

Manchester Centre for Audiology and Deafness
A3.11 Ellen Wilkinson Building
Oxford Road
Manchester
M13 9PL

IMPROVING CLINICAL PRACTICE FOR BABIES WITH HEARING LOSS

Participant Information Sheet

Your child is being invited to take part in a research study that aims to improve the care of babies who have, or may benefit from, wearing hearing aids.

Before you decide if you would like your child to take part in the study, it is important you understand why the research is being done and what it involves. We would like you to read this information sheet and you may want to discuss it with others. A member of the study team can explain the information with you and answer any questions. Take your time to decide if you want your child to take part in the study. If you agree to participation, we will ask you to sign a consent form. You will be free to withdraw your child from the study at any time, without giving a reason and this will not result in any detriment to your child's standard clinical care.

Who will conduct the research?

The team is led by Professor Kevin J Munro, Consultant Clinical Scientist, School of Psychological Sciences, University of Manchester. The research team involves a number of individuals including medical, scientific and technical staff and parents of children with a hearing loss.

Title of the Research: Improving clinical practice for babies with hearing loss

What is the aim of the research?

All babies are offered a hearing check soon after birth and, where appropriate, hearing aids are now prescribed in infancy. However, the range of tests available to check the necessity for, and appropriateness of hearing aids in babies is limited. The aim of our study is to develop a routine clinical test for babies who wear hearing aids. The procedures under investigation are called '*Aided Cortical Auditory Evoked Potentials*' and '*Aided Auditory Steady-State Responses*'. They are similar to the standard hearing tests that are currently carried out on babies. This research will provide information about: (i) the benefits of the new hearing tests, (ii) how long it takes to complete the measurements, and (iii) what you think about this new test. Although there will be little direct benefit to you and your baby, the findings should help ensure babies obtain maximum benefit from their hearing aids.

What do the tests involve?

The hearing tests will be carried out in our mobile hearing van that will visit you at home and at a time that is convenient to you. We will carry out the new hearing test between 3-7 months of age in babies while they are wearing hearing aids (or in babies who are being considered for a hearing aid). The procedure involves the baby sitting on your lap, or in a high chair, while we present sounds from a loudspeaker and record the brain's response from recording leads placed on the head (similar to existing hearing tests for babies). At a later date when your baby is around 9 months of age, we will carry out a conventional hearing test so that we can compare the results with our new test. We will also take a few minutes to ask you a few questions at the start of each test session about your baby's responsiveness to sounds and about their use of the hearing aids. During the week after the first test session, you will be invited to spend a few minutes completing an online survey and about what you think of the new hearing test. We will also ask a selection of families if they would be willing to be interviewed about their test experience. The interview will last approximately 20 minutes and be carried out by telephone, and audio recorded, a few weeks after the first test session.

Why has my baby been chosen?

Your baby has been chosen because they are under 7 months of age, have a hearing loss and have (or are being considered for) hearing aids. We will recruit 150 babies from all over the country.

PIS: Improving clinical practice for babies with hearing loss (28th February 2019, V5.0)

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

There will be a total of four test sessions and each one will last around 60 minutes. The first two visits will be a day or two apart, or on the same day with at least one hour's break, and will involve carrying out the new hearing test. When your baby is a little older, we will carry out a conventional hearing test on two occasions, again a day or two apart, on the same day with at least one hour's break.

Before enrolling your baby onto the study, we will check that you understand what is required and ask you to sign a consent form. We ask your consent for the research team to review relevant sections of your child's medical notes (details from the audiology clinic and newborn hearing screening service). We will inform your GP that your baby has been enrolled onto the study. We will ask you a few questions about your baby's history and responsiveness to sound e.g., do they smile when they hear your voice. If your baby already has a hearing aid, we will carry out a check to ensure it is working properly and ask about your experience with the hearing aid e.g., how easy is it to change the battery? We will look in your baby's ears and check for congestion (glue ear).

The new hearing test that will be carried out between 3-7 months of age involves attaching three leads to the scalp with disposable sticky tabs. With your baby on your lap or in a high chair, we will use the leads to record the response to sounds that are presented from a loudspeaker placed directly in front of your baby and presented at a comfortable listening level. The standard hearing test that is carried out at around 9 months of age does not involve attaching leads to the scalp. Instead, sounds are presented from a loudspeaker and we record when your baby turns their head to look for the sound.

What happens to the data collected?

The data will be analysed to see if the new test provides helpful information that supplements existing baby hearing test procedures. We will present the anonymised findings at academic conferences and publish the work in academic journals. A summary of the findings will be available to you on our website: <http://www.psych-sci.manchester.ac.uk/audiologyanddeafness/>. If you would like to receive email updates about the study results, we will take consent to send you updates.

How is confidentiality maintained?

