



The FUN Study - Fatigue in Unilateral Hearing Loss

Parent/Guardian Information Sheet

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Why is this project important?

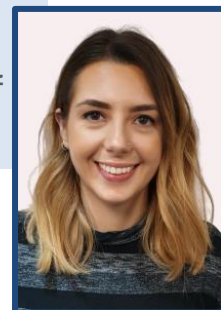
Fatigue is a known problem in children with Unilateral Hearing Loss (UHL) and Bilateral Hearing Loss (BHL).

The nature of fatigue in children with hearing loss and the reason why they experience this fatigue is not yet known.

By taking part in these studies, you and your child may help improve the lives of other children hearing loss who also experience fatigue.

Who am I?

My name is Bethany Adams. I am a PhD student studying fatigue and unilateral hearing loss (UHL) in children at the University of Nottingham.



1 Why are we doing the FUN Study?

- The nature of fatigue in children with UHL, and how/if it differs to children with hearing loss in both ears (bilateral hearing loss; BHL) or children with normal hearing (NH) is unknown.
- The reasons behind this fatigue in children with hearing loss is also unknown
- Fatigue is also difficult to measure in children, especially children with a hearing loss.
- This project aims to help us understand fatigue in children with hearing loss, why children with hearing loss experience fatigue and review current measures of fatigue.

For more information or to take part

Email: bethany.adams@nottingham.ac.uk
Phone: 0115 823 2631

2 What is UHL and Fatigue?

Unilateral Hearing Loss (UHL)

'Unilateral' means on one side only. Unilateral hearing loss means a hearing loss in only one ear.

Sensorineural UHL is a hearing loss that is only present in one ear. UHL can be present at birth (found during the newborn hearing screening) or can be developed at any point during your child's development.

A hearing loss is identified by an audiologist, who will play sounds at different volumes and frequencies, allowing them to determine the quietest sounds your child can hear.

Fatigue

Fatigue is a term used to describe an overall feeling of tiredness, lack of vigour, or lack of energy. Children with a hearing loss are more likely to experience fatigue, which may affect performance in everyday tasks.

Reports have shown that children with hearing loss in one ear only (UHL) also experience fatigue, and they may experience this fatigue at the same rate as a child with BHL.

Studies have also shown that fatigue in children can lead to poorer academic performance and language comprehension. This can have a knock on effect on a child's mental health.

What are we trying to find out?

In this study, we want to learn more about the nature of fatigue in children with different types of hearing loss. We would also like to review the relevancy of current measure of fatigue in children with hearing loss.

Furthermore, we would like to compare the fatigue experienced by children with UHL to the fatigue experienced by children with BHL and children with normal hearing, and understand the mechanisms behind this hearing-related fatigue.

Understanding more about this may provide insight on possible future treatments to reduce or help children to cope with fatigue.

3 Why and how have I contacted you?

You have received this information sheet, either because you have responded to advertisement for this study, or I am inviting you and your child to take part because your child falls within the criteria.

With permission from the University of Nottingham, I have visited Audiology departments to find children with hearing loss.

Being invited to take part does not mean that I think anything is wrong with the care your child is being given.

4 What is involved?

This study is split into **3** different elements, including:

You can choose to take part in **all, any, or none** of the following parts of the study.

Discussions/interviews

- You and/or your child with hearing loss will fill out some simple questionnaires and take part in an informal interview surrounding hearing loss, fatigue and its impact on day-to-day life.

Experimental tasks

- Your child will take part in some listening tasks whilst wearing a device to measure factors that could contribute to fatigue, such as movement and heart rate.

Observational sessions

- We will observe your child during home or school activities to see if we can determine what contributes towards fatigue. Your child may be asked to keep a diary.

Please see separate information sheet for experimental and observational studies!

5 What will happen to the information?

If you take part, after the study has finished the information we have recorded will be written up as a paper and submitted to be published in a peer reviewed scientific journal. Your name will not appear anywhere in the paper.

6 Discussions with parents/guardians

What does taking part involve?

