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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 exploring the challenges families face in establishing regular hearing aid use with children aged 0-24 months, and the factors that help. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. 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 part of a wider project to develop an intervention to support families to establish consistent hearing aid use with children aged 0-24 months. To help us develop the intervention, we would like to know more about the challenges families face, which is the purpose of this research. You have been invited to be interviewed because of your experience working with families of young children using hearing aids.

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

We hope the outcomes of this study will provide insight into the barriers and facilitators to consistent hearing aid use in infants aged 0–24-months. 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 is convenient for you for a short interview. The interview will be conducted using the video conferencing software 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. Prior to 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 series of questions to which you can choose to agree or disagree.

The consent statements and 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 within your role, and about your experiences of working with families, focussing on hearing aid use in children under 2 years of age. We anticipate 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 develop our knowledge of the challenges families face in establishing regular hearing aid use with children aged 0-24 months, and the factors that help. This will help us to develop an intervention to support families to overcome the barriers and increase hearing aid use for optimal benefits. We also hope taking part will be a positive experience for you.

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

We do not anticipate any risks in taking part. The only anticipated burden of taking part is the time that we ask you to give in order to participate.

* **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 provide verbal consent. Providing consent includes giving your permission for the interview to be video or audio recorded so that we document the interview accurately. 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 still free to withdraw at any time without giving a reason and without detriment to yourself. 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 job title
* Video recordings that will capture your face, shoulders, surrounding environment, 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 regarding 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 following the interview. Access will be restricted to authorised individuals 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 transcribed by the digital audio transcription service, 1st Class Secretarial, which is a University of Manchester approved supplier and therefore has a confidentiality agreement in place. 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 transcribed, the audio recording of the interview will be digitally shredded and all personal identifiable information will be removed from the final transcript. The key that links your ID number to your personal information will be destroyed once all data has been collated. Anonymised transcripts will be destroyed after 5 years, which is the standard retention period for data once anonymised. 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.

We may use anonymised direct quotations from the interview in publications/conference presentations. Quotations will be anonymised using participant ID numbers and pseudonyms. Neither you nor 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 nor any other personal information will be identifiable, and we will ask your permission to do this.

If, during the interview, you disclose information about misconduct or poor practice, we have a professional obligation to report this and will therefore need to inform your employer/professional body.

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**](mailto: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**](mailto: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](mailto: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](mailto: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.**