

# A feasibility study for an RCT of a pelvic floor muscle training intervention for pelvic organ prolapse

**Submission date**  
06/09/2005

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
12/09/2005

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
21/10/2009

**Condition category**  
Urological and Genital Diseases

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Suzanne Hagen

### Contact details

NMAHP Reserach Unit  
Govan Mbeki Health Building  
Glasgow Caledonian University  
City Campus  
Cowcaddens Road  
Glasgow  
United Kingdom  
G4 0BA  
+44 (0)141 331 8104  
s.hagen@gcal.ac.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00158626

## Secondary identifying numbers

CZH/4/95; NRR N0470119684

# Study information

## Scientific Title

## Acronym

POPPY (Pelvic Organ Prolapse Physiotherapy)

## Study objectives

To address the feasibility of undertaking a multi-centre randomised controlled trial of the effectiveness of a pelvic floor muscle training (PFMT) intervention for women with pelvic organ prolapse. The feasibility of all aspects of such a trial will be assessed, and pilot data will be collected which will allow sample size calculations to be refined. Ultimately, a multi-centred trial would aim to establish if PFMT is better than standardised management for reducing prolapse specific symptoms, prolapse severity, the need for surgical prolapse repair and the costs associated with the condition.

Added 21/10/09:

This feasibility study lead to a full trial, details may be viewed at <http://www.controlled-trials.com/ISRCTN35911035>

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Added 07/10/09:

1. Southern General Hospital Ethics Committee approved 25 September 2002 (ref: EC/02/S/115)
2. Grampian Research Ethics Committee approved 11 March 2003 (ref: 02/0243)

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Pelvic organ prolapse

### **Interventions**

Intervention arm:

Women receive an individualised programme of PFMT delivered by a physiotherapist via 5 sessions of physiotherapy over a 16 week period. This programme includes pelvic muscle assessment, teaching, prescription of pelvic floor exercises and lifestyle advice.

Control arm:

Women receive an information leaflet containing lifestyle advice.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

Prolapse related symptoms and associated quality of life

### **Secondary outcome measures**

POP-Q, days of symptoms, SF12

### **Overall study start date**

22/09/2003

### **Completion date**

31/08/2005

## **Eligibility**

### **Key inclusion criteria**

Women with previously untreated stage I or stage II pelvic organ prolapse attending gynaecology, urogynaecology and prolapse specific out-patient clinics at South Glasgow University Hospitals NHS Trust and Grampian University Hospitals NHS Trust

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Female

### **Target number of participants**

**Key exclusion criteria**

Women who have had previous surgical or conservative treatment for prolapse (e.g. pessary management or previous pelvic floor muscle training) or women not considered suitable for physiotherapy treatment

**Date of first enrolment**

22/09/2003

**Date of final enrolment**

31/08/2005

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

Scotland

United Kingdom

**Study participating centre**

**NMAHP Reserach Unit**

Glasgow

United Kingdom

G4 0BA

**Sponsor information****Organisation**

Glasgow Caledonian University (UK)

**Sponsor details**

c/o Professor Catherine Niven

NMAHP Reserach Unit

Govan Mbeki Health Building

Glasgow Caledonian University

City Campus

Cowcaddens Road

Glasgow

Scotland

United Kingdom

G4 0BA

+44 (0)141 331 8103

k.niven@gcal.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.gcal.ac.uk>

**ROR**

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

## Funder(s)

**Funder type**

Government

**Funder Name**

Chief Scientist Office, Scottish Executive (UK) (ref: CZH/4/95)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

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

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2009		Yes	No