- The discussion will be conducted by the Study Coordinator and will take approximately 60 minutes (2 hours maximum).
- You can take part in a discussion either face-to-face or remotely (over the telephone or skype). If you travel to us, we will reimburse your travel for up to £15.
- We will talk to you about your child's hearing loss, fatigue, and the effects it has on everyday life.
- Interviews will be video or audio-recorded
- Before taking part in the discussion, you may be asked to fill out a diary for up to 2 weeks to help you think about hearing loss and fatigue related issues.
- You will also be asked to fill out some simple questionnaires.
- If your child is taking part in any part of this study, we ask that you **DO NOT** discuss that the study is about fatigue.

Who can take part?

You can take part in this discussion if you speak fluent English and are a parent/guardian of a child who:

- Is aged 6 to 16 years old
- Has a diagnosis of UHL or BHL

How do I take part?

If you would like to take part in this discussion, please contact [Bethany Adams](#) (details in section 13).

Why take part?

Advantages

- This research may help our understanding of fatigue in children.
- You will be able to give us a unique and personable understanding of hearing loss and fatigue, which will help direct future research

Disadvantages

- You may find discussing your child's hearing loss and fatigue difficult
- The questions asked will be approached sensitively and if you prefer not to answer a question, that is okay.

Will I benefit from taking part?

You will not directly benefit from taking part in this study.

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

- Your participation is voluntary and you are free to withdraw at any time, without giving a reason.
- On withdrawal, no further information will be collected. However, it will not be possible to erase the information already collected, and this information may still be used anonymously in the project analysis.

7 Discussions with children

What does taking part involve?

- A relaxed, one-on-one discussion involving fun and interactive tasks that will encourage your child to share their thoughts and experiences (30-60 minutes).
- Discussions will take place via video call, but could take place at Ropewalk House, Nottingham, dependent on advice issued by Public Health England and your convenience. If you do attend in person, you will be reimbursed for your travel for up to £15.
- The interviews will be video-recorded and you (parent/guardian) will be able to watch it live in another room.
- We would like to see if your child naturally brings up fatigue/tiredness **WITHOUT** being prompted. We therefore ask that you **DO NOT** discuss fatigue when describing the interview with your child.

Who can take part?

Your child can take part in this discussion if they are:

- Aged 6 to 16 years old
- Has a diagnosis of UHL or BHL
- Use English in their home or school environment.

7 Discussions with children

How can my child take part?

If your child would like to take part in this discussion and you (parent/guardian) agrees, please contact Bethany Adams.

Your child will receive a £5 gift voucher for taking part in the study!

Why take part?

Advantages

- This research may help our understanding of fatigue in children with hearing loss
- Your child will be able to give us a unique perspective of hearing loss and fatigue, which will help direct future research.

Disadvantages

- For some children, discussing their hearing loss may be upsetting
- The questions asked will be approached sensitively and if you prefer not to answer a question, that is okay.

To reduce the risk of distress, where possible:

- We ask to speak to your child about the study, and that we will be discussing their hearing loss and hearing loss related problems.
- The discussions will be age-appropriate and will include ice-breakers and interactive tasks to help your child feel comfortable.
- A break-out space will be provided for children to leave the discussion at any point in time.
- Parents/guardians will be asked to remain close in case their support is needed.

Will my child benefit from taking part?

Your child will not directly benefit from taking part in this study.

What will happen if my child doesn't want to carry on with the discussion?

- Your child's participation is voluntary and they are free to withdraw from the discussion at any time, without giving any reason, and without their medical care or legal rights being affected.
- On withdrawal, no further information will be collected. However, it will not be possible to erase the information already collected, and this information may still be used anonymously in the project analysis.



Interactive discussion with a child

8 Confidentiality & Data Protection

If we take part, will my child's details be kept confidential?

Yes. We will follow ethical and legal practice and all information about your child will be handled in confidence and will be kept **strictly confidential**. It will be looked after only by authorized persons, stored in a secure and locked office, and on a password protected database at the University of Nottingham. The data collected for the study might 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.

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 will have access to personal data. confidentiality. Only members of the research team.

What are the legal requirements?

Under UK Data Protection laws, the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Pádraig Kitterick) 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.

8 Confidentiality & Data Protection

Continued...

