

Modified Pilates as an adjunct treatment for urinary incontinence

Submission date 12/12/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/12/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/07/2018	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Berthold Lausen

Contact details
University of Essex
Wivenhoe Park
Colchester
United Kingdom
CO4 3SQ
-
blausen@essex.ac.uk

Additional identifiers

Protocol serial number
12421

Study information

Scientific Title
Modified Pilates as an adjunct to standard physiotherapy care for urinary incontinence: a pilot study

Study objectives

Urinary incontinence is a distressing condition affecting more than 5 million women in the UK. Treatment usually involves pelvic floor exercises (pelvic floor muscles are those that control continence mechanisms). More recently Modified Pilates (MP) has been suggested as an additional means of improving symptoms and the quality of life of sufferers. MP is a mind-body technique involving slow controlled movements focusing on posture and breathing.

However, no research has evaluated the effectiveness of MP in a group setting for patients suffering from urinary incontinence.

To properly evaluate the effectiveness of MP a large randomised clinical trial will be necessary. In preparation we are planning a smaller (pilot) study to provide some early information, and help design the larger study.

In the pilot study 100 women will be randomly assigned to two groups:

Group 1 will receive pelvic floor exercises and lifestyle advice only

Group 2 will attend a 6 week course of MP classes in addition to receiving pelvic floor exercises and lifestyle advice

Participants in the two groups will be matched according to their height/weight ratio and severity of symptoms.

Both groups will be assessed at the start of the study, when they have completed their treatment, and 5 months later.

Measures will include severity of symptoms, frequency of incontinence, quality of life, self-and number of individual treatment sessions. Some participants will also be interviewed about their experiences of the treatments to explore perceived benefits and limitations.

Findings will inform design of the larger trial, provide information about the feasibility of offering MP to this patient group, and produce preliminary findings about its effectiveness. Findings will be sent to patient and professional interest groups and to service commissioners.

Ethics approval required

Old ethics approval format

Ethics approval(s)

First MREC, 18/07/2012, ref: 12/EE/0241

Study design

Randomised interventional study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Renal and Urogenital Disease

Interventions

Modified Pilates (MP)

Treatment usually involves pelvic floor exercises (pelvic floor muscles are those that control continence mechanisms). The intervention group receives pelvic floor exercises and modified pilates (MP). MP is a mind-body technique involving slow controlled movements focusing on posture and breathing.

Intervention Type

Behavioural

Primary outcome(s)

1. Symptom severity index (SSI)
2. Incontinence related quality of life
3. Rosenberg self esteem index

Key secondary outcome(s)

No secondary outcome measures

Completion date

04/02/2014

Eligibility

Key inclusion criteria

1. Women aged 18 and over
2. Diagnosed with stress, urge, or mixed UI (defined by Abrams et al [25])
3. Medically fit to perform physical activity

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Aged under 18 years
2. No UI diagnosis
3. Unable to actively contract pelvic floor muscles
4. Suffering faecal incontinence
5. Pregnant
6. History of pelvic malignancy

7. Received gynaecological surgery in previous 6 months
8. Given birth in previous 6 months
9. Disease of Central Nervous System (e.g. Multiple Sclerosis, Cerebrovascular accident)
10. Unable to walk without walking aid
11. Having insufficient mental capacity to complete questionnaires and/or follow exercise instructions (according to the principles of the Mental Capacity Act 2005)

Date of first enrolment

05/10/2012

Date of final enrolment

04/02/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Essex

Colchester

United Kingdom

CO4 3SQ

Sponsor information

Organisation

Colchester Hospital University NHS Foundation Trust (UK)

Funder(s)

Funder type

Government

Funder Name

NIHR Research for Patient Benefit Programme (UK) ref: PB-PG-1010-23220

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	12/01/2018		Yes	No