



Information Sheet for Parents

Title of Study: Factors Influencing Feeding Outcomes after Neonatal HIE

Participant ID: _____

Invitation and Brief Summary

You are being invited to take part in a research study. Before you decide if you want to take part, it is important that you understand why the research is being done and what it will involve. Please read this information carefully. You can talk to other people about it if you want to. Take time to decide whether or not you wish to take part. If you do decide to take part, you will be asked to sign a consent form. However, you are free to withdraw at any time, without giving any reason. There is no disadvantage to you if you decide not to take part.

What is the purpose of the research?

Babies who have a hypoxic ischaemic encephalopathy (HIE) event can have problems with feeding and swallowing. We need to know more about these feeding problems so we can give families helpful information. The research will also help us to create feeding therapies for these babies.

In this study we will collect information about feeding in babies and young children who have had an HIE event. We will also find out what can make feeding better or worse. We will use this information to help parents and health care professionals understand how feeding can change in the first few years after HIE and to develop therapies. The research is being done as part of a PhD study at Newcastle University.

What does taking part involve?

If you take part in this study, you will be asked to complete a set of questionnaires. The questions will be about your child's feeding. The questionnaires are completed online. There is no need to attend any appointments. The questionnaires are completed once; there is no follow up. The full set of questionnaires take around 30 minutes to complete. You will receive a £10 Love2Shop voucher after you have completed them.

Why have I been invited to take part?

You have been invited to take part for two reasons. Firstly, because your child had an HIE event around the time of birth. Secondly, because your family is registered with the Peeps HIE charity.

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What are the possible benefits of taking part?

There is no direct benefit to participants. Findings from the study will be used to help future parents by giving them information. The information will be free and published on the Peeps HIE website. Study findings will also be used to develop feeding therapies. These therapies may lead to better feeding for children with HIE.

What are the possible disadvantages and risks of taking part?

The questionnaires are about your child's feeding, including how their feeding affects you and your family. Some parents may find some of the questions upsetting. If this is the case, you may wish to take a break before going on with the questionnaire. If you want to, you can leave the study at any time. Support is available from charities such as Peeps HIE (<https://www.peeps-hie.org>) and Mind (<https://www.mind.org.uk>).

Information about you and your child will be stored securely. In the unlikely event of a data breach, we will tell you as soon as possible.

What information will be collected and who will have access to the information collected?

We will collect your contact details and information about your child's feeding. This information will be stored in a secure password protected folder on the Newcastle University server that can only be accessed by the research team. Everyone involved in this study will keep your data safe and secure. We will follow all privacy rules.

Personal information

We (the research team at Newcastle University) will collect and store the following personal information about you and your child:

- Your name
- Your address
- Your email address
- Your phone number
- Your child's name
- Your child's date of birth

We will use your name and contact details to contact you about the research study. Your child's personal information will be stored with a participant ID number. This ID number will be used to label your child's questionnaire information so it doesn't have their name on it. This means that people in the research team who need to use your child's questionnaire information, but who do not need to know who you or your child are, will not be able to see any of your personal information.



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Personal information on you and your child will only be seen by members of the research team. They will only see this information when it is needed to carry out the research. If you consent, we will store your contact details for 10 years after finishing the study. This is so we can tell you about opportunities to take part in future research related to this project; If you don't want us to store your contact details after the study, we will delete all your personal information a year after the study ends.

Medical information and information from feeding questionnaires

We will collect details from you about your child's medical history and feeding through the online questionnaires. If the questionnaires show that your child might have some difficulties with feeding, we will talk to you about it. If you want us to, we can give your child's GP or paediatrician a copy of the questionnaire results. The medical and feeding information you give us on the questionnaires will be stored in de-identified form. This means it will be labelled using the participant ID number so it won't have your child's name on it. It will be kept separately to the personal information collected about you and your child. Staff at Newcastle University may look at your research information to check the study is being done correctly.

What are your choices about how your information is used?

You can stop being part of the study at any time. You don't have to give a reason. If you stop being part of the study, we will delete your personal information. We will also delete any questionnaires answers you have given in the past two weeks.

If you agree to take part in this study, you will have the option to take part in future research using your information saved from this study. Once the study is completed, the de-identified research information you have given us can be made available as "open data". This is through a research data repository called data.ncl, (more information about data.ncl can be found at <https://research.ncl.ac.uk/rdm/sharing/>). This means the de-identified study information will be publicly available and may be used for purposes not related to this study. You and your child cannot be identified from this "open data". Your identities and personal information will stay private. You do not have to agree to have your questionnaire information included in the data repository. It is your choice.

Where can you find out more about how your information is used?

You can find out more about how we use your information by sending an email to Sarah.Edney@newcastle.ac.uk

Who is the data controller for this research?

Newcastle University is the data controller for this study.

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Who is funding this research?

The study is funded by a Wellcome 4Ward North PhD Fellowship.

Who has reviewed the study?

The study has been reviewed by the funders, the research team, and a panel at Newcastle University. The project was developed with a steering group of health professionals and a parent advisory group, including a representative from the Peeps HIE charity. This study was approved by the Faculty of Medical Sciences Research Ethics Committee, part of Newcastle University's Research Ethics Committee. This Committee includes members who are internal to the Faculty. This study was reviewed by members of the Committee, who must provide impartial advice and avoid significant conflicts of interests (reference number: 2657).

What will happen to the results of the research study?

We will tell you about the results when the study is finished. We also plan to publish the results in a professional journal and present them at conferences. You will be able to get a copy of any published paper once it is available. You and your child will not be identified in any report or publication.

To make sure that the results of this study are useful to as many parents as possible, we will publish an easy-to-understand summary of the results on the Peeps HIE charity website.



Who should I contact for further information relating to the research?

Ms Sarah Edney
PhD student and Speech and Language Therapist
Sarah.Edney@newcastle.ac.uk

Who should I contact in order to file a complaint?

If you have a question or concern, please get in touch with one of the research team and we will try to help you. Our contact details are:

- Sarah Edney, PhD student researcher (Sarah.Edney@newcastle.ac.uk)
- Prof Lindsay Pennington, project supervisor (Lindsay.Pennington@newcastle.ac.uk)
- Dr Anna Basu, Chief Investigator and project supervisor (Anna.Basu@newcastle.ac.uk)
- Prof Judith Rankin, project supervisor (Judith.Rankin@newcastle.ac.uk)

Thank you for reading this leaflet. Please let us know if you have any questions. If you do agree to take part, please keep this copy of the information sheet and sign the consent form attached.