

Premenstrual syndrome and use of psychoactive substances

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21106

Bron

Nationaal Trial Register

Verkorte titel

PMS-SUD

Aandoening

PMD Premenstrual Disorders

PMS Premenstrual syndrome

PMDD Premenstrual dysphoric disorders

Substance related disorders

Ondersteuning

Primaire sponsor: Novadic-Kentron in association with UMC Radboud

Overige ondersteuning: this is non funded study

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

this is a crosssectional study with one measurement

Onderzoeksproduct en/of interventie

This is an non-intervention study

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria :

- Women between the ages of 18 and 45

- The ability to understand and sign written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	04-10-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7315
NTR-old	NTR7532
Ander register	Commissie Mensgebonden Onderzoek : 2018-4349

Resultaten

Samenvatting resultaten

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.

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.