Once you have signed your informed consent form for your baby, your baby will be assigned a study code. During the study, the researchers will collect the hearing test information on your babies. This information will not include your babies name or personal identity, but will identify your baby with a study code that will be held by the lead researcher. This code key will remain at the study site together with the hearing test information for at least 15 years. The data will be kept securely in accordance with the NHS confidentiality guidelines. All stored data will be anonymised and kept on password protected computers. Any paperwork will be locked in a cabinet away from public access.

Data will be stored, processed and compiled by the Sponsor both manually and electronically. Qualified representatives of the sponsor organisation, Manchester University Hospitals NHS Foundation Trust, may access and inspect your babies medical/study records and receive information from your babies medical/study records for purposes of quality assurance and data analysis.

Do I have to take part?

No. It is up to you to decide whether or not you want your baby to take part in our study. If you decide that you would like your baby to participate then we will ask you to sign a consent form that gives us permission to include your baby in our study. You will always be free to withdraw your baby from the study at any time without specifying a reason to the researchers and, importantly, this will not result in any detriment to your baby's standard care.

Will I be paid for participating in the research?

No, but we will give you a £10 shopping voucher at the completion of each of the four test sessions.

What is the duration of the research?

There are four test sessions, each lasting around 60 minutes. The first two sessions will take place in close succession while your baby is in the age range of 3-7 months. The final two test sessions will take place in close succession when your baby is around 9 months. In some cases we may ask whether we can return

for repeat testing, for example if the researchers are unable to complete the testing or if the infant may be suffering from congestion which could affect the results.

Where will the research be conducted?

The research audiologists will conduct the research in our mobile hearing van. Unfortunately the van is not wheelchair accessible and does involve a large step to enter the unit. If you have concerns please discuss this with the research team.

Will the outcomes of the research be published?

We will present the findings at conferences attended by hearing care professionals. We will publish the findings in scientific journals and professional magazines.

Who has reviewed the research project?

This project has been reviewed by the National Institute for Hearing Research and Oticon Foundation who are funding this research study. The study protocol has also been reviewed by the research practice coordinator at the University of Manchester. Finally, the study has been reviewed and approved by a committee acting on behalf of the National Research Ethics Service.

Contact for further information

If you require any further information before, during or after the study, please feel free to contact Professor Kevin J Munro (email: kevin.munro@manchester.ac.uk; Tel: 0161-275-3360).

You can also follow the progress of the project online at: www.facebook.com/ladiesinthevan and on twitter @ladiesinthevan

What if something should go wrong?

The tests involved are routine procedures and it is highly unlikely that they will cause any harm. However, the University of Manchester has standard arrangements in place to provide indemnity and/or compensation in the event of a claim by, or on behalf of, patients for negligent harm (Employer's Liability) and non-negligent harm, (No Fault Compensation Policy). If you have any grievance relating to any part of the study and wish to make a formal complaint, this should be sent to: *University Research Office, 2nd Floor Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9P (tel: 0161 275 7583).*

Independent information and support

For independent information and support about childhood hearing loss you can contact the National Deaf Children's Society <https://www.ndcs.org.uk/>

**This project has been approved by the North West- Greater Manchester East Research Ethics Committee, Ref 15/NW/0736
IRAS ID: 172044**

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Additional Information Sheet

(Please refer to participant information sheet, 28 February 2019, V5.0)

Monitoring information

The researchers will ask you relevant history about your baby including their medical history, audiological history, and also ethnicity, to allow us to compare the diversity of populations reached with that of previous studies.

The researchers will ask you to complete an anonymous questionnaire to collect further ethnographic information about you. This information will be kept fully anonymous and managed separately to your child's data.

Sharing information with professionals involved in your baby's care

Some information we gather may be of benefit to your audiology team, for example, if the questionnaires reveal you are struggling with a particular aspect of hearing aid management, or if there is a problem with your child's hearing aid or ear health. Where relevant, we would share this information with the relevant professionals involved in your baby's care.

What do the tests involve?

Alongside the tests outlined in the Participant Information Sheet, we will also perform head measurements (circumference and/or diameter) and a real-ear-to-coupler difference (RECD) measurement, which involves measuring the acoustics of your baby's ear canal.

Contact information:

You are able to indicate your interest in taking part by either return the reply slip in the envelope provided or by calling us on 0161 306 1754 or 07543 228856 or emailing us on mft.babyhearingstudy@nhs.net. The Researchers are Anisa Visram, Rhiannon Morgan, Amber Roughley and Caroline Hudson.

You are able to self-refer your baby to the research study if you wish to.

Additional information:

You can find more information about the study using the following links or by using the QR code below:

Story: <https://www.bmh.manchester.ac.uk/stories/ladies-in-the-van/>

Video: <https://www.youtube.com/watch?v=4MTBH7D0YRY&feature=youtu.be>



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