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Exploring the views and experiences of women affected by tears and cuts during childbirth and the healthcare professionals who care for them (the Chapter qualitative sub-study)

Submission date
12/03/2024

Recruitment status
No longer recruiting

Registration date
24/06/2024

Overall study status
Completed

Last Edited
28/04/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
More than 80% of women experience cuts and/or tears during vaginal childbirth in the UK each year. That's about 450,000 women so it's a big problem. When giving birth vaginally, women can experience tears and cuts to the muscles and skin around the bladder, vagina perineum (the skin between the vagina and back passage) and the anal sphincter. All types of tears can result in pain and distress for women, and where there are problems, they need to be treated quickly and effectively.
If tears are not treated properly, women can be left with physical and mental health problems. At the moment, we don't have a standardised care process (tool) to help doctors, midwives and nurses to manage cuts and tears after childbirth if there are problems. It's really important that we develop a tool to make sure that women affected by cuts and tears during childbirth are getting the best care. The information collected as part of this study will be used to inform the development of a tool and guidance and will hopefully improve care for women in the future.

Who can participate?
1. Women who are over the age of 18 years, living in the UK who have experienced cuts and/or tears during childbirth within the last 12 months. Women will need to be able to take part in English or Romanian, Urdu, Bengali, Polish, Arabic or Hindi.
2. Registered healthcare professionals who are over the age of 18 and working in the NHS to provide care to women who have experienced cuts and/or tears.

What does the study involve?
Participants will be asked to give consent and complete a short background questionnaire (e.g. age and ethnicity).
For women there are two options for taking part, either a one-to-one discussion (interview) or a group discussion with other women affected by tears and cuts during childbirth (discussion group). Healthcare professionals will be able to take part in an interview. Taking part will be arranged at a date and time to suit the participant and can be done on the phone, Zoom, Teams,

or face-to-face. An interview will take about an hour. A discussion group will take between 1.5 and 2 hours. Interviews and discussion groups will be audio recorded and the recording used to make a written record of what is discussed.
Women and healthcare professionals will be asked about their experiences of cuts and/or tears during childbirth including, care following childbirth, what is important during recovery, and what might be important questions within a tool that doctors and midwives will use to help care for women affected by cuts and tears.

What are the possible benefits and risks of participating?
Participants may benefit from sharing their experiences and what participants tell us may help us to improve care for women affected by tears and cuts during childbirth. People who take part in an interview will be offered a £25 shopping voucher and those who take part in a discussion group will be offered a £40 shopping voucher each as a thank you for your time. The discussion groups take longer and so this is why those participants receive more.
There are no physical risks to taking part in this study. However, conversations in the interview /discussion group may be upsetting as they may relate to personal experiences. If this happens, the participants will be asked if they want to stop and have a short break, or if they want to stop completely. The researchers also give contact details of specialised organisations/professionals who can offer more support.

Where is the study run from?
Institute of Applied Health Research, University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
November 2023 to March 2025

Who is funding this study?
National Institute for Health and Care Research (NIHR) (grant reference: NIHR202869) (UK)

Who is the main contact?
Dr Victoria Hodgetts Morton, v.a.h.morton@bham.ac.uk

Study website
https://www.birmingham.ac.uk/research/applied-health/research/chapter-study.aspx

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Version 2.0 14.12.2023

Study information

Scientific Title
Exploring women's and healthcare professionals' views and experiences of childbirth related perineal trauma to inform the development of a wound management tool and care pathway (the Chapter qualitative sub-study): a qualitative study

Acronym
CHAPTER-Qual

Study objectives
This qualitative study forms a work package within the Chapter programme of research about 'optimising the care of women following childbirth related perineal trauma' (CRPT). The aim of this qualitative study is to explore women's and healthcare professionals' (HCPs) views and experiences of CRPT wound management and healing, to understand what they would want from a wound assessment tool (WAT) and related care pathway.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/12/2023, University of Birmingham Science, Technology, Engineering and Mathematical Ethics Review Committee (Edgbaston, Birmingham, B15 2TT, United Kingdom; +44 (0)121 414 3344; researchgovernance@contacts.bham.ac.uk), ref: ERN_23-0666

Study design
Qualitative research; qualitative cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Community

Study type(s)
Diagnostic, Quality of life, Screening, Treatment

Participant information sheet
See study outputs table

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

Interventions
Qualitative interviews and focus groups with women/people assigned female at birth who have experienced CRPT. Qualitative interviews with HCPs caring for patients with CRPT.

