

# How women perceive and evaluate management of vulvovaginal symptoms by their GP.

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Primary Objective: The aim of this qualitative study is to obtain more insight into how patients with PVD perceive and evaluate management of their vulvovaginal complaints by their GP. Secondary Objective: Optimizing support and treatment by GP\*s to...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON45471

### Source

ToetsingOnline

### Brief title

PVD study

### Condition

- Other condition

### Synonym

Vulvar pain, vulvar vestibulitis syndrome

### Health condition

vrouwelijke geslachtsdelen

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Nederlandse Vereniging voor Seksuologie

## Intervention

**Keyword:** Expectations, Experience, General practitioner, Provoked vulvodynia

## Outcome measures

### Primary outcome

Three to five main themes describing the most important experiences and expectations

### Secondary outcome

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## Study description

### Background summary

There are indications that uncertain vulvovaginal candidiasis could be a marker of PVD. GPs might reconsider their diagnostics and management when women present recurrent and persistent vulvovaginal complaints, especially if accompanied by dyspareunia, functional syndromes, micturition symptoms and psychological conditions. However, GPs feel reluctant to take a sexual history and perform a vulvovaginal examination. It seems that the management by GPs is not in accordance with the needs of women.

### Study objective

**Primary Objective:** The aim of this qualitative study is to obtain more insight into how patients with PVD perceive and evaluate management of their vulvovaginal complaints by their GP.

**Secondary Objective:** Optimizing support and treatment by GP\*s to patients who suffer from PVD and other vulvovaginal symptoms.

In general, primarily, we want to investigate which barriers and facilitators did affect women with PVD when they consulted a GP in need for a treatment.

What did women expect and experience regarding discussing sexuality and undergoing physical examination? What would they, afterwards, advice their GP? In short, what lessons could be learned in order to improve diagnostics and management of PVD in general practice?

## **Study design**

The interviewer will be the student-researcher. After each interview, all audiotaped material will be transcribed and independently coded by the student-researcher and PhD candidate (P. Leusink, MD). Discrepancies in coding will be discussed until consensus is reached. Analysis obtained by coding and evaluating after two interviews, will be used to revise the interview guide for the next interview, if necessary. The aim is to perform enough interviews until saturation in topics is reached. Subsequently all the transcripts will be uploaded and digitally coded using software program MaxQDA. Finally 4-5 major themes will be distracted from these codes in order to describe the main findings.

## **Study burden and risks**

We do not expect any risks. The burden consists of filling in a short questionnaire and participating in one qualitative interview (during which intimate questions will be posed). If the questionnaire and/or the interview are mentally taxing for the participant, help will be offered.

## **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

- Women
- aged 18-50
- Speaking Dutch
- With provoked vulvodynia (PVD), as was diagnosed by a GP/sexologist or gynaecologist
- Who minimally visited once a GP prior to the diagnosis
- The first visit to a GP regarding PVD or related complaints was < 2 years ago

### Exclusion criteria

The diagnosis of PVD was set after menopause

The diagnosis of PVD was not established definitely

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 19-01-2017

Enrollment:	20
Type:	Actual

## Ethics review

Approved WMO	
Date:	25-10-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	16-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	01-09-2017
Application type:	Amendment
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	NL59046.018.16