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

Submission date	Recruitment status	[_] Prospectively registered
25/10/2000	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/10/2000	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/10/2009	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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure

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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/1997

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

Age group
Not Specified

Sex
Female

Target number of participants
345

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
England

United Kingdom

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

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
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Sponsor type
Research council

Website
http://www.mrc.ac.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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2006		Yes	No