

Improving behavioural assessment of hearing in babies (3- to 7-months)

Parental Information Sheet (PIS)

You and your child are being invited to take part in a research study to improve tests of babies' hearing. 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 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. Take time to decide whether or not you and your child wish to take part. Thank you for taking the time to read this.

NB. Due to the current COVID-19 pandemic some adjustments may be made to the way in which this research study will be conducted. This is to ensure we are adhering to the latest government, NHS, and University of Manchester guidance, and taking all reasonable precautions in terms of limiting the spread of the virus.

We may need to re-arrange or postpone your visit if guidance changes. We will provide as much notice as we can if this occurs, but we may need to contact you at short notice. We will ask you to provide a mobile number for this reason.

While COVID-19 restrictions apply, you should not take part in this research if you belong to a vulnerable or high risk group. You can find more information on high risk groups here:

<https://www.nhs.uk/conditions/coronavirus-covid-19/people-at-higher-risk/whos-at-higher-risk-from-coronavirus/>

About the research

What is the purpose of the research?

We are interested in how babies respond to different sounds. Our aim is to improve techniques currently used to test hearing in babies. It is vital that we can properly investigate hearing at a young age for children to have the best possible outcomes in cognitive and language development

Our work will find out what kinds of sounds babies pay most attention to, so that we can get more information about babies' hearing during hearing tests. We will also use video software to detect small changes in babies' movements and faces when they hear different sounds. This software may be able to pick up responses to sounds that are too subtle to be seen by eye.

Who will conduct the research?

This research is being led by Dr Anisa Visram and Dr Iain Jackson in the Manchester Centre for Audiology and Deafness (ManCAD; School of Health Sciences, University of Manchester). The wider research team also includes colleagues in the Manchester Centre for Audiology and Deafness, and in the Division of Informatics, Imaging & Data Sciences, both groups at the University of Manchester, as well as collaborators at the Interacoustics Research Unit in Denmark.

Who is funding the research project?

This project is funded by the William Demant Foundation and receives additional support from the NIHR (National Institute for Health Research) Manchester Biomedical Research Centre (BRC).

What will the outcomes of the research be?

The data we collect will help us investigate what sorts of sounds babies pay attention and respond to most. This information could help to improve hearing tests for babies.

We plan to present our findings to other researchers and health professionals through publications in academic journals and presentations at conferences.

What will my child and I be asked to do if we take part?

We will ask you some questions about your and your baby's hearing and health, such as whether your baby has had any ear infections, for example. We will also ask you about what sort of sights and sounds your baby usually responds to. We might ask you to make short recording of yourself or something you think gets your baby's attention, and to send it to us in advance of your visit. We will provide you with instructions for how to make and send any recordings. If you send us a recording, we will also ask you if you are happy for it to be shown to other babies in the study as well as your own. This will be optional.

You will be invited to attend a testing session at our research facility at the Royal Manchester Children's Hospital or on the University of Manchester Campus. We will provide you with travel/parking information with your invite.

On arrival for your session we will explain the aims of the study to you, explain what will happen during the session, and answer any questions you have about the research.

Once your child is settled and comfortable, we will ask you either to secure them in an infant car seat (or high chair, or similar) in front of a display screen, or to sit in front of the screen with your child on your lap.

During the study we will show some simple images or animations to your child and occasionally play a sound over speakers. The sounds we play will not be louder than an adult's voice speaking at normal conversational level.

We will video your child's movements and responses to the sounds throughout the study. Afterwards, we will use software to analyse these responses. Finding out what movements are

associated with hearing sounds will allow us to train a computer to automatically look for them in the new hearing tests we are developing.

During the recording phase of the study we might ask you to sit behind or out of view of your child, and not to interact with them unless necessary for their comfort. You will be in the same room as your child at all times.

We will also give you a link to a short online form to collect information about you and your child such as age, gender, occupation and other protected characteristics. The purpose of this form is to collect anonymous information about the people who consent to take part in our research studies. The National Institute for Health Research Manchester Biomedical Research Centre (NIHR BRC) is committed to ensuring that its research projects are accessible to everyone regardless of race, gender, ability, religion, sexual orientation or age. The information you give on this form will help us comply with our policy of ensuring equality in our work. This form is optional and you do not have to complete all/any of the questions if you do not want to. The responses are completely anonymous so we won't know who has completed or not.

How long will the study take?

Before the study begins we will take time to talk through the aims and answer any questions you might have, and also to ensure your child is settled and comfortable. The overall duration can vary, but we expect the study to take around 30-60 minutes in total.

Where will the research be conducted?

This research will take place either in the NIHR Manchester Clinical Research Facility at Ward 79 of the Royal Manchester Children's Hospital (Oxford Road, Manchester, M13 9WL), or on the University of Manchester's campus, near Oxford Road.

We will confirm with you where and when your testing sessions will take place prior to your visit, and provide relevant information about transport and parking.

Will I be compensated for taking part?

Taking part in the study is voluntary, but you will be offered £10 to thank you for your time, which you can choose to receive either as cash or as a voucher by email. If you choose to receive a voucher your full name and email address will be shared with our Finance department who will send the voucher to you. Your full name and email address will be securely retained by Finance for a period of up to 7 years for audit purposes only and then destroyed. It will not be used by them for any other purpose.

We will also contribute up to £10 towards your travel/parking expenses.

What happens if my child does not want to take part, or if I change my mind?

It is up to you to decide whether or not you would like your child to take part. If you decide to take part you will be given a copy of this information sheet to keep and will be asked to sign a consent form.

Video recording is essential to the goals of this project. If you decide to take part you are still free to stop the video recording at any time, and/or withdraw from the study without giving a reason and without detriment to yourself.

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 and my child?

