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A multi-centre randomised controlled trial of a pelvic floor muscle training intervention for women with pelvic organ prolapse

Submission date
03/11/2006

Recruitment status
No longer recruiting

Registration date
04/01/2007

Overall study status
Completed

Last Edited
03/09/2014

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims.
Pelvic organ prolapse in women is mostly treated by surgery, ring pessary or by exercises. At present, there is little research to show whether or not exercises can improve the symptoms of prolapse. This study aims to find out the effect of exercises on prolapse and the symptoms associated with it.

Who can participate?
Potential participants will be new attendees at outpatient gynaecology clinics presenting with symptoms of prolapse. Women will be asked to take part in the study if prolapse of stage 1, 2 or 3 is confirmed by their gynaecologist on vaginal examination at their clinic appointment.

What does the study involve?
Eligible and consenting women will be placed at random into either Study Group 1 or Study Group 2. Those in Study Group 1 will be taught exercises and given an advice leaflet on things to do which may help reduce prolapse symptoms. Those in Study Group 2 will also be given an advice leaflet about things to do that might help reduce prolapse symptoms but will not be taught exercises. Both groups will be asked at the start of the study to complete a booklet of questions about the problems caused by their prolapse and how this affects their life.
Women in Study Group 1 will see a physiotherapist at the hospital five times over a 16 week period. The physiotherapist will examine them, teach them the correct way to exercise and give instructions on how often to exercise between visits. Other help and advice will be given as needed. Women in Study Group 2 will be sent an information leaflet. This will contain advice on how prolapse symptoms could be reduced. Women in both groups will return to see their doctor at the hospital 6 months after starting the study. The doctor will measure the prolapse and talk about any further treatment that may be needed. A follow-up booklet of questions will be posted at six months (around the time of returning to see the doctor) and at 12 months. Answers will help us measure how things have changed over time.

What are the possible benefits and risks of participating?
Study Group 1 participants will gain an increased understanding of the prolapse condition and

the function of the pelvic floor muscles, teaching of pelvic floor exercises by an experienced physiotherapist, potential improvement in prolapse symptoms and severity and potential avoidance of need for further treatment- in particular surgery. Study Group 2 participants will get access to lifestyle advice leaflet giving general prolapse-specific advice.
No adverse effects of the intervention are expected. However, if done incorrectly, the pelvic floor muscle exercises may make prolapse worse. To avoid this, specialist women's health physiotherapists (who will receive training on delivering a standardised intervention) will be used.

Where is the study run from?
The Nursing, Midwifery and Allied Health Professions Research Unit, Health Services Research Unit (Aberdeen), NHS Greater Glasgow & Clyde, NHS Grampian and the Centre for Healthcare Randomised Trials

When is the study starting and how long is it expected to run for?
The study is starting in April 2007 and is expected to run for 3 years. The total duration for each woman will be 12 months.

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

Who is the main contact?
Professor Suzanne Hagen
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Study website
http://www.charttrials.abdn.ac.uk/poppy/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00476892

Secondary identifying numbers
CZH/4/377

Study information

Scientific Title

Acronym
POPPY (Pelvic Organ Prolapse PhysiotherapY)

Study objectives
The aim of this study is to determine the effectiveness and cost-effectiveness of pelvic floor muscle training in the management of pelvic organ prolapse in women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Multi-Centre Research Ethics Committee for Scotland on the 19th March 2007 (ref: 07/MRE10/4).

Study design
A multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: https://www.charttrials.abdn.ac.uk/poppy/patientInfo.php

Health condition(s) or problem(s) studied
Pelvic organ prolapse

Interventions

Intervention Group:
The PFMT intervention to be evaluated was tested in the feasibility study and is based on the best current evidence for pelvic floor muscle strengthening, treatment of urinary stress incontinence and conservative prolapse management. It consists of five outpatient appointments (weeks zero, two, six, 11 and 16) with a local trial physiotherapist at a trial centre. The first of these appointments will be arranged by the trial physiotherapist immediately after randomisation, and appointment details sent to the woman by post.

At the first appointment a standardised history is taken from the woman, anatomy and function of the pelvic floor muscles are taught, and types of prolapse described, using diagrams and a model pelvis. Women are taught how to contract the muscles, and also how to contract and hold prior to an event that increases intra-abdominal pressure ('the Knack'). Remaining appointment dates will be scheduled.

Pelvic floor muscles are assessed by vaginal examination and recorded on a dedicated form at each appointment. This determines the content of a single set of exercises for each woman. Three sets of exercises are recommended daily. Women use an exercise diary to record compliance. Tailored advice is given on ways of reducing intra-abdominal pressure, e.g. advice on weight loss, chronic cough, heavy lifting and general exercise. The lifestyle advice leaflet given to the control group women (see below) will also be provided.

Control Group:
Women allocated to the control group will be sent a lifestyle advice leaflet only, and will have no planned contact with the centre until their consultant review appointment at six months. The leaflet gives instructions on seeking advice where appropriate about weight loss, constipation, and avoidance of heavy lifting, coughing and high impact exercise, with a view to minimising increases in intra-abdominal pressure, which may cause prolapse to worsen.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Prolapse symptom score (questions developed in feasibility study and undergoing validation)
2. The primary economic outcome measures of cost effectiveness are:
2.1. Use of health services,
2.2. Average number of days of prolapse symptoms, and
2.3. Further prolapse treatment needed/received

Secondary outcome measures
Secondary outcomes include:
1. Prolapse-related quality of life (single item scored zero to ten)
2. Prolapse severity (POP-Q)
3. Need for further prolapse treatment including a pessary or surgery

Other outcomes include:
1. Lifestyle changes
2. Urinary symptoms (International Consultation on Incontinence Questionnaire [ICIQ] short-form)

3. Bowel symptoms (ICIQ bowel symptoms module)
4. Sexual symptoms (Prolapse Incontinence Sexual Questionnaire [PISQ])
5. General health status (Short Form health survey [SF-12])

Overall study start date
01/01/2007

Completion date
31/12/2009

Eligibility

Key inclusion criteria
Potential participants will be new attendees at outpatient gynaecology clinics presenting with symptoms of prolapse. At their clinic appointment, type and stage of prolapse will be confirmed by their gynaecologist using the Pevic Organ Prolapse Quantification (POP-Q) grading system. Women with any type of prolapse will be included:
1. Anterior vaginal wall prolapse (urethrocele, cystocele, paravaginal defect)
2. Uterine/cervical prolapse
3. Vaginal vault (after hysterectomy) prolapse
4. Posterior vaginal wall prolapse (enterocele, rectocele, perineal deficiency)

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
556

Key exclusion criteria
1. Stage four prolapse
2. Previous treatment for prolapse (surgery or formal instruction in pelvic floor muscle training [PFMT])
3. Unable to comply with PFMT treatment
4. Local atrophy
5. Pregnant
6. Unable to give informed consent

Date of first enrolment
01/01/2007

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
New Zealand

Scotland

United Kingdom

Study participating centre
Glasgow Caledonian Universtiy
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Sponsor information

Organisation
Glasgow Caledonian University (UK)

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Sponsor type
University/education

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ROR
https://ror.org/03dvm1235

Funder(s)

Funder type
Government

Funder Name

Chief Scientist Office (CSO) (Scotland) (ref: CZH/4/377)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

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	15/11/2013		Yes	No
Results article	results	01/03/2014		Yes	No