

# Effect of aversive classical conditioning on sexual response in women with dyspareunia

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|                              |   |
|------------------------------|---|
| <b>Ethical review</b>        | Approved WMO  |
| <b>Status</b>                | Pending   |
| <b>Health condition type</b> | Sexual dysfunctions, disturbances and gender identity disorders |
| <b>Study type</b>            | Observational invasive  |

## Summary

### ID

NL-OMON30416

### Source

ToetsingOnline

### Brief title

Effect of aversive classical conditioning on sexual response

### Condition

- Sexual dysfunctions, disturbances and gender identity disorders

### Synonym

dyspareunia, sexual pain

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** o.a. bijdrage van de wetenschappelijke vereniging seksuele disfuncties

## Intervention

**Keyword:** classical conditioning, dyspareunia, sexual response

## Outcome measures

### Primary outcome

Genital arousal assessed as vaginal pulse amplitude using vaginal photoplethysmography, ratings of subjective sexual arousal, and ratings of positive and negative affect

### Secondary outcome

Skin conductance

## Study description

### Background summary

Dyspareunia, a persistent or recurrent genital pain associated with sexual intercourse is hypothesized to be related to diminished sexual arousal. An explanatory model, described by Spano & Lamont (1975), assumes that in women with dyspareunia the experienced pain during vaginal penetration, or memories of that pain, lead to fear of pain in new intercourse situations. That fear may, in turn, result in diminished sexual arousal and diminished vaginal lubrication.

Only a few studies directly investigated genital response in women with sexual pain disorders. Brauer, Laan, and ter Kuile (2006) observed, in a study in women with and without dyspareunia, diminished genital arousal in response to erotic film presented in a threatening experimental context. These results indicate that threat of pain inhibits sexual responding in women. Based on these findings, it is hypothesized that when sexual stimuli are associated repeatedly with (threat of) pain as in the case of dyspareunia, a learned aversive response may be acquired through classical conditioning, which subsequently may result in diminished genital and subjective sexual response to erotic stimulation. A stronger aversive conditioning effects on sexual response is expected in women with dyspareunia than in controls due to an already learned association of sex and pain in these women. Evidence for prior aversive conditioning in dyspareunia patients might be a stronger magnitude or a delayed extinction of experimental conditioning effects.

## **Study objective**

The purpose of the present study is to clarify the assumed role of fear in women with superficial dyspareunia. The hypothesis will be tested that aversive conditioning in women with dyspareunia and control women will lead to diminished sexual response. It is expected that pairing of an erotic stimulus (the CS+) with a pain stimulus will lead to less genital arousal, less subjective sexual arousal, and stronger negative affect in response to this erotic stimulus, and that these effects will be stronger in women with dyspareunia.

## **Study design**

A differential conditioning design is applied, in which women are presented with two erotic stimuli, of which only one (the CS+) is followed by an aversive unconditioned stimulus (US). As aversive US an electric pain stimulus to the left wrist will be applied. During a pre-conditioning, conditioning, and post-conditioning phase women will view two erotic pictures repeatedly, while genital sexual arousal is assessed as vaginal pulse amplitude using vaginal photoplethysmography (dependent variable). Self-reported ratings of emotional valence and subjective sexual arousal (dependent variables) are collected during the pre-conditioning and post-conditioning phase.

## **Study burden and risks**

Participants will visit the LUMC twice. The screenings visit will take 2 hours and the psychophysiological measurements will take 1 hour.

The questionnaires on sexual functioning, (self)insertion of the photoplethysmograph, viewing of erotic pictures, and/or the applied pain stimuli may be experienced as unpleasant.

The vaginal photoplethysmograph used in this study is a safe device. No harmful events have been reported. The pain stimulus apparatus is protected from any potential power surges or electrical malfunctioning. From other studies (Janssen, 1998) and a pilot study (Both et al., in preparation) it is known that pain stimuli with the length/duration and strength brought about by a pain stimulus device will not cause harm. Moreover, the intensity of the pain stimulus will be individually adjusted. Preceding the pre-conditioning phase pain stimuli will be applied in increasing intensity. The participant will be instructed to indicate which intensity of the pain stimulus is experienced as \*unpleasant and demanding some effort to tolerate\*. The pain stimulation will then be set on the indicated level of intensity.

## 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

dyspareunie  
premenopausal

### Exclusion criteria

other psychiatric or medical illness

## Study design

### Design

|                     |                               |
|---------------------|-------------------------------|
| Study type:         | Observational invasive        |
| Intervention model: | Parallel                      |
| Allocation:         | Randomized controlled trial   |
| Masking:            | Single blinded (masking used) |
| Control:            | Active                        |
| Primary purpose:    | Basic science                 |

### Recruitment

|                           |             |
|---------------------------|-------------|
| NL                        |             |
| Recruitment status:       | Pending     |
| Start date (anticipated): | 01-10-2006  |
| Enrollment:               | 128         |
| Type:                     | Anticipated |

## Ethics review

|                    |                                     |
|--------------------|-------------------------------------|
| Approved WMO       |                                     |
| Application type:  | First submission                    |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
|                    | metc-ldd@lumc.nl                    |

## 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     | NL14392.058.06 |