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Exploring the views of women and healthcare professionals on whether we can run a future study comparing two types of surgery for pelvic organ prolapse

Submission date
31/08/2023

Recruitment status
No longer recruiting

Registration date
16/10/2023

Overall study status
Completed

Last Edited
05/03/2025

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Many women, of all ages, experience pelvic floor disorders, which can cause lots of problems including worry and embarrassment. When the pelvic floor muscles work well, they hold the bladder, bowel, and vagina in the right position. When the muscles don't work well, a woman's organs can bulge or hang down into the vagina – this is called pelvic organ prolapse. 1 in 2 women experience pelvic organ prolapse in their lifetime. When the womb or neck of the womb hang into the vagina, this is called apical pelvic organ prolapse.
Women with apical pelvic organ prolapse can choose to do nothing, have a non-surgical vaginal support pessary, or have one of two different operations to help with their symptoms. Colpocleisis is an operation that pushes the apical pelvic organ prolapse back into the pelvis by closing or partially closing the vagina. Sacrospinous fixation is an operation where the top of the vagina is stitched to a ligament in the pelvis. Colpocleisis is a simpler surgery compared to sacrospinous fixation, and women are less likely to need further surgery. But having colpocleisis means that a woman can no longer have vaginal intercourse although they can engage in other types of intimacy. Some women might not be able to have sex even if they wanted to because of their bulge symptoms and so surgery might help them. There are important things for women and their healthcare professionals to consider when making treatment decisions.
Currently, we don't have strong evidence on which of the two operations is better. We don't know if women with apical pelvic organ prolapse, and healthcare professionals would accept a study comparing the two operations. This research (called the C-POP study) will explore if it is possible to do such a comparison study.

Who can participate?
1. Adult women (or those assigned female at birth), who have been diagnosed with apical pelvic organ prolapse, are eligible for both colpocleisis and sacrospinous fixation operations (or have already had one or both surgeries previously), able to provide consent to take part, and can speak English, Polish, Urdu, Punjabi or Welsh.
2. Adult healthcare professionals who work in UK complex uro-gynaecology centres who are

involved in the care of women with apical pelvic organ prolapse (either currently or within the last 5 years), able to provide consent to take part and can speak English.
3. Adult stakeholders including (but not limited to) women diagnosed with apical pelvic organ prolapse, health and social care professionals, policymakers, health economists, commissioners, representatives from third sector organisations (e.g., charities and advocacy groups) in the UK, able to consent to take part and can speak English.

What does the study involve?
We have designed a programme of research to explore if it is possible to undertake a study comparing the operations for apical pelvic organ prolapse. This research will include (1) discussions with about 60 women with apical pelvic organ prolapse who are eligible for an operation or have had the relevant surgery, and (2) discussions with about 30 healthcare professionals who care for women with apical pelvic organise prolapse, to understand their treatment decisions and preferences and why.
Women and clinicians will be identified from across the UK to ensure that we hear from those with different views and experiences. We will also ask clinicians to make a note of the number of women with apical pelvic organ prolapse that they see in their clinics over a six-month period. It is important to see how many women we might be able to recruit to the comparative study of the operations. Towards the end of C-POP, we will run a workshop with women, health and social care professionals, and other interested parties to talk about what we have found out and where we might go next with a comparison study.

What are the possible benefits and risks of participating?
We do not know whether women or healthcare professionals will benefit personally from taking part in this study, but the knowledge gained will inform future studies and treatment. This might lead to improved treatment options for women who have apical pelvic organ prolapse. Some people also appreciate an opportunity to talk about their experiences with somebody who is there to listen.
Taking part does not involve any treatments or tests, so there are no physical risks involved. However, the researchers recognise the sensitive nature of the topic and that women may find it difficult to talk about their experiences and healthcare professionals may also find talking about some experiences difficult or upsetting. If participants do experience discomfort at any point, their interviews can be paused or rescheduled or stopped altogether. Participants who become distressed will be signposted to support services if needed.

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?
April 2023 to December 2024

Who is funding this study?
The National Institute for Health and Care Research (UK)

Who is the main contact?
Dr Laura Jones, L.L.Jones@bham.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
317621

Central Portfolio Management System (CPMS)
53282

National Institute for Health and Care Research (NIHR)
151938

Protocol serial number
RG 22-160

Study information

Scientific Title
Exploring the feasibility and acceptability of conducting a study comparing the effectiveness of colpocleisis with sacrospinous fixation in women with pelvic organ prolapse (the C-POP study)

Acronym
C-POP

Study objectives
The overall aim of the study is to explore the feasibility and acceptability of conducting a study comparing the effectiveness of colpocleisis with sacrospinous fixation in women with apical pelvic organ prolapse. This aim will be addressed via five objectives and delivered via four work packages (WP1-4).

