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

Submission date	Recruitment status	[_] Prospectively registered
15/08/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/04/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/09/2009	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
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