

# A prospective randomised controlled trial of pelvic floor exercises plus biofeedback versus pelvic floor exercises alone in treating stress urinary incontinence

**Submission date**

30/09/2004

**Recruitment status**

No longer recruiting

**Registration date**

30/09/2004

**Overall study status**

Completed

**Last Edited**

05/12/2014

**Condition category**

Urological and Genital Diseases

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☐ Results

☐ Individual participant data

☐ Record updated in last year

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Mr Paul Moran

**Contact details**

Worcester Royal Infirmary

Ronkswood Branch

Newtown Road

Worcester

United Kingdom

WR5 1HN

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0282131250

## Study information

### Scientific Title

A prospective randomised controlled trial of pelvic floor exercises plus biofeedback versus pelvic floor exercises alone in treating stress urinary incontinence

### Study objectives

Assess the effectiveness of biofeedback with pelvic floor exercises compared to pelvic floor exercises alone 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 prospective assessment and cross over trial

### Primary study design

Interventional

### Secondary study design

Randomised cross over trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Urological and Genital Diseases: Urinary incontinence

### Interventions

Biofeedback with pelvic floor exercises compared to pelvic floor exercises alone

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome measure

1. Quality of life. Medical Epidemiologic and Social Aspects of Aging (MESA) score
2. Pelvic floor assessment

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

13/11/2003

**Completion date**

15/02/2006

## Eligibility

**Key inclusion criteria**

Not provided at time of registration

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Female

**Target number of participants**

100+ patients

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

13/11/2003

**Date of final enrolment**

15/02/2006

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Worcester Royal Infirmary

Worcester

United Kingdom

WR5 1HN

# 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

Hospital/treatment centre

## Funder Name

Worcestershire Acute Hospitals NHS Trust (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