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Proposal for pilot randomised controlled trial of pelvic floor exercises for premature ejaculation

Submission date 30/09/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Stopped	
Last Edited 31/03/2011	**Condition category** Mental and Behavioural Disorders	

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
N0620154903

Study information

Scientific Title

Study objectives
Exploring the effectiveness of pelvic floor exercises for premature ejaculation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Mental and Behavioural Disorders: Premature ejaculation (PE)

Interventions
Treatment group of men with premature ejaculation (PE) receiving pelvic floor exercises and relaxation advice and a non-treatment control group of men with PE receiving only relaxation advice.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Subjects in both groups to be evaluated for PE initially, and at 3 months by completing a questionnaire.
2. Subjective & objective physiotherapy assessment to include digital anal measurements by clinician.
3. Assessment by Ros Wills, a physiotherapist who is blinded to the subject grouping.

Secondary outcome measures

Not provided at time of registration

Overall study start date
18/10/2004

Completion date
28/02/2007

Reason abandoned (if study stopped)
Lack of recruitment

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
15 men in each arm of the trial, total 30

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
18/10/2004

Date of final enrolment
28/02/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Old Hill Farm
Barnstaple
United Kingdom
EX32 0HR

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Exeter Primary Care Trust (UK)

Funder Name
Own account

Funder Name
NHS R&D Support Funding

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