

Pelvic floor muscle exercises plus pessary for treatment of prolapse versus pelvic floor muscle exercises alone

Submission date 22/08/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/04/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 02/12/2025	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Pelvic organ prolapse is when the organs in a woman's pelvis descend into her vagina. Prolapse is very common, affecting 40% of women over the age of 50, and becomes more common as women age. It has distressing symptoms and negative effects on women's daily lives. One common treatment is pelvic floor muscle training (PFMT) where women are taught by a specialist physiotherapist or nurse how to exercise the muscles around their vagina. If this is done regularly, over time, it can reduce the symptoms of prolapse. A vaginal pessary is another prolapse treatment. The pessary, which is a plastic or silicone device (often shaped like a ring), is inserted into a woman's vagina to lift and hold the pelvic organs in place. UK guidelines recommend that women with prolapse consider PFMT treatment, and separately that they can consider pessary treatment. The guidelines suggest that research is needed to find out if adding a pessary to PFMT would be more effective than PFMT alone. Some physiotherapists in the UK have told us they combine these treatments in their practice, and they think it can be beneficial as it holds up the prolapse during PFMT, and this improves symptoms more. One study in a single hospital in Hong Kong has looked at this question, but the study had some limitations, so a larger study with stronger methods is needed. If combining these two treatments gives better results, this knowledge can be used to improve the lives of women with prolapse. It may also reduce NHS costs if women do not then need further prolapse treatment, such as surgery. This research aims to find out if wearing a vaginal pessary whilst exercising pelvic floor muscles is better at improving symptoms than exercising pelvic floor muscles without a pessary, for women with prolapse.

Who can participate?

Patients over the age of 18 who have been referred for PFMT for pelvic organ prolapse

What does the study involve?

Eligible patients who consent to taking part will be allocated at random, by a computer, to one of the two groups:

Group 1: Women in the PFMT and pessary group will have a 16-week PFMT programme and have a vaginal pessary. The pessary can be kept in or removed and re-inserted from time to time,

depending on preference

Group 2: Women in the PFMT group will have a 16-week PFMT programme.

The PFMT programme in both groups will involve attending 5 appointments, with at least 3 appointments being face to face, will be tailored to individuals and a daily pelvic floor muscle home exercise programme prescribed. Between each appointment, participants will be asked to complete a daily diary for one week to record pelvic floor exercises completed and pessary use (for those in Group 1). The study team will collect information on women's prolapse symptoms, their quality of life, whether they feel an improvement, how acceptable they found treatment, whether they had to have other prolapse treatment and whether their pelvic floor muscles are stronger. This information will be recorded after 6 and 12 months, and the 2

Groups of women will be compared to see which treatment is best and which offers the NHS the best value for money. Women in each group will be asked about their experiences. NHS staff will also be asked about their experiences of the study and the treatments. This will help to explain why the combined treatment did or did not work better for women.

What are the possible benefits and risks of participating?

The PFMT and pessary care patients receive may help them manage their pelvic organ prolapse and improve their quality of life. The information collected in this study may help improve the care of other women with pelvic organ prolapse in the future.

Where is the study run from?

The study is sponsored by Glasgow Caledonian University, based in Scotland, UK. The research is being carried out by teams of experienced doctors, nurses, physiotherapists and researchers working from a number of centres based throughout the UK.

When is the study starting and how long is it expected to run for?

May 2023 to April 2028. Recruitment to the study begins in May 2025 and is expected to run until October 2027.

Who is funding the study?

National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme (HTA), UK

Who is the main contact?

Dr Catriona O'Dolan (Trial Manager), PEPPY@gcu.ac.uk

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
338183

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

NIHR 160810, CPMS 60082

Study information

Scientific Title

Randomised controlled trial of the clinical and cost effectiveness of supervised pelvic floor muscle training plus vaginal pessary compared to supervised pelvic floor muscle training alone for management of pelvic organ prolapse

Acronym

PEPPY

Study objectives

Inserting a pessary may allow the pelvic floor muscles to be trained more effectively than pelvic floor muscle training alone by reducing the obstructing prolapse, leading to a better treatment outcome.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 13/02/2025, West of Scotland REC 4 (272 Bath Street, Glasgow, G2 4JR, United Kingdom; +44 (0)141 314 0213; WoSREC4@ggc.scot.nhs.uk), ref: 25/WS/0001

Study design

Pragmatic multicentre parallel-group superiority randomized controlled trial with an internal pilot and parallel process evaluation and economic evaluation

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pelvic organ prolapse

Interventions

Supervised pelvic floor muscle training (PFMT) is an effective non-surgical option for treating and preventing prolapse symptoms and is first-line management. A vaginal pessary, a support device inserted vaginally to hold the prolapsed organs in place, also provides symptom relief, and two-thirds of women try a pessary when offered.

The researchers will invite women with prolapse who are starting PFMT treatment to take part in the study. Women who agree to take part will have an equal chance of receiving PFMT alone (group 1) or receiving a pessary fitted (group 2). The researchers will collect information on women's prolapse symptoms, their quality of life, whether they feel an improvement, how acceptable they found treatment, whether they had to have other prolapse treatment and whether their pelvic floor muscles are stronger. The researchers will record this information

after 6 and 12 months, and compare the two groups of women to see which treatment is best and which offers the NHS the best value for money. They will ask women in each group about their experiences. They will also ask NHS staff about their experiences of the study and the treatments. This will help explain why the combined treatment did or did not work better for women.

Randomisation will be made using a secure web-based database and randomisation system developed and hosted by the Clinical Trials Unit (The Centre for Healthcare Randomised Trials (CHaRT) at the University of Aberdeen). Allocation will be minimised on age (<52/ ≥52 years), prolapse severity (POP-Q System: stage 0/1, stage 2, stage 3/4) and centre, ensuring balance between randomised groups in these factors.

Intervention Type

Mixed

Primary outcome(s)

Participant-reported symptoms of pelvic floor dysfunction measured using the Pelvic Floor Dysfunction Inventory-20 (PFDI-20) questionnaire at baseline, 6 and 12 months

Key secondary outcome(s)

1. Participant-reported condition-specific quality of life measured using the Pelvic Floor Impact Questionnaire-7 (PFIQ-7) at baseline, 6 and 12 months
2. Patient-reported generic quality of life measured using the general health-related quality of life questionnaire (EQ-5D-5L) at baseline, 6 and 12 months
3. Patient-reported improvement in condition measured using the Global Impression of Improvement (PGI-I) scale validated for prolapse at 6 and 12 months, compared to Patient Global Impression of Severity (PGI-S) at baseline
4. Patient-reported sexual function measured using ICIQ-Vaginal Symptoms module (ICIQ-VS), Sexual Matters subscale at baseline, 6 and 12 months
5. Patient-reported uptake of other prolapse treatment measured using items on unvalidated items on the participant questionnaire at baseline, 6 and 12 months
6. Patient-reported self-efficacy for Pelvic Floor Muscle Training measured using Pelvic Floor Muscle Exercise Self-efficacy Scale at baseline, 6 and 12 months
7. Patient-reported intervention adherence measured using the participant exercise and pessary use diary completed for 7 days at 4 timepoints during the intervention period, and 6 and 12-month questionnaires
8. Pelvic floor muscle strength and function measured using the Modified Oxford Scale (MOS), assessed by a clinician via digital palpation at baseline and 12 months
9. Prolapse severity measured by a clinician using a Pelvic Organ Prolapse Quantification (POP-Q) method at baseline and 12 months
10. Economic outcomes measured using Quality Adjusted Life Years (QALYS) calculated from the EQ-5D-5L at baseline, 6 and 12 months
11. Economic outcomes measured using the Healthcare utilisation questionnaire at baseline, 6 and 12 months

Completion date

30/04/2028

Eligibility

Key inclusion criteria

Women who have been referred for PFMT for prolapse, even if they have had previous prolapse treatment (PFMT, pessary, surgery) as currently PFMT would be offered for all such women. If a woman has significant vaginal tissue atrophy, participation in the trial would be delayed until after this has been treated.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

120 years

Sex

Female

Total final enrolment

0

Key exclusion criteria

1. Women for whom prolapse is not the main presenting problem
2. Women currently using a vaginal pessary (unless they discontinue for 1 month)
3. Women who are pregnant or less than 6 months postnatal
4. Women having active treatment for pelvic cancer
5. Women with severe vulval disease
6. Women who have cognitive impairment affecting capacity to give informed consent

Date of first enrolment

01/05/2025

Date of final enrolment

31/10/2026

Locations**Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre

South Tees Hospitals NHS Foundation Trust

James Cook University Hospital
Marton Road
Middlesbrough
England
TS4 3BW

Study participating centre

North West Glh Led by Manchester University NHS Foundation Trust

St Marys Hospital
Manchester Royal Infirmary
Oxford Road
Manchester
England
M13 9WL

Study participating centre

NHS Tayside

Kings Cross Health & Community Care Centre
Hospital Street
Dundee
Scotland
DD3 8EA

Study participating centre

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
England
NE1 4LP

Study participating centre

NHS Greater Glasgow and Clyde

J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road Glasgow
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Scotland
G12 0XH

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Addenbrookes Hospital
Cambridge
England
CB2 0AU

Study participating centre
NHS Grampian
Aberdeen Maternity Hospital
Aberdeen
Scotland
AB25 2ZL

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill
London
England
SE5 9RS

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
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NR4 7UY

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

Sponsor information

Organisation

Glasgow Caledonian University

ROR

<https://ror.org/03dvm1235>

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

The datasets generated during and/or analysed during the current study will be available upon request from from the Chief Investigator, Suzanne Hagen (s.hagen@gcu.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes