# 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

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# Additional identifiers

# Protocol serial number

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

### Study type(s)

Treatment

### 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(s)

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 .

# Key secondary outcome(s))

Not provided at time of registration

### Completion date

01/03/2006

# **Eligibility**

### Key inclusion criteria

Women between the ages of 30 and 65 with USI

### Participant type(s)

**Patient** 

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

Female

### 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

**United Kingdom** 

England

Study participating centre Willesden Community Hospital

London United Kingdom NW10 3RY

# Sponsor information

# Organisation

Department of Health

# Funder(s)

# Funder type

Research organisation

### **Funder Name**

The West London Research Network (WeLReN) (UK)

# **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?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes