**The COACH Trial**

**Co**mp**a**ring **c**ochlear implants with **h**earing aids in adults with severe hearing loss

**Healthcare Staff Information Sheet- Interviews**

Version 1.3 14Jan2022

IRAS Project ID: **297574**

We would like to invite you to take part in an interview study that is linked to the COACH trial. It is being coordinated by researchers at the University of Nottingham in order to generate further insight to support the findings of the trial. Please take time to read this information sheet before deciding whether or not you wish to take part.

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| 1. **What is the purpose of the study?** |
| The interviews with healthcare professionals will explore experiences of working on the COACH trial. We would like to ask for your views on how the trial has been carried out at your site and your opinions on cochlear implant (CI) provision to this new population of people with hearing loss. |
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| 1. **Do I have to take part?** |
| It is entirely up to you whether to take part. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. You are still free to withdraw at any time. This would not affect your legal rights. |
| 1. **What is involved in taking part?** |
| You will be asked to take part in an interview with an experienced qualitative researcher from the COACH trial team. This could be either over the phone or via video call, or face to face: whichever you prefer. The interview will last approximately 30 to 60 minutes and will, with your permission, be audio-recorded and be kept confidential. If you do not wish to have the interview recorded, you can indicate this on the consent form and the researcher will take handwritten notes during the interview instead. You are free to stop the interview at any time. If you do stop the interview, the information collected so far may still be used in the study.  At the interview, you will be asked about your experiences working on the COACH trial. There will be a focus upon CI provision to this new population of hearing loss patients including your experiences of supporting this population, your opinions and uncertainties in providing CIs to this population and any recommendations for future CI provision. There are no right or wrong answers – it is your opinion that matters. |
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| 1. **What are possible benefits or disadvantages of taking part?** |
| By sharing your experiences and opinions of cochlear implantation within the COACH participant population, you will be helping the researchers make the best possible recommendations about the future cochlear implantation within the NHS.  You may find it both interesting and satisfying to share your experience of being a part of the trial. You will not be asked to share any information you are not comfortable disclosing, and we do not envisage you will have negative experiences from taking part in the interview. |
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| |  | | --- | | 1. **What if I wish to withdraw?** | | Your participation is voluntary, and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw, we will no longer collect any information about you or from you, but we will keep the information about you that we have already obtained 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. To safeguard your rights, we will use the minimum personally identifiable information possible. |  |  | | --- | | 1. **How will the data be used and kept confidential?** | | The only time we will use your personal details is to contact you to arrange the interview. What you say in your interview will be kept strictly confidential in that the recordings or notes will not be shared with anyone other than the individuals in the COACH trial team. However, there may be very rare circumstances where confidentiality may need to be breached. Such a breach would only occur in the most extreme cases, if, for example, information disclosed related to criminal activity or implied that an individual has been, or is, at risk of harm.  After your interview, all data is transcribed and anonymised, this may be by a university approved external third-party company (Clayton Research Support) and stored on a password protected area of the University of Nottingham IT network. Any transfer of data will adhere to the secure transfer of recordings/transcripts procedure specified by the university. The audio recordings will be deleted and the hand-written notes from the interviews will be shredded after the end of the trial. The transcripts will be archived with the rest of the trial data for a minimum of 7 years.  With your agreement, we may quote some of the things you have said in writing about the research, or for training or teaching purposes. But all quotes would be anonymous, and your name will not appear anywhere. We also sometimes agree to share anonymised data to researchers outside of the COACH trial if their research project gains the required ethical permissions and shows a need for the anonymised data in order to answer an important research question.  For more on how your information will be stored, please read the details on the final page. For more information on how the University of Nottingham processes personal data can be found on the university’s web page here: <https://www.nottingham.ac.uk/utilities/privacy/privacy.aspx> | |  | |  | |  | | 1. **Who has reviewed this study?** | | Before any research goes ahead it has to be checked by an independent group of people, called a Research Ethics Committee, to make sure that the research is ethical. This study has been approved by the South West – Frenchay Research Ethics Committee. | | 1. **Who is organising and funding this research?** | | This study is being conducted by independent researchers from the University of Nottingham and is Sponsored by the University of Nottingham. Funding was granted to the researchers by a research grant awarded by Cochlear Ltd. Interviews will be undertaken, and all data analysed by members of the COACH trial team, who are University of Nottingham staff. | |  | |  | | 1. **What do I do now?** | | A member of the trial team will make arrangements with you about the time and date of your interview. You will need to provide consent prior to the interview by initialling all the boxes and signing and dating the consent form, or by giving audio recorded verbal consent. Either way the consent is received, you will be provided with a copy of the consent form. | |  | | 1. **Who can I contact for more information?** | | If you do not understand anything on this information sheet, would like more details or if you are unhappy with any aspect of this study please contact:  **Qualitative Study Lead:**  *[insert name and contact details]*  **Qualitative Study Research Fellow:**  *[insert name and contact details]*  **Trial Coordinating Centre**  *[insert name and contact details]*  **Thank you for reading this information sheet and considering whether to take part.** | |

**Additional information on how your information will be stored**

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. 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>.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Your contact information will be kept by the University of Nottingham for up to 7 years after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham’s, the Government’s and our funders’ policies we may share our research data with researchers in other Universities and organisations, including those in other countries, 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. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.