# Phenotypes and experiences of reproductive affective disorders among women in the Netherlands

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Mood disorders and disturbances NEC |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON55939

**Source**
ToetsingOnline

**Brief title**
Period.

### Condition

- Mood disorders and disturbances NEC
- Gender related factors

**Synonym**
Premenstrual disorders; PMS

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** stichting PMDD stelt uren beschikbaar voor

de opzet en uitvoer van het onderzoek

## Intervention

**Keyword:** Phenotyping, Premenstrual disorders, Quality of life, Validation

## Outcome measures

### Primary outcome

The main study parameter is PMM/PMDD symptomatology as assessed using the

C-PASS questionnaire.

### Secondary outcome

Secondary parameters are clinical diagnosis (SCID in validation study only),

PMDD symptoms, co-morbid somatic and mental symptoms (GRSR, EPDS, PANAS, PQ-16,

BSI-18, ADHD-screener, ASSIST-Lite), personality (DAPP-sf, HSP), quality of

life (Q-LES-Q-SF), days of sick leave, disease course, medication use, service

use, wellbeing, social functioning, psychiatric symptoms and history.

# Study description

### Background summary

Premenstrual disorders (PMDs), including premenstrual syndrome and premenstrual dysphoric disorder, (PMDD) affect millions of women of reproductive age with a significant health impact. Research into aetiology, phenotyping, and treatment of PMDs is hampered by the absence of validated measures and the reliance on retrospective data. Prospective cohorts with valid measures on PMDs are urgently needed. PMDs in general, and PMDD (Premenstrual Mood Dysphoric Disorder) in particular are largely absent from Dutch research. We aim to describe phenotypes of (sub)clinical PMDD and explore the impact of (sub)clinical PMDD on the lives of the affected women.

### Study objective

The primary objective is to explore phenotypes of (sub)clinical PMDD and explore the impact of (sub)clinical PMDD on the lives of the affected women.

The secondary objective is to assess the validity of a Dutch translation of the self-administered C-PASS questionnaire in detecting patients diagnosed with PMDD.

## Study design

This study will be a prospective observational cohort study using a convenience sample of women, self-diagnosed as suffering from premenstrual syndrome (PMS) or premenstrual dysphoric disorder (PMDD). The aim of the study is to describe phenotypes of (sub)clinical PMDD and to explore the impact of these symptoms on the lives of the affected women. Secondly, we aim to study the validity of the Dutch translation of the C-PASS as a diagnostic instrument to screen for PMDD. Premenstrual symptoms will be assessed over a period of three menstrual cycles.

The participants are women suffering from (self) diagnosed PMS or PMDD. The participants will be recruited through the social media channels of the patient*s grassroots organization (Stichting PMDD NL). The participants will be enrolled after they are checked for the in- and exclusion criteria and have signed the informed consent form (IC). After signing informed consent, they will be interviewed by a trained interviewer on hormonal cycle, hormonal and mental health symptoms, illness and treatment history and family history of hormonal disorders and mental illness. A series of fully structured symptom questionnaires will be administered through the use of a datacapture system (CASTOR). Depending on the nature of the symptoms, these will be administered monthly, bi-weekly (in luteal and follicular phase), or daily.

A selection of the participants will be invited to participate in a study to validate the C-PASS screening interview. For this study, stricter in- and exclusion criteria apply. Enrollment will take place after informed consent has been signed. For this study, participants will be interviewed using the SCID interview to establish a clinical diagnosis of PMDD according to DSM-TR criteria, as well as fill in the C-PASS on a daily basis over a three month period.

The study is non-invasive and all questionnaires can be administered online.

## Study burden and risks

In this research, we study a population of women with self-reported clinical and subclinical premenstrual symptoms. However, these women are not part of a clinical population: the subjects will be recruited through the patient association, and will consist of a mix of women with self-reported clinical and subclinical premenstrual complaints.

By participating in this study, women do not receive a direct benefit. They do

benefit from their symptoms being heard and talked about, since this population is usually undiagnosed. Peer-support is also available and beneficial to women who may need this. Participants will need to fill in different questionnaires at various time points in this study, which can be filled in at home. The design of the study is non-therapeutic. The risks of participation are close to zero. No risks are known for self-report questionnaires.

The only minor risk for participating in this study is reporting about childhood trauma through the childhood trauma questionnaire. This questionnaire will be administered once, at the beginning of the study

There will be a few minor burdens for participating in this study, which includes amongst
others: an interview by a trained interviewer about women*s hormonal cycle, hormonal and mental health symptoms, illness and treatment history, and family history of hormonal disorders and mental illness at inclusion (30 min) and a semi-structured clinical interview SCID interview (30 min). Furthermore. the C-PASS and sleep-related questionnaire may form a burden. Participants will administer these daily for 3 months.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (16-17 years)
Adults (18-64 years)

## Inclusion criteria

For the observational prospective cohort study women must meet the following criteria:
All participants must give signed informed consent.
All participants must be of fertile age (16 years of age or older, with a maximum of 60 years).
Participants must experience self-reported PMS or PMDD related symptoms.
Participants must have a detectable cycle, which may either be a natural menstrual cycle or induced by hormonal contraceptives, of no longer than 40 days.

## Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from the observational prospective cohort study:
Current pregnancy, or actively trying to conceive
Insufficient proficiency in Dutch

A potential subject who meets any of the following criteria will be excluded from the validation study:
Current pregnancy, or actively trying to conceive
Insufficient proficiency in Dutch
Any current DSM-5 Axis 1 clinical disorder (other than PMDD) according to the SCID interview
Current use of psychopharmaceutical medication

# Study design

## Design

**Study type:** Observational non invasive
Masking: Open (masking not used)

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| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 17-04-2024 |
| Enrollment: | 250 |
| Type: | Actual |

### Medical products/devices used

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| Registration: | No |

## Ethics review

Approved WMO

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| Date: | 21-11-2023 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

## 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 | NL83427.078.23 |