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Participant Information Sheet for Cochlear Implant Users

Study Title: The perspectives and recommendations of cochlear implant professionals and users for the development of a wearable haptic device.
Researcher: Ahmed Bin Afif
ERGO number: 61075

Please read the following information carefully before you make your decision. If you are happy to participate, you will be asked to sign a consent form. If anything is unclear or if you need additional information, please do not hesitate to contact Ahmed Bin Afif (aaba1n17@soton.ac.uk).

What is the research about?

This research is part of a PhD project. The aims of this study are to explore the perspectives and experiences of UK cochlear implant (CI) users and professionals concerning:

a) The listening challenges experienced by CI users,
b) The current strategies and assistive technology devices used to minimise listening challenges and
c) The perceived potential value of haptic stimulation (vibration to the skin) and variables that must be considered in the development of a potential haptic device for CI users. Haptic or vibrotactile device is worn on skin, either one or both sides of the body, that picks up speech and sounds in the environment and converts them into gentle vibration that can be felt on the skin.

Why have I been asked to participate?

You have been asked to take part because you are an experienced CI who is either unilaterally or bilaterally implanted for at least 12 months.

What will happen to me if I take part?

The research comprises three phases:

a) initial questionnaire,
b) focus group discussion and
c) post-focus group questionnaire.

Phase one

Interested participants who sign the consent form electronically will be sent the initial questionnaire via email. The initial questionnaire comprises two sections that might take approximately 10-15 minutes to complete. In the first section, you will be asked to identify your demographics to ensure you meet the eligibility criteria of the research. Eligible participants will be asked to complete section

two, which consists of four open-ended questions about hearing challenges, strategies and assistive technologies used to minimise challenges and any experience with haptic devices.

Phase two

When the initial questionnaire is received, the researcher will arrange with you via email the date, time and type of focus group. The invitation email will include some instructions and ground rules that you must read. The discussions will cover recommendations concerning the development of a haptic device for CI users. You will have the choice of taking part in either a live online meeting or a 'bulletin board' discussion. For the live meeting, a British Sign Language interpreter can be offered if required.

The online live meeting will be an approximately one-hour discussion with a small group (3–4) of CI users. With your consent, the discussion will be recorded and anonymously transcribed. After the transcription, the recorded videos will be deleted.

Alternatively, the bulletin board is a discussion forum that enables about ten participants to sign in and post written comments, answer questions and read other posts. This discussion thread will last for one week, and it can be accessed at a time/s convenient to you.

Phase three

In this phase, you will receive a survey that will allow you to add any further comments or thoughts you have on the phase two discussion. You will also be asked to provide your feedback on the design of a haptic device prototype. This survey will take approximately 10-15 minutes to complete.

Are there any benefits in my taking part?

There will be no direct benefit to you as an individual; however, providing your insights in this study will contribute towards the improvement of the potential haptic device and may be of benefit to you and other cochlear implant users in the future.

Are there any risks involved?

There are no anticipated risks to participants who take part in this study. Contact details for the researcher and project supervisors have been included below in the event that you may require any support after taking part in the study.

Ahmed Bin Afif: aaba1n17@soton.ac.uk

Dr.Ben Lineton: Bl@isvr.soton.ac.uk

Prof.Nicci Campbell: N.G.Campbell@soton.ac.uk

Dr.Mark Fletcher: M.D.Fletcher@soton.ac.uk

What data will be collected?

The following is a list of all data obtained by researcher Ahmed Bin Afif:

- Your email address to contact you
- Your demographics (i.e. age, gender, geographic location, hearing loss history, CI device information etc.)

- Your answers to the four open-ended questions about listening challenges among CI users, strategies and assistive technologies used to minimise challenges and any experience with haptic devices among CI users.
- The online focus groups will be video-recorded for subsequent anonymous transcription. Following transcription, the recording will be deleted.
- The contextual data of the bulletin board discussion will be anonymously coded.
- Your answers to the post-focus group survey.

All electronic data will be stored on a password-protected computer in the University of Southampton secure servers. The data will be held in accordance with the University of Southampton policy on data retention.

Will my participation be confidential?

Your participation and the information we gather about you during the study will be kept strictly confidential.

Only research team members and responsible University of Southampton members can access data about you for monitoring purposes and/or perform a study audit to ensure that the work complies with relevant regulations. Individuals from regulatory authorities (people who check we are doing the study properly) who may require access to your data. They all have a responsibility to keep your details strictly confidential as a research participant, strictly confidential.

The research team will not disclose whether you or anyone else have participated in this study. All discussions contextual data will be anonymised. Furthermore, any names of individuals mentioned in during discussions will be replaced with a pseudonym. All electronic data will be stored on a password-protected computer. The data will be held in accordance with University of Southampton policy on data retention. Only the researcher and supervisors will have access to it.

With your consent, the researcher will retain your contact information so that you can be contacted once again in relation with future work on this project. The University's data protection policy governing the use of personal data by the University will apply which can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page). If at any time you wish to remove your contact details from future-research contact list, you can contact the researcher or the research team at any time.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

Please contact the researcher (aaba1n17@soton.ac.uk) if you wish to participate. You have to sign a consent form, and all other phases will be arranged.

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected.
If you withdraw from the study, we will keep the information that we have already

obtained for the purposes of achieving the objectives of the study only

What will happen to the results of the research?

The results of the study will be written up and form the basis of my doctoral thesis. Some of the findings may be submitted for publication. All personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

Where can I get more information?

Please contact Ahmed Bin Afif on aaba1n17@soton.ac.uk if you have any queries.

What happens if there is a problem?

If you are concerned with any aspect of this study, you should contact to the researchers who are going to make every effort to address your questions.

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

The researcher: Ahmed Bin Afif (aaba1n17@soton.ac.uk)

Supervisor: Dr. Ben Lineton(Bl@isvr.soton.ac.uk)

Supervisor: Prof. Nicci Campbell (N.G.Campbell@soton.ac.uk)

Supervisor: Dr. Mark Fletcher: (M.D.Fletcher@soton.ac.uk)

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at

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http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for ten years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

Thank you for taking the time to read the information sheet and considering taking part in the research.