MoodCycles in women with ADHD

Published: 27-05-2019
Last updated: 09-04-2024

To investigate the relationship between subjective and objective ADHD and subjective mood symptoms and the menstrual phase in women with and without ADHD.

Ethical review	Not approved
Status	Will not start
Health condition type	Cognitive and attention disorders and disturbances
Study type	Observational invasive

Summary

ID

NL-OMON48119

Source
ToetsingOnline

Brief title
MoodCycles in ADHD

Condition

- Cognitive and attention disorders and disturbances

Synonym
ADHD, attention disorder with or without hyperactivity

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia Bavo Groep (Den Haag)
Source(s) of monetary or material Support: PsyQ

Intervention

Keyword: ADHD in women, Female hormones, Menstrual cycle, Mood

Outcome measures

Primary outcome

The mean outcomes of the ADHD-RS and the QbTests at the three time points

within the ADHD group.

Secondary outcome

Comparison between the groups per time point of the ADHD-RS, QbTest, and QIDS.

Study description

Background summary

Women with ADHD have more often and more severe premenstrual mood disorder symptoms (PMDD), compared to women without ADHD, as was shown in our previous research (46% vs. 3-8%). Dopamine and estradiol levels seem to enhance each other. As ADHD is associated with low dopamine neurotransmission, the hypothesis is that ADHD symptoms and mood instability may increase in the low estradiol (premenstrual) phase of the cycle. Regarding the sleep rhythm, in women with PMDD compared to controls, changes in the circadian sleep rhythm have been found, indicating that disturbed sleep may also contribute to the mood symptoms.

Study objective

To investigate the relationship between subjective and objective ADHD and subjective mood symptoms and the menstrual phase in women with and without ADHD.

Study design

Prospective observational case-control study

Study burden and risks

The burden for the participants consists of monitoring the severity of mood and ADHD symptoms (each evaluated by a rating 1-10 per day) during two consecutive months (time investment about 1 hour in total), prior to inclusion in the study (as required according to DSM-5 criteria for a diagnosis of PMDD), and the study measurements in the third month: 3x measurement of hormone levels in

blood samples after a vena puncture, 3 x 3 days of wrist Actigraphy (instruction time 30 minutes), 3x objective QbTest assessments (time investment 2 hours), filling out questionnaires (MCTQ once; ADHD-RS, QIDS, and sleep questionnaire three times; time investment 1,5 hours in total).

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

- Female gender
- Age 18-45 years old
- regular menstrual cycle
- no use of hormones
- no use of ADHD medication

For ADHD group: ADHD diagnosis

Exclusion criteria

For controle group:
- ADHD diagnosis or fullfill criteria for ADHD diagnosis

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Not approved

Date:	27-05-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL68830.098.19