

# 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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/05/2014	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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  
London  
United Kingdom  
SW1A 2NL

**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