

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?
Results article	results	01/01/2009		Yes	No