

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 13/05/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 13/05/2025	<b>Condition category</b> 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

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

### Contact name

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### Type(s)

Public, Scientific

**Contact name**

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**Contact details**

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number**

334827

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

CPMS 68464, 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 (PFMT) 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

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Other

## **Study type(s)**

Treatment

## **Participant information sheet**

See study outputs table

## **Health condition(s) or problem(s) studied**

Female stress urinary incontinence

## **Interventions**

Women will be provided with information about the study, and if they 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 measure**

Feasibility of participant recruitment within the proposed time scale (I.e. achieve  $\geq 80\%$  of the target recruitment within 6 months)

### **Secondary outcome measures**

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)

### **Overall study start date**

01/04/2025

### **Completion date**

31/05/2026

## **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

### **Age group**

Adult

### **Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

Planned Sample Size: 74; UK Sample Size: 74

**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**

07/10/2025

**Locations****Countries of recruitment**

United Kingdom

**Study participating centre****NHS Grampian**

Summerfield House

2 Eday Road

Aberdeen

United Kingdom

AB15 6RE

**Study participating centre****Leeds Teaching Hospitals NHS Trust**

St. James's University Hospital  
Beckett Street  
Leeds  
United Kingdom  
LS9 7TF

**Study participating centre****Countess of Chester Hospital**

Countess of Chester Health Park  
Liverpool Road  
Chester  
United Kingdom  
CH2 1UL

**Study participating centre****Huddersfield Royal Infirmary**

Calderdale & Huddersfield NHS Trust  
Acre Street  
Huddersfield  
United Kingdom  
HD3 3EA

**Study participating centre****St Mary's Hospital**

Manchester University NHS Foundation Trust  
Oxford Road  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre****Queen Elizabeth University Hospital**

1345 Govan Road  
Glasgow  
United Kingdom  
G51 4TF

**Sponsor information**

**Organisation**

University of Aberdeen

**Sponsor details**

Research Governance Office, First Floor, Health Sciences Building, Foresterhill  
Aberdeen  
Scotland  
United Kingdom  
AB25 2ZD  
+44 1224437221  
researchgovernance@abdn.ac.uk

**Sponsor type**

University/education

**Website**

<https://www.abdn.ac.uk>

**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**

Publication and dissemination plan



Planned publication in a peer-reviewed journal

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

The current data sharing plans for this study are unknown and will be available at a later date

**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?
<a href="#">Participant information sheet</a>	version 3	10/04/2025	13/05/2025	No	Yes