

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

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| Submission date 03/05/2013 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 03/05/2013 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 19/10/2017 | 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

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised interventional trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

Female

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

United Kingdom

England

Study participating centre

University of Sheffield

Sheffield

United Kingdom

S10 2SF

Sponsor information

Organisation

Sheffield Teaching Hospitals NHS Trust (UK)

ROR

<https://ror.org/018hj pz25>

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

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 |