

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

Prospectively registered

Protocol

Registration date

25/10/2000

Overall study status

Completed

Statistical analysis plan

Results

Last Edited

07/10/2009

Condition category

Urological and Genital Diseases

Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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, Medical Research Committee and Advisory 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