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, and a phone number we can contact you on.
- Your child’s name and date of birth.
- Whether your child currently has any issues or difficulties with their hearing or vision, or any significant developmental delay.
- Whether your child has had infections or illnesses that can affect hearing.
- Video recordings of your child’s eye, face, and head movements while we play them a range of sounds.
- Video recordings will contain audio, but your child will not be required to produce vocal responses during the recordings.
- Images/video/audio recordings of your face or voice, or the things you choose to record (e.g. pets, toys, etc.) and send to us.

What else do I need to know?

Disclosure and Barring Service (DBS) Check

All members of our team who work with children have undergone relevant Disclosure and Barring Service checks.

Who has reviewed the research project?

This project has been reviewed by the University of Manchester Proportionate Research Ethics Committee (reference 2020-10804-17344).

What should I do if I am concerned about my child’s hearing?

If you have any concerns about your child’s hearing you should speak to your GP.

The findings of this study might help hearing tests in the future, but in this particular study we are interested only in how babies respond to different sounds. The study is not designed to test for

hearing difficulties in individuals, and we will not be able to provide feedback on the performance of any individual child.

What if I have a complaint?

If you have a complaint that you wish to direct to members of the research team you can email them at bambino@manchester.ac.uk, or phone on **07785 401460 (Iain Jackson)** or **07543 228 856 (Anisa Visram)**.

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:

The Research 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 about complaints relating to your personal identifiable information (by visiting <https://ico.org.uk/make-a-complaint/> or by phone on 0303 123 1113).

How we will look after your data

Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with data protection law which protect your rights. These state that we must have a legal basis (a 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 audio/video recordings or photographs.

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, which can be found here: <http://documents.manchester.ac.uk/display.aspx?DocID=37095>

Will my and my child's participation in the study be confidential, and will our 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 you can find the full details of how we will look after your data in the section at the end of this information sheet.

It will not be possible to fully anonymise all the data we collect as our video recordings will contain images of participants' faces. However, your child will be assigned a unique ID number at the time the data is collected. Their date of birth will also be replaced with their exact age (i.e. number of days old on the day of the test) meaning no individual can be identified by name or by birth date in our processed dataset.

How will my data be securely moved and stored?

The project's electronic data will be stored in a secure internal repository at the University of Manchester and on an encrypted drive held in a locked location at the University of Manchester. Data transfer will take place using encrypted devices and original recordings on the video camera will be deleted. Paper copies of signed consent forms, questionnaires, and any other hand-written forms or notes will also be kept in locked storage.

What data will be shared outside of the research team?

Once the project is complete we will submit fully anonymised, processed data to an open access repository (such as the Open Science Framework, www.osf.io, for example) so that other researchers can also benefit from it and help to speed up new discoveries. This information will be in the form of a simple spreadsheet, and **will not contain any video, images, or any other identifiable information.**

When researchers share the findings of studies it can be helpful to include pictures or video as part of presentations, publications, or as part of lectures for students. You will be given the option to allow us to use pictures or video of your child for these purposes. **We will not use any image or video without your permission.**

(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.)

Who will have access to my and my child's data?

Only the research team and our collaborators at the Interacoustics Research Unit will have access to the information we collect.

The research team for this project consists of the lead researchers, Dr Anisa Visram and Dr Iain Jackson, and our collaborators in the Manchester Centre for Audiology and Deafness (ManCAD), the Division of Informatics, Imaging & Data Sciences, and the Interacoustics Research Unit.

What will happen to my data after the project has finished?

All audio and video collected from participants, and all paper records, will be retained for 10 years, after which footage will be deleted and consent forms will be destroyed.

Will my data be used for future research?

We do not anticipate any future research other than that described above. However, advances in technology mean it might become possible to analyse babies' behaviour more accurately than is currently possible, allowing hearing tests to be further improved. Any future research will be compatible with the aims of this research project and will concern behavioural responses of babies.

Additionally, this project involves different studies with babies of different ages. Babies who take part in one study might also take part in another when they are a little older. For these babies it is more efficient to re-use some data (e.g. date of birth, hearing health, etc.) than to duplicate it.

How does the COVID-19 pandemic affect the research?

Are there any additional considerations that I need to know about before deciding whether I should take part?

We are carefully scheduling appointments to avoid overlap between different participants' visits, and to allow for extra cleaning between participants. You can help us with this by arriving as close to your appointment time as possible.

To reduce and control the number of visitors to our research facilities only one caregiver can accompany children taking part in our study. Partners, siblings, grandparents, etc., will not be able to access the facility on your visit until relevant COVID-19 restrictions are lifted.

What additional steps will you take to keep me safe while I take part?

We will ask you questions about COVID symptoms, and your recent contact with others who may have symptoms, in advance of your visit(s) and again on your arrival. **The research team will immediately postpone any appointments if they themselves experience symptoms.**

All visitors to the facility are required to wear a face covering for the duration of visits. You will be provided with a face covering on arrival if you do not have your own. The research team will also wear face coverings at all times.

You can help to reduce the risk of infection by avoiding public transport. If this is not possible, you should wear face coverings, wash/sanitise your hands regularly, and follow the guidance on the transport you use.

You will not be asked to touch any equipment during your visit. All surfaces will be cleaned between participants.

Additional data use

COVID-19 restrictions mean the number of visitors to research sites is minimised wherever possible. Security personnel may also restrict access to some sites. For this reason it is possible we may need to inform security personnel of the time and reason for your visit, and you may be asked confirm these on arrival.

We may need to provide your contact details to NHS Track and Trace if required.

Contact Details

If you have any queries about the study then please do not hesitate to contact the lead researchers using the project email address **bambino@manchester.ac.uk**, or by phone on **07785 401460 (Iain Jackson)** or **07543 228 856 (Anisa Visram)**.