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A pilot and feasibility study comparing vaginal continence devices and pelvic floor muscle training (PFMT) versus PFMT only for female stress urinary incontinence

Submission date
12/05/2025

Recruitment status
No longer recruiting

Registration date
13/05/2025

Overall study status
Ongoing

Last Edited
04/02/2026

Condition category
Urological and Genital Diseases

[_] 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
Urinary incontinence (UI) is a common and distressing condition that affects over 6 million women in the UK who are over 40 years old. It can cause embarrassment, low self-esteem, social isolation, and reduced productivity. The first treatment option is pelvic floor muscle training (PFMT), but one in three women still need surgery. Vaginal continence devices (VCDs), which are worn inside the vagina, help support the bladder to achieve continence. Guidelines suggest using VCDs when PFMT alone is not effective. Combining VCDs with PFMT might be more effective than PFMT alone, improving quality of life and reducing the need for surgery. However, there is little evidence about the benefits, risks, and cost-effectiveness of VCDs. This study aims to provide such evidence through a preliminary study to ensure a larger clinical trial is feasible.

Who can participate?
Women with urinary incontinence from four to six hospitals in the UK will be invited to participate.

What does the study involve?
Participants will be divided into two groups: one group will receive PFMT alone, and the other group will receive PFMT combined with VCDs. Each participant has an equal chance of being in either group. Information on symptoms and quality of life will be collected before and after treatment at 3 and 6 months.

What are the possible benefits and risks of participating?
Participants may not benefit personally from taking part. By taking part, however, they may be helping us to inform the treatment of future women with stress urinary incontinence. The results of this study will help us plan a larger study, which in turn will help plan effective services offered by the NHS in the future. We do not think that there are any possible disadvantages to participants. All procedures and techniques are already being used in the NHS to treat patients with stress urinary incontinence. Taking part in the FEEL-GOOD study will help us assess these

procedures and should not involve any additional risk to you.
Whichever group participants are in, their treatments will be offered by competent and trained clinicians.
It is important to remember that there are risks related with every treatment. Participants will be informed of any potential risks as part of their routine clinical care. Steps are always taken to ensure that these risks are kept to a minimum. The known side effects associated with pelvic floor muscle training and vaginal continence devices (which are not related to taking part in the study) are:
• pelvic floor muscle discomfort,
• low back pain,
• tummy pain/ discomfort,
• vaginal pain/ discomfort/ irritation,
• the vaginal device coming out on its own,
• vaginal discharge,
• unexpected vaginal bleeding or bleeding when removing the device
• urinary or vaginal infections,
• unable to pass urine which requires catheter in the bladder
If it is the wrong size, the vaginal continence device might fall out. If this happens participants can try a different size or type of device

Where is the study run from?
University of Aberdeen (UK)

When is the study starting and how long is it expected to run for?
April 2025 to May 2026

Who is funding the study?
Chief Scientist Office (UK)

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
334827

Central Portfolio Management System (CPMS)
68464

Protocol serial number
HIPS/23/30

Study information

Scientific Title
FEEL-GOOD study: Female Empowerment through Enhanced Living: a comparison of vaGinal continence devices and pelvic flOOr muscle training (PFMT) versus PFMT only for female stress urinary incontinence: a feasibility and pilot StuDy. Stage 2

Study objectives
The aim of the study is to determine the feasibility to deliver a definitive RCT comparing the clinical and cost-effectiveness of Vaginal Continence Devices (VCDs) and Pelvic Floor Muscle Training (PMFT) compared to PFMT only in the conservative management of stress-predominant urinary incontinence (SUI) in women. The objectives include: (i) To establish the facilitators and barriers for recruitment (and specifically randomisation) for women and healthcare providers for a definitive RCT. (ii) To establish the relevant outcomes for a definitive RCT from women's and healthcare professionals' (HCPs) perspectives. (iii) To establish a reliable sample size and recruitment projection for a definitive RCT, the adherence of participants to the proposed treatments, response rates to questionnaires, and loss to follow-up rate.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/03/2025, South Central - Hampshire A Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 1048135; hampshirea.rec@hra.nhs.uk), ref: 25/SC/0077

Study design

Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Female stress urinary incontinence

Interventions
Women will be provided with information about the study, and if the agree, they will be asked to sign a consent form confirming this and to complete a baseline questionnaire that asks about their quality of life, their symptoms, the impact of these symptoms on their daily life. A member of the research team will complete a case report form with some baseline information about the participant. Then, the participant will be randomised to one of two groups (i) vaginal continence devices and supervised pelvic floor muscle training and (ii) supervised pelvic floor muscle training alone. Whichever group they are in, they will be added to the waiting list for pelvic floor muscle training. In the group randomised to have vaginal continence devices, the clinician will request the participant's GP to prescribe the VCD. This will be prescribed and/or they will start using their VCDs at the time (or as close as practically possible) to their first physiotherapy appointment.