Data will include specific insight on the CRPT outcomes that are important to women and HCPs, what HCPs would want from a CRPT WAT, and what women and HCPs would want from a CRPT care pathway that includes a WAT. The results will contribute to the overall Chapter programme of research which aims to develop a CRPT wound assessment tool, care pathways, professional resources and guidelines for best practice, and patient resources.

Intervention Type
Other

Primary outcome measure
An understanding of the views and experiences of women who have experienced CRPT in the previous 12 months and the HCPs who currently provide CRPT care in the NHS. Data will be primarily qualitative (apart from a non-validated demographic questionnaire that will allow us to describe the sample of participants) in nature including interview and focus group audio files, transcripts, and field notes. Women will take part in a one-off interview lasting approximately 60 minutes or a focus group lasting approximately 2 hours. HCPs will take part in a one-off interview lasting approximately 60 minutes. Data will be collected and analysed over a 10-month period. Interviews and focus groups will be audio-recorded and transcribed. Qualitative data will be analysed using the Framework Method to facilitate a systematic exploration of themes.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/11/2023

Completion date
28/03/2025

Eligibility

Key inclusion criteria
Women:
1. Cis-women
2. Aged 18 years and above
3. Resident in the UK
4. Experienced CRPT in the last 12 months
5. Speak English or one of the six most spoken languages in healthcare settings in the West Midlands (e.g., Romanian, Urdu, Bengali, Polish, Arabic and/or Hindi)

Healthcare Professionals (HCPs):
1. NHS-registered HCPs
2. Aged 18 years and above
3. Currently involved in the provision of NHS care to women in the perinatal period who have experienced CRPT

Participant type(s)
Health professional, Service user

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Female

Target number of participants
Women: Up to 40; HCPs: Up to 25

Total final enrolment
2021

Key exclusion criteria
Women:
1. Transgender men
2. Inability to provide consent
3. Unable to participate in English or one of the six community languages

HCPs:
1. Inability to consent
2. Student HCP

Date of first enrolment
18/12/2023

Date of final enrolment
30/09/2024

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
University of Birmingham (Recruiting Site)
Birmingham Clinical Trials Unit
Institute of Applied Health Research
Public Health Building
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham

Sponsor details
Research Strategy and Services Central
Birmingham Research Park
University of Birmingham
97 Vincent Road
Edgbaston
Birmingham
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United Kingdom
B15 2SQ
+44 (0)7814 650003
researchgovernance@contacts.bham.ac.uk

Sponsor type
University/education

Website
http://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The anticipated publication outputs from the study will likely include:
1. A published study protocol paper
2. Study findings relating to the research question of this qualitative study
3. Qualitative study findings will contribute to the outputs of the Chapter programme of research including a core outcome set for trials investigating the care of women experiencing CRPT, wound assessment tool, and related professional guidelines.

Dissemination:
The qualitative study will contribute to the overall outputs and dissemination of the Chapter programme of research in the development of CRPT tools, professional resources and guidelines for best practice and patient resources. The dissemination strategy has been informed by the NIHR's dissemination and impact guidance. The researchers have identified a range of audiences to target for dissemination including women who have experienced CRPT and those who care for them.

Intention to publish date
30/04/2025

Individual participant data (IPD) sharing plan

Only the research team, the Sponsor, relevant regulatory authorities, and the funder will have access to the final study dataset that will comprise summary participant demographic data and pseudo-anonymised transcripts of interviews and focus groups where participants have given direct consent for their data to be used for future research. After publication of the main findings of the study, the research team will consider external requests to gain access to anonymised data, to be securely shared under the auspices of the Chief Investigator (Katie Morris: R.K.Morris@bham.ac.uk). The qualitative dataset will be preserved and available for this purpose for a minimum of 10 years following the end of the study. All requestors wishing to obtain study data will be asked to provide a brief research proposal including the objectives and timelines of the candidate project, intellectual property rights, and expectations for publications and citations. These details will form the basis of a Data Sharing Agreement between the University of Birmingham and the requestor, to clearly establish the responsibilities of each party. It is expected that requestors will, as a minimum, acknowledge the original research team and NIHR funding, and will consider co-authorship of any subsequent publications, if appropriate. Permission for anonymised data to be shared for the purpose of future academic research will be sought from all participants via the informed consent form.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	06/09/2023	14/03/2024	No	Yes
Participant information sheet	version 2.0	04/12/2023	14/03/2024	No	Yes
Protocol article		24/05/2024	03/12/2024	Yes	No
Protocol article	Qualitative study protocol	25/04/2025	28/04/2025	Yes	No