Participant Information Sheet

CHildbirth Acquired Perineal TRauma Study
A cohort study

Version 2.0 (01 June 2023)

Invitation

We would like to invite you to take part in the CHAPTER cohort study. Joining this study is entirely up to you. To help you decide, we would like to explain why the research is being done and what it will involve for you. A member of our research team will go through this information sheet with you to help you to decide whether or not you would like to take part and to answer any questions you may have. Please take time to read this information and discuss it with your family, friends or staff in the hospital if you wish to. This Participant Information Sheet (PIS) tells you the purpose of the study, what will happen to you if you take part and detailed information about the conduct of the study. Please do take the opportunity to ask any questions you have and to ask for more information if anything is unclear.

Please note, within the CHAPTER study we use the term women to refer to all birthing people as we acknowledge that it is not only people who identify as women who might be affected by Childbirth Related Perineal Trauma (CRPT).

Purpose and background to the research

Each year in the UK, 80% of women who give birth vaginally (450,000 women), experience damage, such as a tear or graze, to the tissues, muscles and skin around the bladder, vagina and perineum (the skin between the vagina and back passage). This is referred to as Childbirth Related Perineal Trauma (CRPT). For most women, these tears are minor and heal quickly. However, some women may experience problems if these tears don't heal properly. Some of these problems may be short-term, such as infection and discomfort. However, some women may suffer from long-term issues and may find themselves struggling to control their usual bodily functions such as passing urine, wind and stool. These symptoms may impact their overall quality of life and ability to care for their newborn baby and older children. Additionally, dealing with these issues can put a strain on women's intimate relationships. Some women may feel too embarrassed to seek help about their symptoms or are unaware of how to access support and treatment.

At the moment, we understand some of the risk factors associated with tearing while giving birth vaginally. However, we know very little about how women recover from these tears. We currently do not collect information to tell us how frequent or serious the complications following a tear are. Additionally, we are unaware where women turn to access care and how satisfied they are with the support and advice they receive. This has led to poor understanding about the extent of these issues amongst healthcare professionals and the wider society.

The CHAPTER cohort study aims to learn more about how experiencing a tear through vaginal birth can impact women's lives and how frequently complications relating to tears occur. This is part of the CHAPTER study, a larger national research programme that is working to improve the care women receive during the healing of their stitches or tear after giving birth vaginally. In order to do this, we intend to recruit 1000 women who have recently given birth and experienced a tear in the cohort study. We will then follow their recovery for the first 12 months after they've given birth, collecting information about how they are feeling at various stages throughout the year. We will ask these women to complete a questionnaire at 6 weeks, 6 months and 12 months after giving birth and collect information about their physical, emotional and psychological wellbeing.

The information we gain from this study will help us put forward recommendations for developing care pathways and education resources for healthcare professionals to ultimately

optimise the quality of care women receive and hopefully improve the lives of thousands of women across the UK.

Why have I been chosen?

The research team at the hospital where you have given birth is involved in the CHAPTER cohort study as they feel that the study is important. As such they are inviting all the women who have recently given birth vaginally and experienced a tear to participate.

What would taking part involve?

If you agree to take part in the CHAPTER cohort study, you would need to agree to information about your birth and immediate postnatal recovery being collected from your medical notes by the CHAPTER research team, and shared with the Birmingham Centre for Observational and Prospective Studies. You will need to sign a consent form and provide your contact details, and preferred method of contact, which will be recorded on a contact information form by a member of the hospital team. Following this we will ask you to complete a questionnaire around 6 weeks after your baby's birth with one of our researchers, either by telephone, online or post. We will ask you questions about how you are healing and if you've had any complications. There will be 2 further, similar questionnaires at 6 months and 12 months to see how you are getting on and if there are any ongoing concerns or issues. The questionnaires will ask some sensitive questions such as how you feel your tear is healing, your ability to control your bowels and bladder. Additionally, they will ask about how your sexual relationship with your partner may have changed for you and how you are feeling emotionally. Should you need further support or information at any point while completing these questionnaires, please contact the CHAPTER study research team and they will be able to direct you towards sources of support.

Each questionnaire will take approximately 20 minutes of your time to complete. We understand you are likely to be busy caring for yourself, baby and family. Therefore, if you are not able to complete the questionnaire when you first receive it, you will be sent gentle reminders fortnightly for a month. If you are unable to complete this within the first month, we will send you a questionnaire by post to the address you provided at the start of the study with a pre-paid envelope addressed to the research team enclosed.

