UNIVERSITY OF Southampton

Participant Information Sheet

Study title: New Tests for Remote Monitoring of Cochlear Implants
Principal Investigator: Helen Cullington
Investigation Site: Southampton
Site Principal Investigator: Helen Cullington

Please read this information carefully before deciding to take part in this research. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor. Feel free to do this. If you are happy to participate you will be asked to sign a consent form. You will be given a copy of this Participant Information Sheet and Consent Form to keep.

What is the research about?

You are invited to take part in a research study that will try out a new set of tests that could be used by clinicians to work out if someone using a cochlear implant needs to come to the cochlear implant centre. The research is sponsored by the company that made your implant: Cochlear. We want to know how people using implants feel about these tests. We will also ask clinicians if there is anything else they need in order to decide if someone needs to the cochlear implant centre or not.

Coming to the cochlear implant centre can be expensive for some people, and can mean time off work for people using implants and their families. We would like to have some tools that people using implants could have at home so they could send the results to the clinician to see if they need to come to the centre or not. It could also help clinicians decide how long an appointment should be.

The tests are very similar to those you do in the clinic: a hearing test, speech understanding test using numbers, telemetry and data logging (checking the internal implant) and some questionnaires. Some will be done on an iPad and some using the usual software the audiologists use: Custom Sound.

Why have I been invited?

You are invited to take part in this research project because you have a Cochlear Limited cochlear implant generation 4 or above, and you are a user of a CP900 series sound processor.

What does the project involve?

The project involves you doing the new test battery before your appointment with the audiologist. The audiologist will then look at the results and see if they give enough

information to decide what you need help with. You will then still have your usual appointment with the audiologist.

What exactly will happen to me if I take part?
If you want to take part, all the study testing would happen just before your next appointment; you would need to come 30 minutes early.

You will do the new tests before you see the audiologist. You will connect a direct connect lead to an iPad and computer so that you can listen without hearing outside sounds. You will have help doing the tests and getting connected. The tests are:

1. Digit Triplet Test: a hearing test listening to numbers and repeating them
2. aided thresholds: listening and responding to quiet beeps, like you do in the clinic
3. telemetry: checking of the internal implant, like the audiologist does in clinic, including downloading settings from the speech processor, for example how much you have worn the processor. The audiologist always does this in clinic too
4. filling in a questionnaire about how you are feeling about your hearing, how much you are using the processor, and if there is anything you need help with. We also will ask you how old you are, how long it took you to get to clinic, and how much it cost, and how you feel about the new tests.
5. the tester will take a photo of your implant site behind your ear

The audiologist will then look at these results and fill in a questionnaire about whether the results would be enough to decide what sort of appointment (if any) was needed.

You will then have your usual appointment with the audiologist

The audiologist will note down what was done in the appointment and why.

Are there any benefits in my taking part?
There will not be any direct benefits to you if you take part. However it may enable us to improve our service for people with cochlear implants in the future.

Are there any risks involved?
New speech testing software will be used to deliver the sounds for the tests. As with any software, there is a small risk of hearing sounds that are uncomfortably loud. If this happens, you can stop the sound immediately by taking off the speech processor coil/headpiece.

If you wish to stop the project at any point, just let us know. You don't have to say why.

Costs

Participation in this study will not cost you anything, and you will not be paid.

Will my participation be confidential?

Participation in the study will be kept confidential, all the information collected from you for the study will be treated confidentially. All data will be secured against unauthorised access. Your privacy and confidentiality of your information will be preserved in reports and when publishing any data.

Both Cochlear and the Investigators named above will have access to the information collected from you for the study. Regulatory authorities, Ethics Committee representatives and sponsor's representatives involved in the clinical investigation will have direct access to source data during and after the clinical investigation for Sponsor monitoring, audits, Ethics Committee review and regulatory authority inspections.

The study results may be presented at a conference or in a scientific publication, but we will not use your name or any other details that people could use to work out who you are.

You can have a summary of the findings; please ask Helen Cullington (023 80 597606, H.Cullington@Southampton.ac.uk).

What is Cochlear's role in the project?

Cochlear is the company that made your implant. They are sponsoring this study. Throughout the study, people who work for the company Cochlear will visit the investigation sites, for investigator training and monitoring and audit of the study (check data entry).

The study will be conducted in accordance to ISO14155 and Good Clinical Practice in Research; the Cochlear staff will make sure these rules are followed. You can have a list of Cochlear staff and their duties if you would like this. The data collected in this study will be used for internal communication, product training and product launch materials.

Cochlear may stop the project if the investigators are not following the study protocol. or for any other reason.

What happens if I change my mind?

It is totally up to you whether you take part or not. Whether you take part or not will not affect your clinical care or your relationship with the company Cochlear in any way. You are free to leave the study at any point without telling us why.

Sometimes during the course of a study, new information becomes available. While you are participating in this study, you will be kept informed in writing of any significant new findings which may affect your willingness to continue in the study.

What happens if something goes wrong?

In the unlikely case of concern or complaint, you should contact the Research Governance Office:

Research Governance Office
George Thomas Building 37
Room 4079
University of Southampton
Highfield
Southampton SO17 1BJ
Tel: 02380 595058
rgoinfo@soton.ac.uk

Please note that the researcher or others persons involved in the study will not deal with any complaints.

You can also contact Cochlear at any time:

Lisa De Bold	+447918741224	ldebold@cochlear.com
Saji Maruthurkkara	+6129425-3637	smaruthurkkara@cochlear.com

You can also contact the Patient Advice and Liaison Service (PALS)
023 8120 8498
patientsupportservices@uhs.nhs.uk

Who has reviewed this study?

All research in the NHS 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 a favourable opinion by the East of England - Cambridgeshire and Hertfordshire Research Ethics Committee.

Where can I get more information?

You can contact:
Dr Helen Cullington (Principal Investigator, **University of Southampton**
Auditory Implant Service)
H.Cullington@Southampton.ac.uk
023 80 597606

or Cochlear:

Lisa De Bold	+447918741224	ldebold@cochlear.com
Saji Maruthurkkara	+6129425-3637	smaruthurkkara@cochlear.com