SIMULTANEOUS MEASUREMENT OF PELVIC FLOOR ACTIVITY, VAGINAL PLETHYSMOGRAPHY AND VAGINAL INNERVATION IN WOMEN WITH AND WITHOUT HYPERACTIVE PELVIC FLOOR SYNDROME.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Sexual dysfunctions, disturbances and gender identity disorders
Study type	Observational invasive

Summary

ID

NL-OMON30865

Source
ToetsingOnline

Brief title
HyPelM-study

Condition

- Sexual dysfunctions, disturbances and gender identity disorders
- Sexual function and fertility disorders

Synonym
Hyperactive Plevic Floor Syndrome

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Hyperactive Pelvic Floor, Pathophysiology, Vaginal innervation, Vaginal Photoplethysmography

Outcome measures

Primary outcome

It is expected that

- the control group will show a larger EMG increase during the voluntary

control excercises than the experimental group;

- the control group will exhibit lower tonus- and higher controlscores in the

pelvic floor exam than the experimental group;

- both groups of women will show hightened EMG activity during the threatening

and sexually threatening film clips;

- both groups of women will demonstrate hightened VPA amplitude during the

erotic flm clip compared to baseline, but the experimental group*s VPA will be

lower than the control group*s VPA;

- women with an increased tonus of the pelvic floor will have a lower threshold

for perceiving stimuli (they will exhibit increased vaginal innervation)

Secondary outcome

It is expected that little control over the pelvic floormuscles as measured in

the pelvic floor exam will be related to a reduced EMG variability during the

flick excercises.

Study description

Background summary

Pelvic Floor hypertonicity is a chronic, nearly always involuntary, increased activity and/or tension of the pelvic floor muscles. This may be the cause of various gynaecological, sexological and urological complaints. Hyperactive pelvic floor syndrome is diagnosed when 1) there is clinical evidence of pelvic floor hypertonicity and 2) co-morbidity with three or more symptoms co-occurring with pelvic floor dysfunction such as chronic abdominal pain, irritable bowel syndrome, diarrhea, dyspareunia, vulvodynia and sexual arousal disorder. The hightened activity and constant tension of the pelvic floor cause the muscles to become fatigued which may lead to problems with conscious muscle contractions.

Study objective

The purpose of this study is to investigate whether the hyperactive pelvic floor syndrome can be assessed by objective measurement. This will be done by means of a newly developed instrument, the so-called VPA/EMG/sensibility-combiprobe, that measures activity of the pelvic floor (EMG) in combination with vaginal vasocongestion (VPA) and innervation of the vaginal wall.

Study design

Ten premenopausal women with the hyperactive pelvic floor syndrome and 10 premenopausal healthy women without any sexual or pelvic floor symptoms are studied by a physician-sexologist in a pelvic floor exam and by a female experimenter in the psychophysiological laboratory. In the pelvic floor exam functionality of the pelvic floor muscles is assessed by means of the Pelvic Floor Index (PFI) and a pressure-measurement by means of a balloon. In the psychophysiological laboratory voluntary and involuntary control of the pelvic floor muscles as well as vaginal vasocongestion and innervation is measured by means of the combiprobe. Involuntary control of the pelvic floor muscles is measured during neutral, erotic, threatening and sexually threatening film clips. Voluntary control is measured by means of flick and hold contractions of the pelvic floor muscles..

Study burden and risks

Several parts of this study may be perceived as unpleasurable, such as the

vaginal exam of the physician-sexologist, insertion of the vaginal probe and being exposed to the film clips. In using the balloon the subject*s pain thresholds are not exceeded. The risk of pain at insertion of the vaginal probe is considered small, since it is a small instrument (in shape and size comparable to a menstrual tampon) which is constructed of smooth material.

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

Inclusion criteria both groups:
1. No sexual compaints for at least one year and sexually active.
2. Heterosexual orientation.
3. Willing to provide informed consent.
4. Control group: Subjects are medically healthy and have no complaints that point to

problems with the pelvic floor.
5. Pelvic floor hypertonia group: Dyspareunia and co-morbidity of three or more symptoms that corrrelate with pelvic floor dysfunctions such as chronic abdominal pain, irritable bowel syndrome, constipation, diarrhea, urethra syndrome, overactive bladder, intercistal cystitis, vulvodynia, sexual arousal disorder, peri-anal pain, haemorrhoids, perineal pain, coccydynia, orgasm pain, lower back pain, muscle ache in other body parts such as neck or shoulders, headache, teeth gnashing, hyperventilation.

Exclusion criteria

Exclusion criteria both groups:
1. Sexual complaints of shorter duration than one year.
2. Pregnancy and lactation.
3. Menstruation during measurement days.
4. Use of medication negatively influencing sexual function or vaginal vasocongestion.
5. Use of drugs 24 hours prior to testing.
6. Affective, psychotic, or substance-abuse disorders.
7. Pelvic floor hypertonia group: chronic pelvic floor hypertonia with generalized secundary vaginismus.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2007
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL16600.018.07