**The COACH Trial**

**Co**mp**a**ring **c**ochlear implants with **h**earing aids

in adults with severe hearing loss

**Participant Information Sheet- Interviews**

Version 1.3 14Jan2022

IRAS Project ID: **297574**

We would like to invite you to take part in an additional study that is linked to the COACH trial. It is being coordinated by researchers at the University of Nottingham. Before you decide whether to take part, it is important for you to understand why this research is being carried out and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

|  |
| --- |
| 1. **What is the purpose of the study?** |
| Talking to you and other trial participants about your feelings and experiences will help us better understand the results of the COACH trial. We would like to know about what made you interested in taking part in the trial, your experiences of the trial, and how taking part in the trial has impacted your everyday life. Speaking with trial participants directly will also help us to understand what recommendations for treatment should be made to the NHS for people with hearing loss similar to yours. |
|  |
|  |
| 1. **Why am I being asked to take part?** |
| We are inviting you to take part as you are already taking part in the COACH trial and have previously indicated that you might be interested in taking part in an interview about your view on cochlear implants.  We want to understand a range of people’s feelings, so we are inviting participants from the COACH trial to take part: people from different parts of the country, from different ages and backgrounds, and who are in the cochlear implant group and hearing aid group. |
|  |
| 1. **What will I have to do if I take part?** |
| We have sent this information sheet to you because on the consent form that you completed at the start of the trial, you agreed that you would be happy for a research team member to contact you to see if you would like to take part in an interview.  If you are still interested in taking part, we will contact you to arrange a time to talk to you. You will also be asked to provide consent stating that you are happy to talk to the researcher before your interview. The interview will be conducted by an experienced qualitative researcher from the University of Nottingham. You may be asked to give either written or verbal consent, following the study consent form. Either way the consent is received, you will be provided with a copy of the consent form.    Your interview may either be over the phone, as a video call with closed captions or in-person, at a time that is convenient for you.  During the interview, the researcher will talk to you about your personal experience of treatment for your hearing loss and about your experience of the research processes involved in the COACH trial. There will be an opportunity for you to raise issues or topics which you think are relevant to hearing loss treatment and/or hearing loss research.  We will not ask you a fixed set of questions as such, but, instead, we will use a guide to explore a range of topics. The interview will last approximately 30 to 60 minutes, and will, with your permission, be recorded using a digital recorder. All recordings will be kept strictly 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. |
| 1. **Do I have to take part?** |
| No. It is for you to decide. Even if you initially decide to take part and sign the consent form, you are free to not go ahead with the interview, or stop the interview at any time, without giving a reason. Whether or not you choose to take part will not affect your participation in the COACH trial or the standard of care that you receive. If you withdraw from the interview study, we will keep the information about you that we have already collected. |
|  |
|  |
| 1. **What are the possible benefits of taking part?** |
| If you do take part, you will be contributing to our knowledge about people’s experiences of having a hearing loss and taking part in medical research. We hope that this information will help guide practice for the future care of patients with hearing losses. You may also find the experience of talking to the researcher interesting as you will have the opportunity to confidentially tell us what you really think about your experiences. |
|  |
| 1. **What are the possible disadvantages of taking part?** |
| Talking to the researcher will take up a small amount of your time. Although not intended, there is a small possibility that you might be asked questions about certain topics which are sensitive or may upset you. You can decide not to answer any questions which you feel uncomfortable with and can stop the interview at any time.   |  | | --- | | 1. **What will happen if I don’t want to carry on with the study?** | | 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 my 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 research 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 destroyed 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 pages here:  https://www.nottingham.ac.uk/utilities/privacy/privacy.aspx | |  | |  | | 1. **Will my GP be informed?** | | If you choose to be interviewed, your GP does not need to be informed. | |  | | 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 fair. This study has been approved by the South West – Frenchay Research Ethics Committee. In addition, service users (people who have hearing loss) have provided useful feedback about the design of this study and the participant information leaflet. | | 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 Research Team, who are University of Nottingham staff. | | |  | | |  | | |  | | |  | | | 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]*  If you would like independent advice about whether or not to take part, the Patient Advice and Liaison Service (PALS) can be contacted on <insert local PALS details>.  **Thank you for reading this information sheet and for 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. |