Inventory of sexual dysfunctions in patients with post-traumatic stress disorder (PTSD) and patients with obsessive compulsive disorder (OCD)

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

Summary

ID

NL-OMON51189

Source
ToetsingOnline

Brief title
Sexual dysfunctions in PTSD and OCD

Condition

- Sexual dysfunctions, disturbances and gender identity disorders

Synonym
Sexual dysfunctions/Sexual (dis)satisfaction and functioning

Research involving
Human

Sponsors and support

Primary sponsor: ProPersona (Nijmegen)

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

Intervention

Keyword: Obsessive compulsive disorder (OCD), Post-traumatic stress disorder (PTSD), Sexual dysfunctions

Outcome measures

Primary outcome

The degree of sexual (dis)satisfaction (Female Sexual Distress Scale, FSDS; also a separate version for men), as well as the presence and nature of possible sexual dysfunctions (measured by administrating a short interview about sexual history as well as the abbreviated version of the Female Sexual Function Index, FSFI; or of the International Index of Erectile Function, IIEF respectively).

Secondary outcome

Indication of care needs (measured by administrating a short interview), disgust (1-item Likert scale), body image (Body Image Self-Consciousness Scale; BISC), shame (Trauma Related Shame Inventory; TRSI) and pelvic floor overactivity (Amsterdam Hyperactive Pelvic Floor Scale-Women ; AHPFS-W).

Study description

Background summary

Based on results from previous research there was suggested that sexual dysfunctions are common among patients with PTSD and OCD. However, information is still lacking about the actual prevalence and nature of sexual dysfunctions in this target group, as well as about their care needs and to what extent the guideline treatments aimed at PTSD and OCD reduce the severity of sexual dysfunctions. Some theoretical models - in which disgust, body image, shame, pelvic floor overactivity and / or psychotropic medication play a role -

attempt to explain how trauma, PTSD and OCD may cause sexual dysfunctions. Again, however, the actual relationship between sexual dysfunction and trauma, PTSD and OCD is still unknown. Gaining insight into the presence of sexual dysfunctions, the relationship with other problems and the effect of the guideline treatments aimed at PTSD and OCD on these sexual dysfunctions within this target group can - in time - lead to a (better) treatment aimed at diminishing sexual disfunctioning. Sexual functioning is evaluated as an important aspect of quality of life, also in patients with psychological problems, and furthermore, sexual dysfunction can also maintain PTSD and OCD symptoms because avoidance behavior is not stopped.

Study objective

Primary objectives are to investigate (1) the prevalence and nature of sexual dysfunctions in patients meeting the criteria for PTSD or OCD, and; (2) whether sexual dysfunctions decreases after the guideline treatment aimed at PTSD or OCD. Secondary objectives are to investigate (1) the care needs of the subjects who suffer from sexual dysfunctions (with regard to these sexual dysfunctions); (2) the relationship between the severity of sexual dysfunctions and the severity of PTSD or OCD symptoms; (3) the possible mediation of the relationship between PTSD or OCD symptoms and sexual dysfunctions due to disgust, body image or shame, pelvic floor overactivity, or psychotropic medication.

Study design

This study is an observational study.

Study burden and risks

Subjects spend extra time completing the questionnaires (total study duration is a maximum of 70 minutes) for which they do not have to travel (extra) to a (treatment) location. A possible advantage of participation is that their care needs concerning (possible) sexual dysfunction is investigated and that subjects are directed to appropriate care when needed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- age >= 18 years
- participation in the Intensive Exposure Treatment (IET; aimed at PTSD) OR FOCUS-treatment (aimed at OCD)
- meeting the criteria for PTSD OR for OCD

Exclusion criteria

For the current study there are no exclusion criteria: any patient enrolled in the IET- or the FOCUS-treatment is eligible to be informed about the study.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	16-02-2025
Enrollment:	148
Type:	Anticipated

Ethics review

Approved WMO Date:	16-07-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-01-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-01-2025
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	NL75503.091.20