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

| Submission date | Recruitment status No longer recruiting | Prospectively registeredProtocol | | |
|-------------------------------|--|---|--|--|
| 06/09/2005 | | | | |
| Registration date | Overall study status | Statistical analysis plan | | |
| 12/09/2005 | Completed | [X] Results | | |
| Last Edited 21/10/2009 | Condition category Urological and Genital Diseases | Individual participant data | | |
| Z 1/ 10/2003 | Orotogical and deflical Diseases | | | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT) NCT00158626

Protocol serial number 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

Study type(s)

Treatment

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(s)

Prolapse related symptoms and associated quality of life

Key secondary outcome(s))

POP-Q, days of symptoms, SF12

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

Study participating centre NMAHP Reserach Unit Glasgow United Kingdom G4 0BA

Sponsor information

Organisation

Glasgow Caledonian University (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

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 |
| Participant information sheet | Participant information sheet | 11/11/2025 11/11/2025 | No | Yes |