



Using a cochlear implant to objectively measure cochlear health

We invite you to take part in a research study

- Before you decide whether to take part, 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. Discuss it with friends and relatives if you wish.
- You are free to decide whether or not to take part in this study.
- Ask us if there is anything that is not clear or if you would like more information.

Important things that you need to know

- We are looking for adults with an Advanced Bionics cochlear implant (CI) to take part in our study.
- The long term aim of our work is to develop a tool that assesses how healthy the cochlea (the hearing organ) is, using measurements recorded from a CI.
- There are no risks or side-effects associated with any of the tests or measurements taken in this study.
- This study lasts three months and involves you taking measurements using your CI and an electronic tablet at home (although some parts can also be done by researchers at our research centre in Nottingham if necessary).
- Reasonable travel costs will be reimbursed and you will receive a £30 voucher at the end of the study to thank you for taking part.

How to find us

Address: NIHR Nottingham Biomedical Research Centre, Ropewalk House, 113 The Ropewalk, Nottingham, NG1 5DU.

We are located on basement level of Ropewalk House. When you enter reception at ground level, turn right and follow the signs for the research centre. You will need to go down one flight of stairs (or take the lift) and then turn left.

NIHR Nottingham Biomedical Research Centre



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How to contact us

If you have any questions about this study, please contact:
Dr Faizah Mushtaq
faizah.mushtaq1@nottingham.ac.uk
0115 823 2827

1 Why are we doing this study?

A CI can provide a way to access the cochlea, which is otherwise very inaccessible.

The purpose of this study is to see whether we can use measurements made using a CI to tell us about the health of the cochlea. If so, this information could be used to inform future research involving exciting new ways to restore hearing (such as stem cell technologies). Currently, it is difficult to evaluate the safety and effectiveness of these interventions, and that is where this study comes in. We hope to develop a CI-based method for assessing the success of hearing restoration techniques.

How will we measure cochlear health?

We will train you to use a tablet, called AIM, to measure cochlear health. A picture of the tablet is shown below:



This technology is completely safe and does not harm your ear or your CI in any way. In fact, it is already used during CI surgery to monitor cochlear health. In this study, we will be using it post-operatively.

The cochlear health measurements recorded with this device are not medical tests and will not be used for diagnostic purposes.

2 What will I need to do if I take part?

Your involvement in the study will last approximately three months. During this time we will ask you to take three different cochlear health measurements: electrode impedances, electrocochleography (ECochG) and neural

response imaging (MRI). These measurements give us information about the health and survival of cells in the inner ear and are frequently used in CI clinics.

Electrode impedance measurements will be made twice daily. ECochGs will be made daily for one week and then weekly for the remainder of the three month period. MRIs will be made weekly for three months.

All of these measurements can be made by yourself at home as they are pre-programmed and automated on the AIM device and only take a few minutes to complete. All you are required to do is connect the AIM processor and headpiece to your internal CI and, for ECochGs only, place an insert ear tip (usually a soft foam tip) in your ear, and press some buttons on the tablet.

During the first research appointment, we will provide you with full AIM tablet training to ensure that you can make the measurements confidently and can send the data across to us safely and securely. We will also perform a hearing test on you at this appointment. If necessary (e.g., for further training), researchers will be available to see you at any point during the study at our research centre.

3 Am I eligible to take part?

You are eligible to participate if you:

- Are aged 25 – 75 years
- Have normal or corrected-to-normal vision
- Can read and understand English
- Are able and willing to participate in all research activities
- Have no known neurocognitive impairments or cochlear abnormalities
- Are an Advanced Bionics user with one CI

Please note that not all CIs are compatible with the AIM tablet so we will ensure that your CI is suitable before you participate in any research.

4 Will my results be kept confidential?

Yes. All information will be kept strictly confidential and will be stored securely at the NIHR Nottingham Biomedical Research Centre. Research data will be anonymised. Sometimes regulatory authorities or ethics committees ask to see the results so that they can ensure the research is being carried out correctly. It is also possible that some authorised personnel from the University of Nottingham may also look at the data.

5 What will happen to the results?

We cannot provide you with individual results but can send a report of group results once the study has finished. The overall results will be presented at national and international conferences. We will also publish the results in scientific journals. We will not use your name in any publications.

6 Who is organising and funding the study?

This study is being run and funded by the NIHR Nottingham Biomedical Research Centre and the University of Nottingham. Equipment is on loan from Advanced Bionics.

7 Who has reviewed the study?

This study has been approved by the University of Nottingham Faculty of Medicine & Health Sciences (FMHS) Research Ethics Committee.



8 Who do I speak to if problems arise?

Our staff always tries to conduct the research in a way that is caring and respectful.

If you do have any complaint about the way you have been dealt with during the study or any possible harm you might experience, we would be happy to address it with you directly:

- **Professor Douglas Hartley**, Chief Investigator, on 0115 823 2600 or douglas.hartley@nottingham.ac.uk

If we cannot resolve your problem, please contact:

- **The FMHS Research Ethics Committee Administrator**, c/o The University of Nottingham, Faculty PVC Office, E41, Medical School, Queen's Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG7 2UH. E-mail: FMHS-ResearchEthics@nottingham.ac.uk
Please quote ref no: FMHS 04-0420-Cochlear Health Study.

If you are harmed due to someone's negligence, then you may have grounds for legal action, but you may have to pay for it.

9 What should I do if I want to take part?

If you would like to participate or have any questions, please contact:

Dr Faizah Mushtaq

Email: faizah.mushtaq1@nottingham.ac.uk
Telephone: 0115 823 2827



10 Additional information

Why we (University of Nottingham) collect your personal data

We collect personal data under the terms of the University's Royal Charter in our capacity as a teaching and research body to advance education and learning. Specific purposes for data collection on this occasion are to learn about the feasibility of using a CI to measure cochlear health.

How will we use information about you?

We will need to use information from you (e.g., name, contact details, age, gender and study data) for this research project. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we may store your research data for up to 25 years (at least 7 years) after the research finishes. The researchers who gathered or processed the data may also store the data indefinitely. Personal data (such as names and addresses) will be kept for one year. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

Your participation is voluntary and you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses.

Where can you find out more about how your information is used?

For information about the University's obligations with respect to your data and your rights as a data subject, please visit:

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

If you would like to get in touch, please contact:
Data Protection Officer
Legal services, A5, Trent Building,
University of Nottingham,
Nottingham,
NG7 2RD
dpo@nottingham.ac.uk / (0115) 748 7179

11 How does COVID-19 affect the study?

During the COVID-19 pandemic, **no face-to-face contact will take place** and all research will be conducted in line with University of Nottingham and UK government guidelines. Since this study primarily involves you taking your own cochlear health measurements at home, you are still able to participate in the study during the pandemic.

Instead of meeting with you in person, we will arrange for the AIM tablet and all associated equipment and documentation to be delivered to your home. A researcher will train you to use the device using phone and video calls at times that are convenient for you. We will send consent and other forms to you via email, which you can sign and return electronically. You will also be asked to send your results via email. We will not conduct your hearing test (which has to be performed at our research centre) until it is safe to do so, and, if necessary, this can even be completed after you have finished the three month study test period.

Therefore, if you are interested in taking part in this study during the COVID-19 pandemic, you **must** have access to the internet and a computer/smartphone etc., to enable researchers to contact you via phone and video call and to ensure that you can fill and return forms online.