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A pilot study to evaluate the effectiveness of dynamic lumbo-pelvic stability training as a treatment strategy for women with stress incontinence: a randomised controlled trial

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
29/05/2014

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0544139651

Study information

Scientific Title

Study objectives
Is a program of dynamic lumbo-stability training (modified Pilates) an effective strategy to reduce symptoms in women with stress urinary incontinence?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

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

Health condition(s) or problem(s) studied
Urological and Genital Diseases: Stress incontinence

Interventions
1. Control Group will be taught standard static pelvic floor training exercises
2. Intervention Group will learn dynamic lumbo-pelvic stability training exercises (modified Pilates method)

Accessible participants will be informed about the research trial using a research subject information sheet submitted in a question and answer format.

Women not wishing to take part in the trial will be offered standard physiotherapy treatment through the normal patient booking procedures.

Consenting women will complete the Kings Health Questionnaire, a validated and reliable tool to measure stress incontinence symptoms and quality of life and attend the physiotherapy department for a full physiotherapy urogynaecological assessment with the chief investigator or a research assistant. A second, senior, postgraduate qualified physiotherapist will attend the urogynaecological assessment to perform a vaginal examination of the pelvic floor muscles and assessment of muscle action (strength and endurance) as is standard physiotherapy procedure. During this vaginal assessment all women will be taught correct pelvic floor muscle contraction, shown the extent of the muscle, cuing techniques will be used to maximise muscle recruitment. Fast contractions and slow contractions without accessory muscles or breath holding will be facilitated. The patient will be instructed how to self-examine the pelvic floor. Patients' questions about how to activate the pelvic floor will be answered.

After these cuing/teaching activities a final grade will be given for strength and endurance. The grading will be carried out using a reliable and validated method. The measurements will be recorded and kept securely but the chief investigator will not view the measurements until the analysis procedure at the end of the trial.

Those scoring Grade 0 ,1 or 2 on pelvic floor assessment will be unable to take part in the trial and will be offered the appropriate physiotherapy treatment of biofeedback/stimulation. Those scoring Grade 3, 4, or 5 on the Modified Oxford Scale will be invited to continue to randomisation.

Eligible, consenting women will be randomly allocated by computer-generated block allocation method to the control or intervention group. Both groups will be offered six physiotherapy training sessions over a 12-week period with the expectation that the patient will practice the training programme at home between training sessions. Training sessions will take place in the physiotherapy outpatient department. All training sessions will be conducted by the chief investigator or second researcher who have postgraduate training in both the training strategies. The control group will be taught standard static pelvic floor training exercises; the intervention group will learn dynamic lumbo-pelvic stability training exercises (modified Pilates method). Protocols describe the exact detail of the training methods to be used.

At 13 weeks the participants will be asked to complete a second Kings Health Questionnaire. The same physiotherapist who performed the baseline assessment of pelvic floor muscle action will complete a second vaginal examination of the pelvic floor muscles. The assessor will be masked to group allocation and participants will be advised not to discuss with the assessor the exercise program that they have been following.

Data collected will be anonymised and kept securely at all times. Results will be analysed on an intention-to-treat basis.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date
19/12/2003

Completion date
18/12/2006

Eligibility

Key inclusion criteria
Participants will be recruited from January 2004 to June 2004 subject to Local Research Ethics Committee approval. Women over 16 years referred to the Addenbrookes Hospital physiotherapy department with stress urinary incontinence will be invited to participate in the trial.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
19/12/2003

Date of final enrolment
18/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Physiotherapy dept
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrookes (UK)

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