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**Prioritizing Outcomes in Children With Hearing Loss**

**Participant Information Sheet (PIS)**

You are being invited to take part in an **online survey/ranking exercise**investigating what really matters to children with childhood hearing loss and what are the most important outcomes that should be measured in trails examining hearing loss in children and young people. This study is also a part of the researcher’s Master degree in audiology. 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?**

Shiyu Yuan (MSc audiology PGT Student) and Karolina Kluk-De Kort (Supervisor) who are in School of Health Science, Ellen Wilkinson Building, University of Manchester, Oxford Road, Manchester UK

Oren Ziv who is a research Fellow at Manchester Children's Hospital ENT.

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

Hearing loss is very common. In the UK, there are approximately 45000 children with hearing loss. In addition, hearing loss has a profound effect on children’s growth and development. Because hearing loss can have varied impact on lives of children, we need to identify which outcomes matter for patients and their parents, and which outcomes are important to them. As a first step in the process we conducted a systematic literature review and created a long list of outcomes (what researchers consider to matter to children with hearing loss). Next, we interviewed children with hearing loss and their families and identified outcomes that children and their parents consider important. We combined the two lists and would like to ask you to help us rank them in order of importance to create a core outcomes set. It will enable provision of individualised care across the lifespan and for optimising outcome reporting in the field of hearing loss research.

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

The project has been reviewed by the Division of Psychology, Communication and Human Neuroscience Ethics Committee.

**What would my involvement be?**

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

You will be asked to complete online ranking of outcome measures. We will also ask you to some information about yourself:

* For patients, we need to collect information about the gender (Male/Female), age, confirmation of hearing loss (Y/N), level of hearing loss “L” ear and “R” ear, and country of residency.
* For parents/caregivers, we need to collect information about the confirmation of being a parent/caregiver of a child with hearing loss (Y/N), number of children with hearing loss, ages of children with hearing loss, level of hearing loss “L” ear and “R” ear, and country pf residency.
* For healthcare professionals, we need to collect information about the job title, year since qualified, confirmation that having looked after at least 10 paediatric with hearing loss in the last 12 months (Y/N), and country of residency.
* For researchers, we need to collect information about the job title, confirmation that having undertaken research involving childhood hearing loss in the last 12 months (Y/N), and country of residency.

The **online ranking exercise/survey** will take approximately 10-15 mins to complete. You will be asked to score each item on a 9-point scale. If you are unable to score an item, please select “unable to score an item”. Furthermore, the survey also provides you with the opportunity to add further outcomes that you think may be important.

A month later, we will email you the link to the second ranking exercise/survey.

At the start of the second survey, you will see the summary of the results from first ranking exercise/survey. And you will be asked to complete the same survey again.

Your privacy is very important to us. Please note, that the survey will not collect your IP address. All results are completely anonymous and will be used solely for research purpose.

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

No, there will be no compensation provided for participating in this study. Your participation is entirely voluntary and appreciated.

* **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 do decide to take part you will be given this information sheet to keep and will be asked to tick a box to confirm consent. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself up until the point that you submit your online responses. It will not be possible to remove your data from the project once you have submitted your responses as they are collected anonymously and 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.

For detailed information about how we plan to use and store the information that you share with us, please read our **Data Protection, Confidentiality and Further Details page** .

**Contact Details**

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s)

**Shiyu Yuan**

**E-mail:** shiyu.yuan-2@postgrad.manchester.ac.uk

**Data Protection, Confidentiality and Further Details information**

[note: you need to provide a mechanism for participants to download a copy of this information if they wish]

**Data Protection and Confidentiality**

* **Will my participation in the study be confidential?**

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 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:

* The study team will store your anonymized data for 5 years after the end of the study on encrypted and secure University storage systems.
* In accordance with the University of Manchester’s Research Privacy notice and with your consent, we would like to be able to share your anonymised data with other University of Manchester researchers who are doing studies similar to ours.
* At the end of the project we would like to deposit a fully anonymised dataset in an open data repository where it will be permanently stored. We will use Qualtrics or REDCap at the University of Manchester Library. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.
* **Will the outcomes of the research be published?**

The processed anonymous aggregated data may be presented for publishing or shared at conferences in the forms of numerical outcomes and interpretations.

* **Will my information be shared with others?**

No, your information will not be shared with others. All data collected during this study will be used solely for the purposes of this research project and will remain confidential within the research team.

* **Will my information be put into an archive?**

No, your information will not be put into an archive. Once the study is completed, all collected data will be securely deleted in accordance with data protection laws and University policies.

* **Auditing and Monitoring**

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.

**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:

**Dr. Karolina Kluk-de Kort**

**E-mail:** [**Karolina.Kluk@manchester.ac.uk**](mailto:Karolina.Kluk@manchester.ac.uk)

**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.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)

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