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Modified Pilates as an adjunct treatment for urinary incontinence

Submission date	Recruitment status	[_] Prospectively registered
12/12/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/12/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/07/2018	Urological and Genital Diseases	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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

Secondary outcome measures
No secondary outcome measures

Overall study start date
05/10/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
UK Sample Size: 100

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
England

United Kingdom

Study participating centre
University of Essex
Colchester
United Kingdom
CO4 3SQ

Sponsor information

Organisation
Colchester Hospital University NHS Foundation Trust (UK)

Sponsor details
Colchester General Hospital
Colchester District General Hospital
Charter Way Turner Road
Colchester
England
United Kingdom
CO4 5JL

Sponsor type
Hospital/treatment centre

Website
http://www.colchesterhospital.nhs.uk/

Funder(s)

Funder type
Government

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

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	12/01/2018		Yes	No