

# Pelvic organ prolapse, self-image and acceptance

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON24158

### Source

NTR

### Brief title

PROSA

### Health condition

Pelvic organ prolaps and diabetes mellitus type 2

## Sponsors and support

**Primary sponsor:** none

**Source(s) of monetary or material Support:** none

## Intervention

## Outcome measures

### Primary outcome

1. To determine if and in what way the pelvic organ prolapse influences the sexual function and the self-image of the patient
2. To compare the POP group and the control group on level of sexual function and (sexual) self-concept and to determine whether potential differences are specific to the POP group or can be attributed to disease awareness by comparing the sexual function and (sexual) self-

concept between patients with POP and controls, and compare the results to differences between patients with diabetes mellitus type 2 and controls.

## **Secondary outcome**

1. To determine the level of agreement between the self-concept of the female participant and the self-concept as perceived by the partner
2. To determine whether level of agreement between female participant and partner is associated with quality of life, relationship and sexual outcomes.
3. To determine whether the quality of life is related to the symptoms of pelvic organ prolapse or chronic disease.
4. To compare the self-image of the women with the self-image of their partners
5. To compare the quality of life of the partner of the chronic disease group with the quality of life of the partner of the healthy control group

## **Study description**

### **Background summary**

Rationale: Pelvic organ prolapse (POP) is a very common disorder among women. Studies show that patients with POP report sexual dysfunction. A study shows that genital self-image is associated with sexual dysfunction. POP directly involves the female genitals and is likely to affect sexual identity. This may become a threat to the sense of the self-concept, which may explain women's fear and negative experiences in sex. Despite its heuristic and clinical significance, the sexual self-concept has received little research attention so far. It is plausible to assume that not only POP, but also other chronic disease influence the self-image and sexual functioning, therefore we want to determine whether the sexual self-concept in relation to sexual function and sexual experiences is specific to POP, or rather determined by general factors related to being chronically ill. It is known that men with diabetes Mellitus (DM) suffer from sexual dysfunction, the sexual function of women with DM on the other hand is less known. The aim of this study is to determine whether and to which extent the pelvic organ prolapse is associated with poor sexual function in heterosexual couples and assess if it is comparable to patients with diabetes mellitus when compared to healthy controls.

Method: This is a cross-sectional, observational study in patients with POP-Q stadium 2 and their partners, women with diabetes mellitus type 2 and their partners, and healthy controls and their partners. Eligible patients are recruited from 3 hospitals in the Netherlands. A total of 63 couples in each arm of the study (prolapse, DM and healthy controls) are included. Patients and their partners are asked to fill in questionnaires separately (for female: Female Sexual Function index (FSFI), Female Sexual Distress Scale-Revised (FSDS-R), Body Image Scale, Rosenberg Self-Esteem Scale, Female genital self-image scale, Sexual Self-concept, Hospital Anxiety and Depression Scale (HADS), and SF-36. For men: International Index of Erectile Function, Rosenberg Self-Esteem Scale, Female genital self-image scale, Sexual Self-concept, HADS, and SF-36).

Main study parameters/endpoints: The main study endpoint is the score on the FSFI, for

women in the POP group, the DM type 2 group, and the control group. Sexual function in men with the international index of erectile function (IIEF), body image using the Body Image Scale and genital body image using the female genital self-image scale (FGSIS), sexual distress with the Female Sexual Distress Scale (FSDS-R), sexual self-concept measured using an adapted version of the Sexual Self Scale of Snell, self-esteem using the Rosenberg Self-Esteem Scale, Anxiety and depression using the Hospital Anxiety and Depression Scale (HADS), and Quality of Life (QoL) measured using the SF-36.

## **Study objective**

We hypothesize that patients with pelvic organ prolapse have a lower score on the general and sexual well-being than a healthy control group, but also compared to patients with diabetes mellitus. Furthermore, we hypothesize that sexual self-concept is an important determinant of sexual function and behaviour. In addition, we hypothesize that a discrepancy of the patient's self-image in comparison to the image of the patient by the partner does exist and can be determinative for the sexual behaviour and functioning.

## **Study design**

September 2019 start inclusion

## **Intervention**

none

## **Contacts**

### **Public**

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### **Scientific**

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## **Eligibility criteria**

## Inclusion criteria

All groups: Women, 40 - 70 years of age, in a heterosexual relationship with sexual contact including penetration

Pelvic organ prolaps group:

- Pelvic organ prolapse POP-Q stadium 2, no further differentiation in stadium

Diabetes mellitus type 2 group:

- Subjects have diabetes mellitus type 2.

Healthy women group

Male partner from every group:

- 40 - 70 years of age.

## Exclusion criteria

All groups: subjects that are not able to give informed consent and subjects who do not understand Dutch

Diabetes mellitus type 2 group:

- Polyneuropathy caused by diabetes mellitus
- Macro vasculopathies caused by diabetes mellitus, defined as:
  - Cerebrovascular accident
  - Myocardial infarction
  - Peripheral vascular disease
  - Suspicion of vasculopathies by clinician on the basis of physical examination and anamnesis
- Primary hypogonadism

Healthy women group:

- Subjects with pelvic organ prolapse or diabetes mellitus.

Male partners from every group:

- Pre-existing sexual dysfunction including erectile dysfunction

## Study design

### Design

Study type: Observational non invasive

Intervention model: Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	05-08-2019
Enrollment:	189
Type:	Anticipated

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	26-07-2019
Application type:	First submission

## 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
NTR-new	NL7906
Other	METC Radboud UMC : 2018-4372

## Study results