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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 05/12/2014	**Condition category** 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

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