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Impact of Physiotherapy on sexual function in women with Stress Urinary Incontinence (SUI)

Submission date	Recruitment status	[_] Prospectively registered
03/05/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/05/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/10/2017	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
11623

Study information

Scientific Title
IPSU study: Impact of Physiotherapy on Sexual function in women with Stress Urinary Incontinence (SUI) and a comparison of electrical stimulation versus standard physiotherapy: a randomised controlled trial

Acronym
IPSU

Study objectives
This study aims to evaluate the effect of physiotherapy on the sexual function in women with urinary incontinence. It also compares 2 different methods of pelvic floor muscle training comparing electrical stimulation to standard physiotherapy as a prospective parallel group randomised controlled trial (RCT). The clinical and cost effectiveness of these 2 interventions on the sexual function of women with urinary incontinence and the response to treatments over a 6-month period will be compared.

Ethics approval required
Old ethics approval format

Ethics approval(s)
26/05/2011, ref: 11/YH/0170

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Reproductive Health and Childbirth/Stress Urinary Incontinence

Interventions
Physiotherapy, 114 women (57 to each arm) will be randomly allocated to each treatment arm via the web based randomization procedure. Pelvic floor symptoms, including incontinence

severity before and after treatment will be assessed using the Electronic Pelvic Floor Assessment Questionnaire (ePAQ). Changes in sexual function will be assessed using the Prolapse and Incontinence Sexual function Questionnaire (PISQ). SF-36 domain scores; EQ-5D score; ePAQ urinary & sexual domain scores before and after physiotherapy.

Follow Up Length: 4 months

Study Entry: Single Randomisation only

Sample size estimation of the primary outcome will be the mean PISQ-31 physical dimension score at 6-months post randomisation. Responses to the items of the physical domain are on a 5 point ordinal scale from 0 (always) to 4 (never). Dimension scores are calculated by totaling the scores for each question. The 10-item physical dimension of the PISQ-31 is scored on a 0 to 40 scale with higher scores indicating better sexual functioning.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Physical dimension score (PISQ-31), at baseline and 6 months

Secondary outcome measures
1. PISQ-31 Behavioral Emotive dimension and Partner-Related dimension scores
2. SF-36 domain scores
3. EQ-5

Overall study start date
01/11/2011

Completion date
01/12/2013

Eligibility

Key inclusion criteria
1. Women aged 18-60 years must have given written (personally signed and dated) informed consent
2. Women who are able to understand, and are willing to comply with the requirements of the protocol
3. Women who are sexually active and are between the age of 18yrs and with urinary incontinence attending physiotherapy for pelvic floor muscle training (PFMT)
4. Women who score either greater than 25% on the urinary domain of the sexual function dimension, and/or greater than 33% for the degree of bother for the same symptom

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Female

Target number of participants
UK Sample Size: 114

Key exclusion criteria
1. Women with a prolapse as their predominant problem
2. Women who have had any previous incontinence surgery
3. Women who have a Grade 3 or above muscle strength as measured using the modified Oxford Scale on vaginal examination
4. Women with vaginal discharge or UTI
5. Women fitted with an implanted pacemaker
6. Women who are pregnant
7. Women with undiagnosed pelvic pain
8. Women with a known sensitivity to the electrodes or the electrode gel
9. Women with inflammation or infection of the vulva and vagina
10. Women who have experienced recent haemorrhage or haematoma
11. Women with atrophic vaginitis
12. Any other medical condition or abnormality (e.g. Malignancy or complication) that in the opinion of the investigator would impact upon the safety or efficacy of the study treatment or any study assessments
13. The patient is enrolled in another interventional trial
14. Non-English speaking women or with a specific language problem

Date of first enrolment
01/11/2011

Date of final enrolment
01/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Sheffield
Sheffield

United Kingdom
S10 2SF

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Trust (UK)

Sponsor details
Royal Hallamshire Hospital
Glossop Road
Sheffield
England
United Kingdom
S10 2JF

Sponsor type
Hospital/treatment centre

Website
http://www.sth.nhs.uk/

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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	01/03/2018		Yes	No