Physical therapy for premature ejaculation - a pilot study

Published: 21-05-2010
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To study the results of pelvic floor physiotherapy for premature ejaculation.

Ethical review	Approved WMO
Status	Pending
Health condition type	Sexual function and fertility disorders
Study type	Observational invasive

Summary

ID

NL-OMON32912

Source
ToetsingOnline

Brief title
n.v.t.

Condition

- Sexual function and fertility disorders

Synonym
ejaculatio praecox, rapid ejaculation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: pelvic floor physiotherapy, premature ejaculation, rapid ejaculation

Outcome measures

Primary outcome

I. intravaginal ejaculatory latency time (IELT), measured by a stopwatch

Secondary outcome

II. ejaculatory control (PEP questionnaire)

III. sexual satisfaction (SQOL-M questionnaire)

IV. pelvic floor activity (Male Pelvic Floor Symptom Score questionnaire) and

V. partner reported outcome (the Female Sexual Function Index questionnaire and

Female Sexual Distress Scale)

at 8 weekly intervals up till 6 months

VI. registration of pelvic floor activity (with an anal pressure probe), pre-

and post-treatment

Study description

Background summary

Current treatment choices for premature ejaculation include behaviourally oriented sex therapy including the well-known stop-start and squeeze techniques for improving ejaculatory control, local anaesthetics and oral pharmacotherapy involving the off-label use of common antidepressants. However, these treatment approaches entail significant drawbacks that limit their acceptance by patients and their large-scale use. With respect to these therapies one of the main problems is that patients, and particularly their female partners, often experience these interventions as mechanical and/or technical interference with sensuality and eroticism, requiring the couple to interrupt sexual activity.

Study objective

To study the results of pelvic floor physiotherapy for premature ejaculation.

Study design

Observational pilot

Study burden and risks

There are no medical risks. If the results of pelvic floor physiotherapy would be zero, one could say that expliciting one's sexual life may be a psychological burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Subjects aged > 18 years
Subjects and partner have provided written informed consent.

Subjects must be in a stable, monogamous, heterosexual relationship with the same partner for at least 6 months.
Subjects must be insured for physiotherapy.
The male subjects must be in good general health with no clinically relevant abnormalities as phimosis and prostatitis, normal complete blood count, normal blood chemistry, normal total testosterone.
Subjects and their partner must be prepared to attempt intercourse on a regular basis and at least once a week.
Subjects must meet criteria for diagnosis of PE using a multivariate definition of PE (McMahon, 2008) and a baseline threshold intra-vaginal ejaculatory latency time of < 60 seconds.

Exclusion criteria

The male subjects must not have used investigational drugs within the past 1 month; they also must not have pelvic floor physiotherapy within the past.
The male subject must not have a history of pelvic/retroperitoneal surgery or radiotherapy, multiple sclerosis, cerebro-vascular accident, spinal cord injury or prostatitis, which may be associated with the onset of PE symptoms and considered a potential cause of PE.
The male subject must not have a current or past history of depressive or anxiety disorder, dysthymia, suicidality, (hypo) manic episode, panic disorder, agoraphobia, social phobia, obsessive-compulsive disorder, posttraumatic stress disorder, or psychotic disorders.
The male subject with a current or past history of alcohol abuse and dependence, non-alcohol psychoactive substance use disorder
The male subject may not use any drug that may influence IELT (selective serotonine reuptake inhibitors, monoamineoxydase inhibitors, antipsychotics, cimetidine, phenobarbital, phenytoin, tramadol, St. John*s Wort and local topical anaesthetics
Male subject with hypoactive sexual desire, retrograde, delayed or absent orgasm or ejaculation or erectile dysfunction
The male subject with hypogonadism, hyperprolactinemia, or untreated or insufficiently treated hypothyroidism/hyperthyroidism
The female subject with clinically significant sexual dysfunctions including hypoactive sexual desire and dyspareunia, which may significantly impact the sexual relationship

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2010
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL30266.042.09