We will follow women up with questionnaires (which they can complete by post or electronically) after they have been in the study for 3 and 6 months. These questionnaires will contain similar questions to those they completed at baseline, and also ask about any adverse events they have experienced since joining the study.

At at least one of the sites, we will seek to audio-record the initial consultations between HCPs and potential participants where trial participation is discussed. We will ask participants if they want to take part in an interview about their experience in the study, including any motivation to take part. We will also invite women who decide not to take part in the main study if they would like to be interviewed about their decision not to take part in the study.

Intervention Type
Mixed

Primary outcome(s)
Feasibility of participant recruitment within the proposed time scale (I.e. achieve >/= 80% of the target recruitment within 6 months)

Key secondary outcome(s))
1. Adherence to VCD use is measured using clinician-reported adherence logs and participant self-report diaries at baseline, 3 months, and 6 months
2. Adherence to PFMT is measured using participant self-reported attendance logs to individualised planned program appointments at baseline, 3 months, and 6 months
3. Retention rate is measured using study records of participant completion status at 6 months
4. Rates of missing data are measured using case report forms and electronic data capture system audit logs at baseline, 3 months, and 6 months
5. Patient-reported success rates of VCDs are measured using the Patient Global Impression of

Improvement (PGI-I) scale at 3 months and 6 months
6. Adverse events related to VCDs are measured using adverse event reporting forms and participant interviews at baseline, 3 months, and 6 months
7. Use of self-funded VCDs is measured using participant self-report questionnaires at baseline, 3 months, and 6 months
8. Waiting times for physiotherapy are measured using clinic administrative records and participant self-report at baseline and 3 months
9. Recruitment projection reliability is measured using screening and enrolment logs compared to projected targets at monthly intervals throughout the recruitment period
10. Refinement of pre-defined progression criteria for a potential future RCT is measured using feasibility study outcomes and stakeholder feedback at study end (6 months)

Completion date
30/11/2026

Eligibility

Key inclusion criteria
1. Women aged 18 years or over with clinically diagnosed stress predominant UI and deemed by their clinician to be suitable for VCDs, and willing to self-manage VCDs.
2. Inclusion criteria for the health care professionals invited to take part in a focus group are: clinicians, physiotherapists and specialist nurses in the pilot sites who are involved in the care of women with stress predominant SUI.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Vaginal prolapse more than POP-Q Stage 2a (POP-Q= Pelvic Organ Prolapse Quantification score)
2. Neurogenic bladder
3. Urgency predominant UI

4. Evidence of active pelvic or vaginal infection
5. Vaginal ulceration
6. Allergy to silicone or rubber
7. Known vaginal cancer
8. Current pregnancy or within 6 months postpartum
9. Completed full course of supervised Pelvic Floor Muscle Training and has been discharged by the physiotherapist within the last two years
10. Contraindications to vaginal devices:
10.1. Current vaginal infection or irritation
10.2. History of Toxic Shock Syndrome
10.3. Pelvic surgery in the last 6 months
10.4. Ongoing therapy for pelvic malignancy
10.5. Current urinary infection
10.6. Problems with manual dexterity which could cause insertion or removal issues
11. Women lacking capacity to consent
12. Inability to understand the PIL, consent and/or questionnaires in English

Date of first enrolment
06/05/2025

Date of final enrolment
30/01/2026

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
Scotland
AB15 6RE

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
England
LS9 7TF

Study participating centre
Countess of Chester Hospital
Countess of Chester Health Park
Liverpool Road
Chester
England
CH2 1UL

Study participating centre
Huddersfield Royal Infirmary
Calderdale & Huddersfield NHS Trust
Acre Street
Huddersfield
England
HD3 3EA

Study participating centre
St Mary's Hospital
Manchester University NHS Foundation Trust
Oxford Road
Manchester
England
M13 9WL

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
Scotland
G51 4TF

Sponsor information

Organisation
University of Aberdeen

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	10/04/2025	13/05/2025	No	Yes
Protocol file	version 4	18/09/2025	04/02/2026	No	No