ISRCTN17011317 https://doi.org/10.1186/ISRCTN17011317

# The Chapter Cohort Study: Following women for 12 months following tears or cuts after childbirth: How widespread are health problems, and what are these health problems?

**Submission date**
08/08/2023

**Recruitment status**
No longer recruiting

**Registration date**
25/08/2023

**Overall study status**
Completed

**Last Edited**
12/01/2024

**Condition category**
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

## Plain English summary of protocol

Background and study aims
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.

Who can participate?
Women aged 16 years or older who have sustained childbirth related perineal trauma

What does the study involve?
Participants who agree to take part in the CHAPTER cohort study would need to agree to information about their birth and immediate postnatal recovery being collected from their medical notes by the CHAPTER research team, and shared with the Birmingham Centre for Observational and Prospective Studies. They will need to sign a consent form and provide contact details, 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 participants to complete a questionnaire around 6 weeks after their baby's birth with one of our researchers, either by telephone, online or post. We will ask participants questions about how they healing and if they have had any complications. There will be 2 further, similar questionnaires at 6 months and 12 months to see how participants are getting on and if there are any ongoing concerns or issues. The questionnaires will ask some sensitive questions such as how participants feel their tear is healing, their ability to control their bowels and bladder. Additionally, they will be asked about how their sexual relationship with their partner may have changed for them and how they are feeling emotionally. Should participants need further support or information at any point while completing these questionnaires, they can contact the CHAPTER study research team and who will be able to direct participants towards sources of support.
Each questionnaire will take approximately 20 minutes to complete. We understand participants are likely to be busy caring for themselves, baby and family. Therefore, if they are not able to complete the questionnaire when they first receive it, they will be sent gentle reminders fortnightly for a month. If they are unable to complete this within the first month, they will be sent a questionnaire by post to the address 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 and risks of participating?
It is unlikely that taking part in the CHAPTER cohort study will have any direct benefit to participants. However, participants may feel it is important to share their 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 participants or from the information that you put on the questionnaire that participants might be suffering from a health problem, a member of the CHAPTER research team would contact them to ensure that they are aware of how to seek appropriate help.

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 time and may be inconvenient.

Where is the study run from?
Birmingham Women's and Children's NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
November 2021 to February 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Sue Tohill, s.tohill@bham.ac.uk

# Contact information

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Scientific

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
320118

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
CPMS 56469, NIHR202869, IRAS 320118

# Study information

### Scientific Title
The Chapter Study – Childbirth-acquired perinatal trauma study; a cohort study

### Study objectives
A prospective multi-centre cohort study of childbirth-related perineal trauma (CRPT)
1. To determine the current prevalence of each type of CRPT in the UK.
2. To determine the prevalence and type of complications and health problems associated with CRPT.
3. To describe the current assessment pathways for CRPT complications
4. To describe the management of CRPT complications
5. To describe the risk factors associated with the development of CRPT- associated complications
6. To describe the risk factors for development of health problems following CRPT-associated complications
7. To determine the burden of CRPT on the NHS

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 27/06/2023, Wales REC 7 (Health and Care Research Wales, Castlebridge 4, Cardiff, CF11 9AB, United Kingdom; +44 2922 941107; Wales.REC7@wales.nhs.uk), ref: 23/WA/0169

### Study design
Observational cohort study

### Primary study design
Observational

### Secondary study design
Cohort study

### Study setting(s)
Hospital, Other

## Study type(s)
Other

## Participant information sheet
See additional files

## Health condition(s) or problem(s) studied
Childbirth-related perineal trauma

## Interventions
Potentially eligible participants will be identified and approached by members of their clinical care team, namely the midwife or obstetrician caring for them around the time of birth. The initial approach to potential participants will take place while women are still an inpatient and can be in one of two settings:
- On the labour ward for those patients anticipated for early discharge
- On the postnatal ward
- For those women who have a home birth or who are discharged before the have been approached for inclusion, they will be asked to participate when they are seen by a community midwife usually at Day 1 post-partum.

Patients will be provided with background information about the study, including the premise and what their participation would involve. The patient will have an opportunity to ask questions and a written Chapter Cohort study Participant Information Sheet (PIS) will be provided as an adjunct to this conversation. Those for whom English is not their first language will also be supported by Language Line (a UK language translation service agency that provides interpreting and translation services for over 200 languages, including British Sign Language) if that service is used by the participating trust. Otherwise, standard trust provision for translation will be used.
Once the patient has consented and they are registered onto the Chapter study, baseline information will be collected about the participant. This will include data on demographics (e.g. age, ethnicity), maternal characteristics (e.g. body mass index, obstetric history, medical conditions) and delivery characteristics (e.g. mode of delivery and CRPT type and repair). There are no additional study-specific follow-up visits once the patient is entered onto the Chapter study.

