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Evaluation of the efficacy of pelvic floor therapies in the management of genuine stress incontinence

Submission date 25/10/2000	**Recruitment status** No longer recruiting
Registration date 25/10/2000	**Overall study status** Completed
Last Edited 07/10/2009	**Condition category** Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
G9410491

Study information

Scientific Title

Study objectives
To investigate the efficacy of standard pelvic floor therapies designed to strengthen pelvic floor and reduce incontinence in women with sphincteric incontinence.

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)
Not Specified

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

Interventions
1. Vaginal cone therapy - the use of vaginal cones to build up pelvic floor contractions and to provide feedback about proper contraction.
2. Pelvic floor therapy - instructions on the contraction of the pelvic floor together with vaginal assessment to confirm proper contraction and bio-feedback.
3. Pelvic floor awareness - simple verbal and written instructions on contraction of the pelvic floor.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Clinical assessment using urinary diaries and 24 h home pad test and 1 h ICS pad test. Digital, perineometry and urodynamic evaluation of the pelvic floor and urinary sphincter.

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/03/2002

Eligibility

Key inclusion criteria

1. Failed conservative therapies for urinary dysfunction (nursing interventions) in women
2. Urodynamically proven genuine stress incontinence

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Female

Key exclusion criteria
1. Pregnancy
2. Malignancy
3. Fistula

Date of first enrolment
01/06/1997

Date of final enrolment
31/03/2002

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Epidemiology and Public Health
Leicester
United Kingdom
LE1 6TP

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article	results	01/11/2006		Yes	No