Inadequate pain behavior in dyspareunia and vaginismus

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By revealing mechanisms for task-persistence and fear-avoidance we expect to be able to improve psycho-sexual treatment of women with sexual pain disorders.

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

Summary

ID

NL-OMON33111

Source
ToetsingOnline

Brief title
IP-study

Condition

- Sexual dysfunctions, disturbances and gender identity disorders

Synonym
Investigation of inadequate pain behavior in women with sexual pain disorders

Research involving
Human

Sponsors and support

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

Intervention

Keyword: dyspareunia, Inadequate pain behavior, vaginismus

Outcome measures

Primary outcome

FSFI

FSDR

MPQ-DLV

Demographic questionnaire

Inadequate pain behavior:

Motives to have intercourse: YSEX?

Partner sollicitousness: MPI - Significant Other Response Scale

Attitudes and cognitions about vaginal penetration: VPCV

Autonomy: AGS-30, 3-items about sexual autonomy

Secondary outcome

STAI-trait

BDI-II

MMQ

SESII-W

AHBBS-V

Study description

Background summary

On basis of clinical impression there seem to exist two distinct groups of women wityh sexual pain disorders (i.e., dyspareunia and vaginismus). One group consists of woman who continue to have intercourse and other pain-inducing (sexual) activities despite their pain (task-persistence), whereas the other

group avoids all sexual activities, including non-pain inducing behaviors (fear avoidance). Task-persistence as well as fear avoidance are coined inadequate pain behavior.

Study objective

By revealing mechanisms for task-persistence and fear-avoidance we expect to be able to improve psycho-sexual treatment of women with sexual pain disorders.

Study design

Results of three groups of woman are compared: woman who suffer from dyspareunia, woman who suffer from vaginismus, and woman without sexual complaints. All woman will be asked to fill out questionnaires. Also, partners of woman with dyspareunia and partners of woman with vaginismus are requested to fill out a questionnaire.

Study burden and risks

The burden for participants is minimal and we do not expect risks.

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

Superficial dyspareunia, primary vaginismus, or no sexual complaints at all.
partner relationship min. 6 months
aged between 18 and 45
premenopausal

Exclusion criteria

Menopause, pregnancy, breast-feeding, use of antidepressants, male partner sexual dysfunction.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-03-2009
Enrollment:	150
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	NL27295.018.09