All follow-up will be conducted remotely.
There are three follow-up timepoints:
• 6-weeks post-partum
• 6 months post-partum
• 12 months post-partum.

At 6 weeks, 6 months and 12 months post-partum all participants will be sent a series of electronic questionnaires for completion. Participants will be given the option to complete these questionnaires individually or over the phone with the support of the research midwife.

At each of the 3 timepoints, participants will be asked to complete questionnaires online relating to:
• Urinary incontinence, flatus incontinence, faecal incontinence
• PTSD/anxiety/depression
• Overall quality of life

In addition, at 6 and 12-months completion of questionnaires related to pelvic organ prolapse symptoms, sexual function and physical activity will be requested.

Where completed questionnaires indicate that a participant has had to seek medical care related to her CRPT further data will be collected by reviewing the medical records.

The study's Public Advisory Group (PAG) has been involved in all stages of its development including consideration of ethics, development of materials, recruitment strategy, design and methodology.

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome measure
Perineal infection within 6-weeks post-partum measured via both the bespoke patient-reported CHAPTER study 6-week questionnaire and through clinician-reported outcomes on the presence of a perineal infection using the online 6 week eCRF

## Secondary outcome measures
1. Clinical Outcomes:
Clinical outcomes based on routinely collected data held in patient notes transcribed into electronic case report forms (eCRFs)
1.1. Antibiotic use for perineal infection within 6 weeks post-partum assessed using the 6 week eCRF
1.2. Number of participants who experienced wound breakdown by 6 weeks post-partum assessed using 6 week eCRF
1.3. Number of participants experiencing urinary and faecal incontinence at 6 weeks assessed using the 6 week eCRF
1.4. Use of analgesia at 6 weeks assessed using the 6 week eCRF
1.5. Number of participants requiring readmission or triage visit for CRPT-related complications assessed using the 6 week eCRF
1.6. Number of participants requiring referral or review within a Specialist Perineal clinic assessed using the 6 week eCRF

2. Patient reported outcomes:
At 6-weeks, 6 and 12-months post-partum:
2.1. Urinary incontinence via the Revised Urinary Incontinence Scale (RUIS)
2.2. Faecal incontinence via the Revised Faecal Incontinence Scale (RFIS)
2.3. Anxiety and depression via the Edinburgh Postnatal Depression Scale
2.4. General health related quality of life using the EQ-5D-5L
2.5. PTSD via selected domains from the City Birth Trauma Scale.

At 6 and 12-months post-partum:
At 6 and 12 months post-partum, all of the validated questionnaires above are used plus additional questions, together this is referred to as the “CHAPTER Bespoke Questionnaire”. The following are assessed using the “CHAPTER Bespoke Questionnaire”:
2.6. Sexual function via the Bespoke Chapter Questionnaire
2.7. Physical activity via the Pelvic Floor Impact Questionnaire

2.8. Pelvic organ prolapse symptoms via selected domains from the Revised Postpartum Pelvic Floor and Birth Questionnaire
2.9. Maternal satisfaction
2.10. Ability to feed according to mother's preference
2.11. Ability to care for baby
2.12. Social isolation
2.13. Ability to care for older children
2.14. Impact on seeking healthcare
2.15. Future pregnancy and subsequent mode of birth preference

### Overall study start date
23/11/2021

### Completion date
28/02/2025

## Eligibility

### Key inclusion criteria
1. Women (>16 years) who have given birth vaginally, either spontaneously or operatively
2. Women who have sustained childbirth related perineal trauma
3. Able and willing to give informed consent in a participating maternity unit during the data collection period.

*Women who have failed instrument delivery and have given birth via caesarean section and women with multiple births who give birth vaginally and via c-section can still be included in CHAPTER as long as they have sustained CRPT.
** Women who sustain an Obstetric Anal Sphincter Injuries (OASI) CRPT will not be excluded.

