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**Parent and professional perceptions of barriers and facilitators to effective hearing aid use in infants**

**Participant Information Sheet (PIS)**

You are being invited to take part in a research study looking into the challenges families face in establishing regular hearing aid use with children under 2 years of age, and what might help. Before you decide whether to take part, it is important for you to understand why the research is being carried out and what it will involve. Please take time to read this information carefully before deciding whether to take part and discuss it with others if you would like. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

**About the research**

* **Who will conduct the research?**

Dr Ciara Kelly at the Manchester Centre for Audiology and Deafness (Division of Human Communication, Development and Hearing), University of Manchester.

* **What is the purpose of the research?**

This research is the first part of a larger project to develop a programme of support for families to help establish regular hearing aid use with children under 2 years of age. To help us develop the programme, we would like to learn more about the challenges families face. To do this, we are asking parents of children under 2 years of age using hearing aids about their experiences. You have been invited to be interviewed because you are a parent of a child under 2 years of age using hearing aids.

* **Will the outcomes of the research be published?**

We hope the outcomes of this study will help us to get a better understanding of the challenges families face in establishing regular hearing aid use with children under 2 years of age. The outcomes of this study may be published in scientific journals and/or presented at conferences and may be summarised on the project website and relevant blogs. If the outcomes of the study are published, presented, or summarised online, your identity will remain confidential. A summary of the study findings will be available for you when the study is complete. A researcher will ask if you would like to receive a copy.

* **Who has reviewed the research project?**

This project has been reviewed by The University of Manchester Proportionate Research Ethics Committee.

* **Who is funding the research project?**

This project is funded by the National Deaf Children’s Society (NDCS) and supported by the Hearing Health theme of the Manchester Biomedical Research Centre.

**What would my involvement be?**

* **What would I be asked to do if I took part?**

If you would like to take part, the researcher, Ciara Kelly will contact you to answer any questions you have, and to arrange a date and time that works for you for a short interview. The interview will be over video-call using Zoom. If you would prefer not to turn your camera on you can choose this option before you enter the online meeting room, or at any point during the call. Before the day of the interview, you will receive an invitation to attend, which will include a link to the online meeting room. A second email will follow containing a password to access the online meeting room. You will also receive a consent form that you will be asked to complete verbally at the beginning of the video-call. This will involve being asked a number of questions that you can say yes or no to.

The consent questions and answers, and the interview will be recorded separately using the record function in Zoom. The researcher will let you know when they are about to begin recording. During the interview, the researcher will ask you some questions about yourself and your baby, and about your experiences using hearing aids with your child/children. We estimate the interview will last for a maximum of 1 hour.

* **What are the possible benefits of taking part?**

We hope the information we collect will help us to better understand the challenges families face in establishing regular hearing aid use with children under 2 years of age, and anything that might help. This will help us to develop a programme of support for families to help overcome barriers and increase hearing aid use for the best possible benefits. We also hope taking part will be a positive experience for you.

* **What are the possible risks and burdens of taking part?**

Taking part in this study should not harm you in any way but reflecting on some of your experiences may cause some worry or distress. If this is the case, we recommend you seek advice from your health visitor, Teacher of the Deaf, GP or audiologist. Being interviewed can sometimes make people feel a little uncomfortable but you will never be asked to do something you do not want to do, and the interview will be at your pace. You can choose not to answer questions, or to stop completely if you want to. The only anticipated burden of taking part is the time that we ask you to give to take part.

* **Will I be compensated for taking part?**

You will be given a £10 Love to Shop e-voucher as a thank you for your time.

* **What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to take part. If you would like to take part, please contact Ciara Kelly (contact details below). If you do decide to take part, you will be asked to give verbal consent. Giving your consent to be interviewed also includes giving your permission for the interview to be video or audio recorded so that we document the interview accurately. We record interviews because it is hard to take notes of what is said, listen carefully and think at the same time.

If you decide to take part, it is important that you are comfortable with the recording process at all times. If you would like to stop recording you are free to do this at any time. You are also free to change your mind about taking part at any time without giving a reason and without any negative impact to yourself or the services you receive. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part, you do not need to do anything further.

**Data Protection and Confidentiality**

* **What information will you collect about me?**

In order to participate in this research project, we will need to collect information that could identify you, called “personal identifiable information”. Specifically, we will need to collect:

* Your name
* Your contact details
* Your partial postcode (the first part)
* Your ethnicity
* Video recordings that will capture your face, shoulders, surrounding environment/background, and voice (or voice only if you choose) during a one-to-one online interview with the researcher.
* **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

* **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law to do with your personal information. For example, you can request a copy of the information we hold about you, including video/audio recordings.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](http://documents.manchester.ac.uk/display.aspx?DocID=37095).

* **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

Your interview will be recorded in Zoom and your personal data will be processed by Zoom. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. Immediately after the interview, the video recordings will be deleted (digitally shredded) from Zoom and the separate audio-only recordings will be removed from Zoom, assigned a random participant ID number and stored securely on University of Manchester managed file storage as soon as possible after the interview. Access will be restricted to authorised researchers from the research team at The University of Manchester, and only the research team will have access to the key that links this ID number to your personal information.

The audio recording of the interview will be typed up by a transcription service called 1st Class Secretarial. There is a confidentiality agreement in place between the University of Manchester and 1st Class Secretarial. The audio recording(and assigned participant ID number) will be uploaded to a private, secure account held by the researcher with 1st Class Secretarial. Once written up, the audio recording of the interview will be digitally shredded and all personal identifiable information will be removed from the final typed out interview text. The key that links your ID number to your personal information will be destroyed once all data has been collected and combined. We have to keep your anonymised information for 5 years, but after that, all information will be destroyed. Your consent form and the audio recording of your consent will be destroyed at the end of this research (approximately 2 years) and will be stored securely on University of Manchester managed file storage until this time.

Sometimes we like to use anonymised direct quotes of things said during the interview in our study reports. Neither you, your child, or any other personal information will be identifiable from the information we use. It is also important to share data so we are transparent about our research. Therefore, we may share your anonymised data for future research purposes. Neither you, your child, or any other personal information will be identifiable, and we will ask your permission to do this.

If we were ever worried that you, your child or anyone else was at risk of harm, we might need to tell the relevant health and social care authorities. We will always tell you if we are going to do this and talk to you about what we are going to do.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

If you would like a summary of the findings for this study and/or would like to be contacted about other research projects, your contact details will be stored securely on University of Manchester managed file storage for 2 years.

**What if I have a complaint?**

* **Contact details for complaints**

If you have a complaint that you wish to direct to members of the research team, please contact:

**The researcher, Dr Ciara Kelly by emailing:** **ciara.kelly@manchester.ac.uk** **or by telephoning: 0161 275 3376.**

**Or you can contact the Principal Investigator of the study, Professor Kevin Munro by emailing:** **kevin.j.munro@manchester.ac.uk** **or by telephoning: 0161 275 3360.**

**If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact:**

TheResearch Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk  or by telephoning: 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner’s Office](https://ico.org.uk/concerns) about complaints relating to your personal identifiable information Tel. 0303 123 1113.

**Contact Details**

If you have any queries about the study or if you are interested in taking part, then please contact the researcher:

**Dr Ciara Kelly by emailing: ciara.kelly@manchester.ac.uk or by telephoning:** **0161 275 3376.**

**Thank you for taking the time to read this information.**