your implant.
- You will be left alone in a sound proof research facility for the duration of the sound sequences and lights will be turned off to mitigate other factors which may affect brain activity.
- After these measures you will also be asked to listen to some words and sentences and say what you hear. Also you will be asked to recall some sequences of words and to make some judgements about different types of words.

- At the end of the recording session, you will be again asked if you have any questions about the study now that you've heard the stimuli.

6. What are the possible disadvantages and risks of taking part?

Apart from the time you spend and any inconvenience, we do not believe that there are any disadvantages in your taking part in this study.

7. What are the possible benefits of taking part?

We do not expect direct, short-term benefits to participants, but the information we get is expected to help the development of a better understanding of brain activity of speech processing and aid research in cochlear implants.

8. What if something goes wrong?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, you should ask to speak to a member of the study team who will do their best to answer your questions.

The Chief Investigator for this research is:
Dr Deborah Vickers
UCL Speech Hearing and Phonetic Sciences
2 Wakefield St, London WC1N 1PF
Email: d.vickers@ucl.ac.uk

In the unlikely event that you are harmed by taking part in this study, compensation may be available. If you suspect that the harm is the result of the Sponsor's (University College London) negligence then you may be able to claim compensation. After discussing with your researcher, please make the claim in writing to the Chair of the UCL Research Ethics Committee – ethics@ucl.ac.uk

9. Will my taking part in this project be kept confidential?

All data will be handled according to the General Data Protection Regulation. All information which is collected about you during the course of the research will be kept strictly confidential and will be stored on computer databases that can only be accessed by the research project team. With your consent, we may store basic information such as name, address and age on a long-term basis to enable use to invite you to take part in similar future research.

We will make public the results of the tests we perform, but we will never make public the identities of any of participants in the study. You have the right to check the accuracy of data held about you and to correct any errors.

10. Limits to confidentiality

Confidentiality will be respected subject to legal constraints and professional guidelines.

11. What will happen to the results of the research project?

We will report our research findings to other researchers at conferences and in printed reports. Individual participants will not be identified in any report or publication.

12. Data Protection Privacy Notice

Notice:

The data controller for this project will be University College London (UCL). The UCL Data Protection Office provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk. UCL's Data Protection Officer can also be contacted at data-protection@ucl.ac.uk.

Your personal data will be processed for the purposes outlined in this notice.

The legal basis that would be used to process your *personal data* will be "the performance of a task in the public interest."

The legal basis used to process *special category personal data* will be for scientific and historical research or statistical purposes/explicit consent.

Your personal data will be processed so long as it is required for the research project.

We will store minimal personal data (contact details, reason for deafness) in a locked filing cabinet and anonymise data stored electronically. We will endeavour to minimise the processing of personal data wherever possible.

You have certain rights under data protection legislation in relation to the personal information that we hold about you. These rights apply only in particular circumstances and are subject to certain exemptions such as public interest (for example the prevention of crime). They include:

- The right to access your personal information;
- The right to rectification of your personal information;
- The right to erasure of your personal data;
- The right to restrict or object to the processing of your personal data;
- The right to object to the use of your data for direct marketing purposes;
- The right to data portability;
- Where the justification for processing is based on your consent, the right to withdraw such consent at any time; and
- The right to complain to the Information Commissioner's Office (ICO) about the use of your personal data.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk.

If you remain unsatisfied, you may wish to contact the ICO. Contact details, and further details of data subject rights, are available on the ICO website at: <https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/>

13. Who is organising and funding the research?

The University College London, Biomedical Research Centre

14. Contact for further information

Dr Axelle Calcus
UCL Speech Hearing and Phonetic Sciences
2 Wakefield St, London WC1N 1PF
Email: a.calcus@ucl.ac.uk

Dr Deborah Vickers
UCL Speech Hearing and Phonetic Sciences
2 Wakefield St, London WC1N 1PF
Email: d.vickers@ucl.ac.uk

Thank you for reading this information sheet and for considering to take part in this research study.