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

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
03/05/2013		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
03/05/2013	Completed	[X] Results		
<b>Last Edited</b> 19/10/2017	Condition category Urological and Genital Diseases	[] Individual participant data		
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#### Plain English summary of protocol

Not provided at time of registration

### Contact information

#### Type(s)

Scientific

#### Contact name

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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

#### Study design

Randomised interventional trial

#### Primary study design

Interventional

#### 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

Sheffield United Kingdom S10 2SF

# Sponsor information

#### Organisation

Sheffield Teaching Hospitals NHS Trust (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**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

Output type	Details	Date created Date add	ded Peer reviewed	? Patient-facing?
Results article	results	01/03/2018	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2	025 No	Yes