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Sound-Sensitivity in Children

Is your child sensitive to sound?




Help develop a clinical questionnaire

Part A

Purpose of the study

Sound-sensitivity (sometimes called hyperacusis) can be very distressing for some children and their families. However, **clinicians have no standard way of assessing sound sensitivity** that is specifically developed for use with children.

The purpose of this study is to **test a new questionnaire before it can be used to help clinicians** to assess sound sensitivity in children before and after therapy.

- We are looking for parents/carers of children who are sensitive to some sounds to take part in an interview to discuss our newly developed questionnaire.

Why have I been invited to take part?

You are invited to take part if your child:

- **gets distressed by some sounds** (e.g., hoover, blender, traffic noise, school bell)
- **is aged 2-11 years**

To understand whether the questionnaire is useful, appropriate, relevant and reliable, we are inviting 6 parents/guardians to complete it and interview.

What will happen to me if I take part?

You will be asked to:

- **complete a newly developed questionnaire**
- **answer questions** about how clear and easy to use it is in an interview.

This can be online via **MS Teams or face-to-face** and may take about **30 minutes.** The interview will be led by the Study Co Ordinator, Iskra (Part C).

What do I need to do now?

Contact Iskra for more information or to take part:
Iskra.Potgieter@nottingham.ac.uk
01158232628/ 07812277092

Part A Continued

Do I have to take part?

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 be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time, without giving a reason and without your child's care being affected. This would not affect your legal rights.

Disadvantages of taking part

It is possible that you may find discussing your child's sound sensitivity upsetting. To prevent this, we have designed the interview discussion guides to approach topics in a sensitive manner. If it becomes challenging for you to speak about your child's experiences, the interviewer will utilise projective/ "third person" techniques that encourage you to suggest the feelings and attitudes of other children with sound sensitivity to the situation being discussed.

Are there any benefits to taking part?

We cannot promise that the study will help your child, however by taking part, you will help us to develop a clinical questionnaire that will be used to assess children with sound sensitivity. As a thank you for taking part in the study, you will be given a £15 gift voucher.

What will happen to me if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible

For more information or to take part:

Email: Iskra.Potgieter@nottingham.ac.uk

Tel: 01158232628/ 07812277092

Will my time/travel costs be reimbursed?

If you choose to take part face-to-face session at NIHR Nottingham BRC, your travel expenses will be covered up to £15 including mileage or public transport. Please keep any receipts related to travel or parking.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting Faculty of Medicine and Health Sciences Ethics: fmhs-researchethics@nottingham.ac.uk

If you are an NHS patient, you can contact the Patient Advice and Liaison Service (PALS):

Please call Freephone: 0800 183 0204 (free from a UK landline) or from a mobile or abroad: 0115 924 9924 ext: 65412 or 62301 Email: pals@nuh.nhs.uk.

Or you can write to: NUH NHS Trust, c/o PALS, Freepost, NEA 14614, Nottingham NG7 1BR

In the event that something does go wrong, and you are harmed during the research, and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Part B

Confidentiality & Data Protection

What will happen to the data provided?

- All interview and focus group discussions will be audio recorded. Questionnaire data will be coded and stored into a secure digital database.
- All data will be anonymised using a study identification number and kept confidential.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence. If you participate in the study, we will use information collected about you during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws, the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Derek Hoare) is the Data Custodian (manages access to the data). This means we are responsible for looking after the information and using it properly. Rights to access, change or move your information are limited as we need to manage the information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally – identifiable information possible. You can find out more about how we use your information and read our privacy notice at: https://www.nottingham.ac.uk/utilities/privacy.aspx.

Who will know that I am taking part in this study?

The data collected for the study will be looked at and stored by authorized persons from the University of Nottingham who are organizing the research. They may also be looked at by authorized people from regulatory organizations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.
All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Audio recordings will be destroyed immediately after anonymous transcription. Your personal data (address, telephone number) will be kept for 12 months after the end of the study. All other data (research data) will be kept securely for 7 years. After this time ,your data will be disposed of securely. During this time, all precautions will be taken by all those involved to maintain your confidentiality. Only members of the research team will have access to personal data.
In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organizations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymized (so that you could not be identified) but if we need to share identifiable information, we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

Part C

Meet the team

Iskra Potgieter (PhD Student) – Study Coordinator

Iskra.Potgieter@nottingham.ac.uk
Tel: + 44 (0) 115 8232628
Mob: 07812277092

I am responsible for coordinating all phases of the research project. I will conduct the individual interviews, facilitate the focus group and collect questionnaire data. My wider team includes my academic supervisors: Dr Derek Hoare and Dr Kathryn Fackrell, and clinical advisors: Claire Benton, Dr Veronica Kennedy, Dr Zara Jay and Dr Sudhira Ratnayake.

Derek Hoare – Chief Investigator

Derek.Hoare@nottingham.ac.uk

Tel: + 44 (0) 115 82 32630

The research team are happy to answer any questions you have before or during your participation in the project.

Who is organising and funding the study?

This project is funded by the National Institute for Health Research (NIHR) Nottingham Biomedical Research Centre and University of Nottingham.

Who do I speak to if problems arise?

Our staff always try to conduct research in a way that is caring and respectful. If you do have any concerns about any aspect of the study, you should contact:

Chief Investigator: Derek Hoare

- Email: Derek.Hoare@nottingham.ac.uk
- Tel: + 44 (0) 115 82 32630

Who has reviewed the study?

This study has been reviewed and given favourable opinion by:

- ✓ Research Ethics Committee [21/SC/0419].
- ✓ The Study Sponsor (University of Nottingham) and Nottingham University Hospitals NHS Trust Research and Development.