

A randomised controlled trial of educational group sessions and conventional individual management in the physiotherapeutic treatment of female urinary incontinence (FUI)

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/08/2021	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mrs Sara Demain

Contact details

Physiotherapy Department
Victoria Hospital
Friary Road
Lichfield
United Kingdom
WS13 6QN
+44 (0)1543 414 555 ext 2154
abc@email.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

593

Study information

Scientific Title

A randomised controlled trial of educational group sessions and conventional individual management in the physiotherapeutic treatment of female urinary incontinence (FUI)

Study objectives

To test the hypothesis that the new treatment approach of an educational group has a significantly greater effect on:

1. Physical symptoms
2. Life quality in women with FUI than the individual home help method

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

Urological and genital diseases: Incontinence

Interventions

Not provided at time of registration

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Pad test, pelvic floor muscle power, Incontinence report questionnaire, Symptom severity Index and Visual Analogue Scale.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/1996

Completion date

01/03/1998

Eligibility**Key inclusion criteria**

All female patients aged 18-75 years with a clinical diagnosis of stress and/or urge incontinence will be considered for inclusion.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Female

Target number of participants

Not provided at time of registration

Total final enrolment

44

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/10/1996

Date of final enrolment

01/03/1998

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Physiotherapy Department

Lichfield

United Kingdom

WS13 6QN

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive West Midlands (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2001	09/08/2021	Yes	No