Participant Information Leaflet

Introduction

We are asking you to take part in an important research study about neonatal encephalopathy.

This Participant Information Leaflet will tell you about this research study, and what taking part means for you.

Please read this leaflet carefully and ask the COHESION research team if you have any questions. We have put the contact details (phone number, email address and postal address) at the end of this leaflet.

Before you decide if you would like to take part, it is important to understand why this research is being done and what it would mean for you.

The aim of the study, called 'COHESION', is to develop a core outcome set for use in research studies of treatments for neonatal encephalopathy.

Why is this study important?

Neonatal encephalopathy is a condition that can occur in newborn infants when they have had a lack of oxygen, and this can cause complications with the infant's brain. Neonatal encephalopathy is one of the leading causes of brain injury in newborn infants.

At the moment, different studies into how to best treat neonatal encephalopathy measure how well the treatment works in different ways (called 'outcomes'). This often means that when health care professionals or parents want to compare or combine different studies, they are unable to do so.

What is a core outcome set?

Core outcomes sets (COS) are the minimum set of outcomes that should be measured and reported in studies evaluating a health intervention. An intervention is anything that aims to make a change to someone's health. For example, providing a counselling service, giving a drug, or giving people information and training are all described as interventions. An outcome is something that can be measured to determine the effect that an intervention is having. Researchers may wish to explore other outcomes relevant to their research, but the COS should always be included. Agreeing the set of outcomes that must be reported in all studies allows us to pool the evidence from different studies, which helps inform health care decisions and also reduces research waste.

How do I know if I can take part in this study?

You can take part in this study if you are over 18 years of age and are a parent or other family member who care, or have cared for, an infant who has been diagnosed with and received treatment for neonatal encephalopathy.

What will I have to do?

If you agree to take part in this study, we would like to ask you some questions. This is called a research interview. The interview will be done via a video call, using a video conferencing software called Zoom. The interview will take place at a day and time that suits you.

This interview will give you the chance to let us know what you think about some of the outcomes that we have found from looking through studies that have already been published. The interview will last about 30-45 minutes. If you agree, we will record (voice only) the interview so that we can type out what you have said later on. This means we will be able to listen carefully to you while you share what you think.

Are there any benefits or risks to me taking part?

Your participation will help us establish which outcomes are important and should be measured in all future studies of treatments for neonatal encephalopathy.

There are no physical risks with taking part in this study. There is always a chance that talking about certain topics may upset you. If this happens, you will be asked if you would like to take a break and have the voice recording paused. You can decide to walk away from the interview at any time.

Do I have to take part?

No. You do not have to take part if you don't want to. You have the right to stop being in the study at any time. If you decide not to take part in this study, or if you decide to stop, you do not have to give a reason. If you decide not to take part, or to stop, your baby's care will not be changed in any way. If you do decide to stop being in the study, please send an email to the COHESION research team to tell us this.

Confidentiality

Your identity will remain confidential. All data will be coded, and data will be grouped, meaning that your name will not be published, and it will not be disclosed to anyone outside the interview. All data (audio recording, paper and electronic) collected during the study will be stored securely on a password protected NUI Galway server in the National University of Ireland, Galway under the stewardship of the Principal Investigator and destroyed after seven years as per National University of Ireland, Galway Data Retention Policy.

Please note that if any participant should disclose information during the research study regarding unacceptable work practices or issues of risk, the researcher is obliged to report this information to the appropriate management/ authority. In such cases, confidentiality may be broken.

What will happen to the findings of this study?

The findings of the interview will help inform the next stage of our research which is a questionnaire survey. The findings of the interviews may be submitted to a journal for publication.

Compensation

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Funding

This study has been funded through the Health Research Board (HRB), as part of the HRB Neonatal Encephalopathy PhD Training Network (NEPTuNE).

Has this study received ethical approval?

Yes, this study has received approval from:

National University of Ireland, Galway Research Ethics Committee
Research Office
Room 212
Research and Innovation Centre
NUI Galway
Tel: 353 91 495312

Who can I ask if I have questions?

You can get more information about the study by asking the COHESION research team. Contact details are as follows:

COHESION (Core Outcomes in Neonatal Encephalopathy) Team
Fiona Quirke, PhD Fellow, NUI Galway, F.QUIRKE1@nuigalway.ie

Dr Linda Biesty, Lecturer in Midwifery, NUI Galway linda.biesty@nuigalway.ie

Prof. Declan Devane, Professor of Midwifery, NUI Galway,
declan.devane@nuigalway.ie

Additional Information
If you have any issues or queries about the data protection for this project, please find the contact email address of the NUI Galway Data Protection Officer at dataprotection@nuigalway.ie

Please note that you have the right to request from the data controller for COHESION, access to your data, to rectify or erase your data, or to object to the processing of your data.

Please note that you have the right to lodge a complaint with the Data Protection Commissioner, see www.dataprotection.ie for contact details

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If you would like to take part in this interview please, contact *(+353 91 495481)* **or email** (*f.quirke1@nuigalway.ie)* **to talk about this and ask any questions you may have.**

Please note that it might not be possible to interview every person who agrees to take part. This would only occur if more people choose to take part than we could reasonably interview. Please be aware that if a lot of people wish to take part in this study, we will chose a random sample of participants and you may not be asked.

Thank you for taking the time to read the information within this Participant Information Leaflet. We hope you will think about taking part.