There are no further hospital visits or examinations required for this study.

What are the possible benefits of taking part?

It is unlikely that taking part in the CHAPTER cohort study will have any direct benefit to you. However, you may feel it is important for you to share your views and experiences in order to help improve the way women who have experienced a tear are cared for in the future. At the moment, this area of women's health is under-researched. Gaining more knowledge about this issue and running studies like this with women like you may lead to increased awareness about how tears experienced during vaginal birth can impact women's quality of life following birth and beyond.

We are hoping that this study will give us more knowledge and understanding to develop new and better ways to support women in the future. If we identify from our conversations with you or from the information that you put on the questionnaire that you might be suffering from a health problem, a member of the CHAPTER research team would contact you to ensure that you are aware of how to seek appropriate help.

What are the possible disadvantages and risks of taking part?

We do not expect there to be any disadvantages or risks to taking part in the CHAPTER cohort study. However, we know that taking part takes times and may be inconvenient.

Who is organising and funding the research?

The CHAPTER cohort study is organised by a research group consisting of midwives, obstetricians and researchers. It has been funded by the National Institute of Health and Care Research (NIHR). This is the UK's largest funder of health and care research. The study is being coordinated by a team based at the University of Birmingham, UK.

How have patients and the public been involved in this study?

A group consisting of women and members of the public have helped to develop this research study. They have shared their opinions and experiences with us, and this information has been very valuable when planning this research. They have also reviewed this study documentation to make sure it is clear and easy to understand.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given favourable opinion by Wales REC 7 Research Ethics Committee.

Will my taking part in this study be kept confidential?

Yes. If you take part in the study, some personal information such as your name, address and other contact details will be collected. These details will be held securely by the study managers in Birmingham and will only be used by members of the research team to contact you for the purposes of the questionnaires. You will be assigned a unique study ID and the research team will use this information to conduct the research.

With your consent, we will inform your GP of your involvement in the study by letter. As an optional part of the study you can agree or decline to be contacted in the future regarding additional studies related to Chapter.

What will happen to the data I give?

In this research study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data in case we need to check it **AND/OR** for future research. We will make sure no-one can work out who you are from the reports we write.

The University of Birmingham takes great care to ensure that personal data is handled, stored and disposed of confidentially and securely. All information collected from you for this study will be stored according to the General Data Protection Regulation and Data Protection Act 2018. Our staff receive regular data protection training, and the University has put in place organisational and technical measures so that personal data is processed in accordance with the data protection principles set out in data protection law.

You can find out more about how we use your information from one of the research team, or at www.hra.nhs.uk/information-about-patients or the University's Data Protection Officer at dataprotection@contacts.bham.ac.uk

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to a member of the research team who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting Patient Advice and Liaison Service (PALS) at your local hospital. Please see their details in Section 16.

What if I do not want to take part?

Taking part is completely voluntary. Your care will not be affected by your decision. If you do not wish to take part, please inform a member of the research team. **Likewise, if you initially consent to take part in this study and then change your mind, please use the contact details for the study investigator below to inform us, and we will remove you from the study.**

If you decide not to take part, you don't have to give any reason why and no-one will think badly of you for not wishing to take part in, or continue with the study. Your care will not be affected in anyway. You can decide not to continue with the study at any time, but if you do, we will keep the information about you that we already have and it will be included in the study analysis.

What will happen to the results of the research study?

Once this study has finished, we will publish the results in a medical journal so that other women can benefit. We will also publicise the results on the study's website: www.birmingham.ac.uk/chapter-study. No individual women will be identifiable in any publications.

How long will my personal data be kept?

Your data will be retained for 25 years after the publication of the research outcomes. If you withdraw from the project, we will keep the information we have already obtained but, to safeguard your rights, we will use the minimum personally identifiable information possible.

Do you have any further questions?

If you have any further questions about the CHAPTER cohort study, please discuss them with the local study investigator.

Details of local study investigator/ person to contact:

Name	
Job Title	
Contact details	

Support can also be found through the NHS Patient Advisory and Liaison Service (PALS):

Local PALS contact number	
Local PALS email address	

The Chapter cohort study office is located at the University of Birmingham, Birmingham Centre for Observational and Prospective Studies (BiCOPS), Institute of Applied Health Research, University of Birmingham, Edgbaston, Birmingham, B15 2TT.

Web address: www.birmingham.ac.uk/chapter-study; e-mail: Chapter@contacts.bham.ac.uk

Thank you for taking the time to read this Participant Information Sheet.