Group treatment: an acceptable and effective method of physiotherapy provision for female urinary incontinence?

Recruitment status No longer recruiting	Prospectively registered		
	☐ Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category	Individual participant data		
	No longer recruiting Overall study status Completed		

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PRF/01/2

Study information

Scientific Title

Acronym

INCON

Study objectives

The aims of this study are to:

- 1. Compare the effectiveness of group versus individual treatments in terms of quality of life and cost effectiveness in the UK health care setting
- 2. Establish patients' preferences for group versus individual physiotherapy for the management of female urinary incontinence (FUI)
- 3. Identify patients' concerns with regards to participation in group settings, and changes in preferences as a result of treatment

Ethics approval required

Old ethics approval format

Ethics approval(s)

This study received an ethics approval before participant recruitment.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Stress incontinence and/or urge incontinence

Interventions

Group: three group sessions for an hour each over a three-week period, with a maximum of 10 women in each treatment group.

Individual: an assessment given and any of the techniques used in the group sessions were taught on a one to one basis. A maximum of three sessions of 1-hour duration were permissible.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Symptom severity questionnaire (SSI) (Black et al., 1996)
- 2. Incontinence-related quality of life (IQOL) (Uebersax et al., 1995)

Secondary outcome measures

- 1. Cost related to treatment attendance and complementary therapies and other products
- 2. The need for further physiotherapy
- 3. General practitioner (GP) utilisation and surgery will be recorded although not reported here

Overall study start date

12/08/2002

Completion date

30/04/2005

Eligibility

Key inclusion criteria

- 1. Females aged 18 years or over
- 2. Ability to understand and capability of giving written informed consent with an interpreter if necessary
- 3. Clinical symptoms of stress and/or urge incontinence

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

150

Key exclusion criteria

- 1. Pregnancy
- 2. Recent pelvic surgery (less than three months)
- 3. History of pelvic malignancy
- 4. Current urinary infection
- 5. Grade III prolapse
- 6. Diseases of the central nervous system (e.g. multiple sclerosis, cerebrovascular accident)

- 7. Acute mental illness and dementia
- 8. Previous physiotherapy for incontinence within the last 12 months

Date of first enrolment

12/08/2002

Date of final enrolment

30/04/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre University of Warwick

Coventry United Kingdom CV4 7AL

Sponsor information

Organisation

Physiotherapy Research Foundation (UK)

Sponsor details

The Chartered Society of Physiotherapy 14 Bedford Row London United Kingdom WC1R 4ED

Sponsor type

Charity

ROR

https://ror.org/04sn78z72

Funder(s)

Funder type

Charity

Funder Name

Physiotherapy Research Foundation (PRF) - PRF/01/2

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	01/04/2008		Yes	No
Results article	interview study results	10/09/2009		Yes	No
Results article	results	14/09/2009		Yes	No