To safeguard your child's rights we will use the minimum personally – identifiable information possible. You can find out more about how we use your child's information and read our privacy notice at:

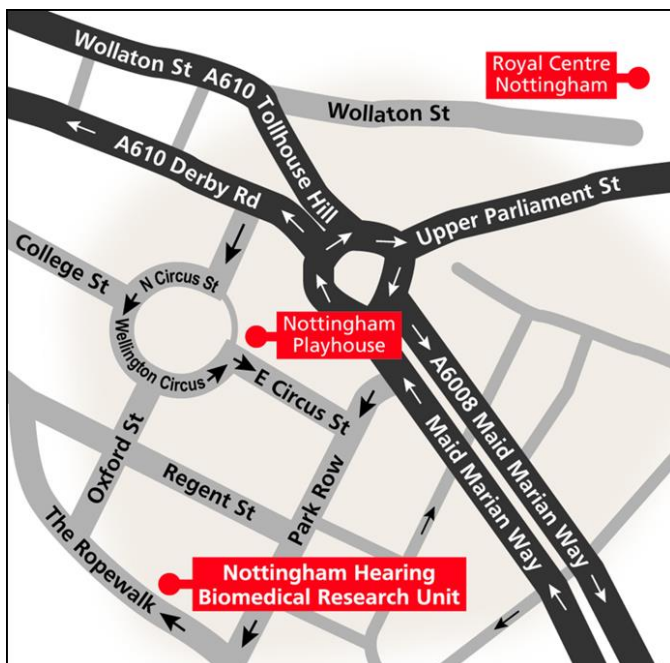
<https://www.nottingham.ac.uk/utilities/privacy.aspx>

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.

9 Who has reviewed the project?

This study has been reviewed and given favourable opinion by:

- ✓ **HRA and HCRW** Research Ethics Committee.
- ✓ The Study Sponsor (University of Nottingham) and Nottingham University Hospitals NHS Trust Research and Development.



Map of surrounding areas

10 Patient and Public Involvement

The research materials, questions and activities have been reviewed by children and families to ensure they are relevant and understandable to all participants.

11 Who do I speak to if I have concerns about the project?

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: Pádraig Kitterick (see section 13 for contact details)

If a complaint is not resolved and you wish to complain formally, you should then contact: Patient Advice and Liaison Service (PALS), Freepost NE 14614, Nottingham University Hospitals NHS Trust (QMC), Nottingham, NG7 1DR.

12 How to find us?

We are based within Ropewalk House in 'Castle Zone' of Nottingham City Centre, just off Derby Road and Maid Marian Way.

Our address is:

**Nottingham Biomedical Research Centre
Ropewalk House
113 The Ropewalk
Nottingham
NG1 5DU**

Phone:
0115 823 2600

On arrival:

If you go into the main entrance turn right then walk straight ahead for about 20 yds then first left you see lifts or stairs which you take down to the Mezzanine level. Hearing Sciences is on the left and ring the buzzer to allow reception to open the doors and request to see Bethany Adams. There is a lift. Disabled clients who require assistance should telephone 0115 823 2600 in advance to make arrangements.

Parking

Follow signs for the city centre and the 'Castle Zone'. Nearest car parks are Mount Street and St James's Street. Metered car parking on The Ropewalk is available (£1/hour), including spaces for blue badge holders (no charge).

By bus:

For bus times call Nottingham City Transport on 0115 950 6070, Traveline on 0871 200 2233, www.travelineeastmidlands.co.uk, closest bus stops are on Maid Marian way.

By tram:

'Market Square' and 'Royal Centre' are the two closest tram stops to our unit. Park and ride sites are available. See: www.thetram.net.

By Train:

Nottingham train station is close by. See: www.nationalrail.co.uk/stations_destinations/not.aspx



Ropewalk House entrance

Due to the COVID-19 pandemic and restrictions given by Public Health England, interviews with children can be conducted remotely via video link.

13

Meet the team



Bethany Adams (PhD Student) – Study Coordinator

Email: Bethany.Adams@nottingham.ac.uk

Phone: 0115 823 2631

This study is part of my PhD research project titled "The Basis of Fatigue in Children with Unilateral Hearing loss".

I am responsible for coordinating the study and will be conducting all elements of the study.

My wider team includes my supervisors, Padraig Kitterick, Sally Thornton, Ian Wiggins and Graham Naylor.



Padraig Kitterick

Chief Investigator

Padraig.Kitterick@nottingham.ac.uk

Phone: 0115 823 2626



Sally Thornton

Co-investigator

Sally.Thornton@nottingham.ac.uk

Phone: 0115 823 2642

The research team are happy to answer any questions you have before you agree to take part or when you are taking part.