

Pelvic organ prolapse, self-image and acceptance

Published: 17-07-2019

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Primary Objective: 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...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON48949

Source

ToetsingOnline

Brief title

PROSA

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Vulvovaginal disorders (excl infections and inflammations)

Synonym

cystocele, Pelvic organ prolapse

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: genital self-image, pelvic organ prolaps, sexual function, sexuality

Outcome measures

Primary outcome

Study parameters/endpoints

To assess the study outcomes, a questionnaire will be completed both by the patient and her partner. We will make sure that both partners complete the questionnaires independently to limit issues of social desirability or positive partner biases. Because being in a heterosexual relationship is one of the inclusion criteria, the questionnaire for the partner is specific to male participants.

Main study parameter/endpoint

The main study endpoint is the score on the Female Sexual Function Index (FSFI), for women in the POP group, the DM type 2 group, and the control group.

Secondary outcome

Secondary study parameters/endpoints

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 description

Background summary

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 influences 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.

Study objective

Primary Objective:

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 Objectives:

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 design

This study is a cross-sectional, observational study in patients and their partners with POP, diabetes mellitus type 2, and healthy controls.

Study burden and risks

not applicable

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

- Heterosexual relationship
- 40 - 70 years of age.
- Pelvic organ prolapse POP-Q stadium 2 or more

Exclusion criteria

- Subject that are not able to give informed consent
- Subjects who do not understand the Dutch language

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	14-01-2020
Enrollment:	195
Type:	Actual

Ethics review

Approved WMO	
Date:	17-07-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	24-09-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	24-08-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	28-03-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL66252.091.19