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
16 Years

### Sex
Female

### Target number of participants
Planned Sample Size: 1,000; UK Sample Size: 1,000

### Key exclusion criteria
Does not meet inclusion criteria

### Date of first enrolment
01/09/2023

**Date of final enrolment**
28/02/2024

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Birmingham Women's Hospital**
Mindelsohn Way
Birmingham
United Kingdom
B15 2TG

**Study participating centre**
**The Royal London Hospital**
Whitechapel Rd
London
United Kingdom
E1 1FR

**Study participating centre**
**Whipps Cross University Hospital**
Whipps Cross Rd
London
United Kingdom
E11 1NR

**Study participating centre**
**Royal Bolton Hospital**
Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

**Study participating centre**

**Calderdale Royal Hospital**
Salterhebble
Halifax
United Kingdom
HX3 0PW

**Study participating centre**
**Addenbrooke's Hospital**
Hills Road
Cambridge
United Kingdom
CB2 0QQ

**Study participating centre**
**West Middlesex University Hospital**
Twickenham Road
Isleworth
United Kingdom
TW7 6AF

**Study participating centre**
**Countess of Chester Hospital**
Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

**Study participating centre**
**Doncaster Royal Infirmary**
Thorne Road
Doncaster
United Kingdom
DN2 5LT

**Study participating centre**
**Queen Elizabeth Queen Mother Hospital**
St Peters Road
Margate
United Kingdom
CT9 4AN

**Study participating centre**
**George Eliot Hospital**
College Street
Nuneaton
United Kingdom
CV10 7DJ

**Study participating centre**
**Great Western Hospital**
Marlborough Road
Swindon
United Kingdom
SN3 6BB

**Study participating centre**
**Homerton University Hospital**
Homerton Row
London
United Kingdom
E9 6SR

**Study participating centre**
**King's College Hospital**
Denmark Hill
London
United Kingdom
SE5 9RS

**Study participating centre**
**Kingston Hospital**
Galsworthy Road
Kingston upon Thames
United Kingdom
KT2 7QB

**Study participating centre**
**Liverpool Women's Hospital**
Crown Street

Liverpool
United Kingdom
L8 7SS

**Study participating centre**
**Saint Mary's Hospital**
Oxford Road
Manchester
United Kingdom
M13 9W

**Study participating centre**
**Leighton Hospital**
Middlewich Road
Crewe
United Kingdom
CW1 4QJ

**Study participating centre**
**Scunthorpe General Hospital**
Cliff Gardens
Scunthorpe
United Kingdom
DN15 7BH

**Study participating centre**
**Northumbria Specialist Emergency Care Hospital**
Northumbria Way
Cramlington
United Kingdom
NE23 6NZ

**Study participating centre**
**Royal Free Hospital**
Pond St
London
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NW3 2QG

**Study participating centre**
**Royal United Hospital Bath**
Combe Park
Bath
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BA1 3NG

**Study participating centre**
**Warwick Hospital**
Lakin Road
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**Study participating centre**
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DY1 2HQ

**Study participating centre**
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**Study participating centre**
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United Kingdom
BH15 2JB

**Study participating centre**
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Derriford Road
Plymouth
United Kingdom
PL6 8DH

# Sponsor information

### Organisation
Birmingham Women's and Children's NHS Foundation Trust

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Steelhouse Lane
Birmingham
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United Kingdom
B4 6NH
+44 121 3338749
e.adey@nhs.net

### Sponsor type
Hospital/treatment centre

### Website
https://bwc.nhs.uk/

### ROR
https://ror.org/056ajev02

# Funder(s)

### Funder type
Government

### Funder Name
NIHR Central Commissioning Facility (CCF)

# Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

### Intention to publish date
01/02/2026

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the Birmingham Centre for Prospective and Observational Studies (BiCOPS), BiCOPS@contacts.bham.ac.uk. Requests for data generated during this study will be considered by BiCOPS. Data will typically be available six months after the primary publication. Only scientifically sound proposals from appropriately qualified Research Groups will be considered for data sharing. The request will be reviewed by the BiCOPS Data Sharing Committee in discussion with the CI and, where appropriate (or in absence of the CI) any of the following: the Study Sponsor, the SMG, and the PSC.
A formal Data Sharing Agreement (DSA) may be required between respective organisations once release of the data is approved and before data can be released. Data will be fully de-identified (anonymised) unless the DSA covers transfer of participant identifiable information. In all publications, authors should acknowledge that the study was performed with the support of the NIHR and BiCOPS.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version 2.0 | 01/06/2023 | 14/08/2023 | No | Yes |