ISRCTN10890272 https://doi.org/10.1186/ISRCTN10890272

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

Submission date
22/08/2024

Recruitment status
Recruiting

Registration date
24/04/2025

Overall study status
Ongoing

Last Edited
09/05/2025

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

Study website
https://www.peppy-trial.co.uk/Public/Public/index.cshtml

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
338183

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 that 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information material can be found at https://www.peppy-trial.co.uk/Public/Public/index.cshtml

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

Secondary outcome measures
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

Overall study start date
17/05/2023

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
552 women (276 per group)

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
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
-
United Kingdom
-

Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/03dvm1235

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
Planned publication in a high-impact peer-reviewed journal. A lay summary of the findings will be sent to participants and disseminated to healthcare professionals involved in the trial, centre PIs and staff members.

Intention to publish date
31/03/2029

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