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Re-education of the pelvic floor in women with urinary stress incontinence

Submission date	Recruitment status	[_] Prospectively registered
30/09/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2004	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/09/2015	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Libby Whelpton

Contact details
Willesden Community Hospital
Harlesden Road
London
United Kingdom
NW10 3RY
+44 (0)20 8451 8281 (ans)
abc@email.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
M0001127331

Study information

Scientific Title
Re-education of the pelvic floor in women with urinary stress incontinence

Study objectives
One in four women suffer from Urinary Stress Incontinence (USI). The literature search suggests there is evidence from clinical experience and from research into the management of low back pain that retraining of the transversus abdominis muscle using real time ultrasound can facilitate correct tonic activity of the pelvic floor muscles (Richardson et al, 1999 and Critchely et al 2002). Studies so far of facilitation of the pelvic floor using RTUS have so far only been tested in healthy adult females (Sapsford, 2001).

The aim of this study is to evaluate if by using Real Time Ultra Sound biofeedback (RTUS), a non-invasive technique, patients with urinary stress incontinence can learn more quickly how to co-contract the Transversus Abdominis muscle (TrA) and Pelvic Floor Muscles (PFM) in order to rehabilitate the pelvic floor and thereby reduce or eradicate the distressful symptoms of leakage. If RTUS can shorten the number of sessions required for patients to learn correctly how to co-contract the pelvic floor muscles this would enable physiotherapists to see a greater number of patients.

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: Urinary incontinence

Interventions

Participants will be randomised into two groups, one with RTUS over the abdominal muscles to facilitate instructions to activate co-contraction of the pelvic floor muscles, and the other without real time ultra sound biofeedback. Assessment parameters include a leakage diary, a one hour pad test, and subjective evaluation of life impact questionnaire (Kings Health Questionnaire). Each group will be assessed after 12 weeks training.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The study is to evaluate if by using RTUS, patients with urinary stress incontinence can learn more quickly how to co-contract the Transversus Abdominis muscle (TrA) and Pelvic Floor Muscles (PFM) in order to rehabilitate the pelvic floor and thereby reduce or eradicate the distressful symptoms of leakage. If RTUS can shorten the number of sessions required for patients to learn correctly how to co-contract the pelvic floor muscles this would enable physiotherapists to see a greater number of patients .

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2003

Completion date
01/03/2006

Eligibility

Key inclusion criteria
Women between the ages of 30 and 65 with USI

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
40

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment

01/01/2003

Date of final enrolment
01/03/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Willesden Community Hospital
London
United Kingdom
NW10 3RY

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
Research organisation

Funder Name

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