

# Premenstrual syndrome and use of psychoactive substances

No registrations found.

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

## Summary

### ID

NL-OMON21106

### Source

NTR

### Brief title

PMS-SUD

### Health condition

PMD Premenstrual Disorders  
PMS Premenstrual syndrome  
PMDD Premenstrual dysphoric disorders  
Substance related disorders

## Sponsors and support

**Primary sponsor:** Novadic-Kentron in association with UMC Radboud

**Source(s) of monetary or material Support:** this is non funded study

## Intervention

## Outcome measures

### Primary outcome

association between level of PMS signs and symptoms and level of problematic use of psychoactive substances

## Secondary outcome

craving for psychoactive substances in relation to PMS sign and symptoms

## Study description

### Background summary

#### SUMMARY

**Rationale:** Participants in research on Substance Use Disorders (SUD) is mostly done in men. Limited scientific research is available on women and SUD. A theme that has received little attention is the influence of the menstrual cycle on SUD. In particular, the relationship between a premenstrual syndrome (PMS) and SUD has been given little attention. Premenstrual dysphoric disorder (PMDD) is the severe form of (PMS). Clinical practice shows that women with PMS sometimes use substance to alleviate the symptoms of PMS. Women with PMS-complaints drink more alcohol (12% - 39%) than women in a control group without PMS. Until now it is not clear how many addicted women suffer from PMS and how many women with PMS have SUD.

**Objectives:** Primary aim: to estimate the prevalence of the co-occurrence of PMS and SUD in women. Secondary aim: exploring craving for psychoactive substances a week before menstruation.

**Study design:** Explorative observational prospective cross-sectional study.

**Study populations:** all participants (n=300) patients in Dutch addiction institutes (n=100), outpatient clinics for gynecology (n=100) and primary care practices (n=100).

**Intervention:** this is a non-intervention study

**Main study parameters/endpoints:** This study protocol focuses on the co-occurrence of the Premenstrual Syndrome (PMS) and Substance Use Disorders (SUD) assessed with questionnaires.

**Nature and extent of the burden and risks associated with participation:**

According to the experience of the addiction medicine specialists with this population, no problems are expected with answering the questionnaires. The estimated time for filling out

the questionnaires is 30 – 40 minutes.

Ethical clearance: The study has been reviewed by the ethics committee of the Radboud University Nijmegen Medical Centre on the basis of the Dutch Code of conduct for health research, the Dutch Code of conduct for responsible use, the Dutch Personal Data Protection Act and the Medical Treatment Agreement Act. The ethics committee has passed a positive judgment on the study (2018-4349).

### **Study objective**

PMS increases the chance of problematic use of psychoactive substances.

In case of problematic use of psychoactive substances the prevalence of PMS is higher than in case of non problematic use.

### **Study design**

this is a crosssectional study with one measurement

### **Intervention**

This is an non-intervention study

## **Contacts**

**Public**

**Scientific**

## **Eligibility criteria**

### **Inclusion criteria**

Inclusion criteria :

- Women between the ages of 18 and 45
- The ability to understand and sign written informed consent

## Exclusion criteria

Recent history of clinically significant psychiatric illness including any psychotic disorder e.g. schizophrenia, bipolar disorder or severe depression, suicidal ideation, menopause.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2019
Enrollment:	300
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	04-10-2018
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	NL7315
NTR-old	NTR7532
Other	Commissie Mensgebonden Onderzoek : 2018-4349

## Study results

### Summary results

Qurishi R, Sonneborn C, de Jong-Arts M, de Jong CAJ. Premenstrual syndrome and self-medication with opioids. J Addict Med. 2013 Jan-Feb;7(1):79-82. doi: 10.1097/ADM.0b013e31827884a3. <br>

Qurishi R, Arts-de Jong M, Franzek EJ, Hartman L and De Jong CAJ. Influence of Premenstrual Syndrome on Relapse in Nicotine Abuse a Case Report . Austin J Drug Abuse and Addict. 2015; 2(1): 1005.