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 27/10/2023, North West - Preston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8364; +44 (0)207 104 8156; +44 (0) 207 104 8181; preston.rec@hra.nhs.uk), ref: 23/NW/0288

2. Approved 01/11/2023, Health Research Authority (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; preston.rec@hra.nhs.uk), ref: 23/NW/0288

Primary study design
Observational

Study design
Qualitative research; quantitative cross-sectional study

Study type(s)
Other, Screening, Treatment

Health condition(s) or problem(s) studied
Apical pelvic organ prolapse

Interventions
WP1: Qualitative interviews (women/people assigned female at birth with apical pelvic organ prolapse)

WP2: Qualitative interviews (with healthcare professionals caring for patients with apical pelvic organ prolapse)

WP3: Quantitative data collection of numbers of patients seen in a 6-month period in clinic who may be eligible for a potential future trial

WP4: Qualitative workshop/discussion group with stakeholders who might be involved in a future trial

Intervention Type
Other

Primary outcome(s)
1. An understanding of whether women with apical pelvic organ prolapse, the healthcare professionals who care for them, and other key stakeholders think that a future clinical trial comparing colpocleisis with sacrospinous fixation is feasible and acceptable. 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 audio files, transcripts, and field notes. Participants in WP1 and WP2 will take part in a one-off interview lasting approximately 60 minutes. Data will be collected and analysed over a 17-month period. Participants in WP4 will take part in a one-off 3-hour workshop. Data will be collected and analysed over a 7-month period. Interviews and discussion workshops will be audio-recorded and transcribed. Qualitative data will be analysed using a reflexive thematic analysis approach.

Key secondary outcome(s)
1. A quantitative assessment of the number of potential women who would be eligible for a future effectiveness trial. Local participating sites (an anticipated eight sites across England,

Wales and Scotland) will collect anonymised data (e.g., age, ethnicity, the first part of the woman' s postcode, and first language) on women meeting the eligibility criteria via scrutiny of referral letters and clinic notes. Anonymised data will be reported at least once a month for a total of 6 months. Data will be analysed descriptively and modelled to estimate the number of women across the UK likely to be eligible for recruitment into a future effectiveness trial.
2. A final programme theory providing clear guidance, informed by novel insight from women, healthcare professionals, and diverse stakeholders, on the feasibility of and key considerations for a future effectiveness trial. Aligned with the 2021 MRC/NIHR framework for Developing and Evaluating Complex Interventions data will be primarily qualitative (WP1, 2, 4) with additional quantitative cross-sectional information (WP3). Data will be collected and analysed over 17 months. Data will be analysed using reflexive thematic analysis (qualitative) and descriptive statistics (quantitative).

Completion date
31/12/2024

Eligibility

Key inclusion criteria
WP1:
1. Female (or assigned female at birth)
2. Age 18 years and above
3. Diagnosed with apical pelvic organ prolapse
4. Eligible for both colpocleisis and SSF procedures (or have already had one or both surgeries previously)
5. Ability to provide informed consent
6. Able to communicate in either English, Polish, Urdu, Punjabi or Welsh

WP2:
1. UK-based secondary care healthcare professionals involved in the care of women with apical pelvic organ prolapse (either currently or within the last 5 years)
2. Working in a UK complex uro-gynaecology centre
3. Able to give informed consent and speak English

WP3:
1. Females (or those assigned female at birth)
2. Age 18 years and above
3. Diagnosed with apical pelvic organ prolapse
4. Eligible for both colpocleisis and SSF procedures (i.e., no longer intend to have penetrative vaginal intercourse and who are willing to have either surgical procedure)

WP4:
1. Women as per WP1
2. Healthcare professionals as per WP2
3. Other stakeholders who might be involved in a future effectiveness trial, can converse in English, and who can give informed consent

Participant type(s)
Patient, Health professional, Carer, Service user, Other

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
99

Key exclusion criteria
WP1: There are no exclusion criteria
WP2: HCPs based in primary care
WP3: There are no exclusion criteria
WP4: There are no exclusion criteria

Date of first enrolment
01/11/2023

Date of final enrolment
05/12/2024

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
University of Birmingham
The University of Birmingham College of Medical and Dental Sciences
Institute of Applied Health Research
Birmingham
United Kingdom
B15 2TT

Study participating centre

Glasgow Caledonian University (Recruiting Site)
Nursing and Community Health
Cowcaddens Road
Glasgow
United Kingdom
G4 0BA

Study participating centre
University of Exeter (Recruiting Site)
University of Exeter Medical School
St Luke's Campus
Heavitree Road
Exeter
United Kingdom
EX1 2LU

Study participating centre
Birmingham Women's and Children's NHS Foundation Trust
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

Study participating centre
Singleton Hospital
Swansea
United Kingdom
SA11 3LX

Study participating centre
Greater Glasgow and Clyde
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road

Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
University Hospitals Plymouth NHS Trust
Derriford Hospital
Derriford Road
Derriford
Plymouth
United Kingdom
PL6 8DH

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Jessop Wing
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
The Shrewsbury and Telford Hospital NHS Trust
Mytton Oak Road
Shrewsbury
United Kingdom
SY3 8XQ

Study participating centre
Norfolk & Norwich University Hospital
Colney Lane

Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Lewisham and Greenwich NHS Trust
University Hospital Lewisham
Lewisham High Street
London
United Kingdom
SE13 6LH

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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 demographic questionnaires, audio recordings and transcripts of interviews and stakeholder events, and an anonymised database of potentially eligible women for a future trial. 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 (Dr Laura Jones; L.L.Jones@bham.ac.uk). The 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?
Protocol file	version 6.0	20/10/2023	03/11/2023	No	No
Protocol file	version 7.1	08/03/2024	04/06/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes