Plan Overview

A Data Management Plan created using DMPonline

Title: Hormonal Rhythms and Addiction Vulnerability in Women with ADHD

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Project abstract:

Attention-Deficit/Hyperactivity Disorder (ADHD) and addiction-related behaviors frequently co-occur, particularly in women, yet the mechanisms underlying this association remain poorly understood. Emerging evidence suggests that hormonal fluctuations across the menstrual cycle may influence both ADHD symptoms and reward-related behaviors, potentially increasing vulnerability to substance use and other addictive behaviors. While previous studies have demonstrated menstrual cycle-related changes in ADHD symptom severity and nicotine use, longitudinal research examining the dynamic interplay between menstrual cycle phase, ADHD symptoms, and broader addiction-related behaviors is lacking.

This project aims to investigate how menstrual cycle fluctuations influence the association between ADHD symptoms and addiction-related behaviors in women and whether stimulant medication moderates these effects. We hypothesize that ADHD symptom severity will peak during the luteal phase in women with ADHD who do not use stimulant medication, while this effect will be attenuated among women receiving stimulant treatment. Furthermore, we expect addiction-related behaviors to fluctuate across the menstrual cycle in all women, with stronger fluctuations in women with ADHD. Specifically, reward-driven addictive behaviors are expected to peak during the follicular phase, whereas relief-driven behaviors aimed at coping with worsening ADHD symptoms are expected to increase during the luteal phase.

A total of 120 women aged 18–35 years with regular natural menstrual cycles and no hormonal contraceptive use will be recruited into three groups: women with ADHD using stimulant medication (n = 40), women with ADHD not using stimulant medication (n = 40), and women without ADHD (n = 40). Participants will complete an online baseline assessment followed by a 35-day ecological momentary assessment (EMA) protocol. Daily measures will assess ADHD symptoms, reward- and relief-driven craving, and engagement in addiction-related behaviors, including alcohol use, nicotine/vaping, cannabis and other substance use, and online gaming. Multilevel modeling will be used to examine within-person fluctuations in ADHD symptoms and addiction-related behaviors across the menstrual cycle and to evaluate the moderating effects of ADHD status and stimulant medication use.

By identifying menstrual cycle-related patterns in ADHD symptoms and addiction-related

behaviors, this study will advance understanding of addiction vulnerability in women with ADHD and provide evidence for more personalized prevention and treatment strategies.

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Hormonal Rhythms and Addiction Vulnerability in Women with ADHD

General Information

Name applicant and project number

Anne Marije Kaag - 406.XS.25.03.021

Name of data management support staff consulted during the preparation of this plan and date of consultation.

Alex van der Jagt - apc.vander.jagt@vu.nl

1. What data will be collected or produced, and what existing data will be re-used?

1.1 Will you re-use existing data for this research?

If yes: explain which existing data you will re-use and under which terms of use.

- No

1.2 If new data will be produced: describe the data you expect your research will generate and the format and volumes to be collected or produced.

Various types of data will be collected:

- Screening information on age, sex assigned at birth, use of hormones, menstrual cycle information, ADHD severity. all collected through qualtrics
- Questionnaire data, all collected through qualtrics: information on gender identity, addiction related behavior, ADHD diagnosis and treatment, reward seeking behavior
- Ecological Momentary Assessment Data collecterd through https://avicennaresearch.com/

1.3. How much data storage will your project require in total?

- 0 – 10 GB

During ongoing data collection, data will be stored in Qualtrics andhttps://avicennaresearch.com/.

Data will be back-uped in Research Drive during data analyses and writing of the reports. Data will be archived in Yoda once the project is finished,

2. What metadata and documentation will accompany the data?

2.1 Indicate what documentation will accompany the data.

During data collection

- standard operational procedure documents (SOPs) are written to ensure that data collection takes place according to standard procedures. A codebook file will be stored on research drive to explain all variables in both the qualtrics as Avicienna data
- all subject data will be saved under a subject number; the key will be saved in a seperate document in research drive.

Upon Archiving

- Two data files will be saved. One containing the ecological momentary assessment data, long format; one containing the additional demographic and clinical data, in wide format. Subject numbers will be used, and all identifiable information will be removed.

2.2 Indicate which metadata will be provided to help others identify and discover the data.

SOPs that expain how data is collected
Codebooks that explain the variables in the datasets
Syntax (or scripts) that are used to clean the raw data and calculate scores
if applicable, syntax or code that are used for hte analyses

3. How will data and metadata be stored and backed up during the research?

3.1 Describe where the data and metadata will be stored and backed up during the project.

- Institution networked research storage

Research Drive

3.2 How will data security and protection of sensitive data be taken care of during the research?

- Default security measures of the institution networked research storage

Participants will be assigned a number, that will be used to collect all data. Only researchers that need to have access to the personal information, for example, those involved in data collection, will have access to the key linking the personal information and collected data.

4. How will you handle issues regarding the processing of personal information and intellectual property rights and ownership?

4.1 Will you process and/or store personal data during your project?

If yes, how will compliance with legislation and (institutional) regulation on personal data be ensured?

- Yes

Participants will provide consent for data collection and the preservation in coded form. they have the option to consent for sharing the data anonymously, all personalized data will be removed.

4.2 How will ownership of the data and intellectual property rights to the data be managed?

PI Kaag owns the data and controls access.
Researcher de Bode will manage data storage during the ongoing project
A data-sharing agreement will be in place to share data with researcher Groenman at the UVA.

5. How and when will data be shared and preserved for the long term?

5.1 How will data be selected for long-term preservation?

- Other (please specify)

in line with the VCWE guidelines, data will be stored up to 10 years following the last publication.

5.2 Are there any (legal, IP, privacy related, security related) reasons to restrict access to the data once made publicly available, to limit which data will be made publicly available, or to not make part of the data publicly available?

If yes, please explain.

- No

5.3 What data will be made available for re-use?

- All data resulting from the project will be made available

Only fully anonymised data will be made available, meaning that all identiyable information will be removed from the dataset.

5.4 When will the data be available for re-use, and for how long will the data be available?

- Data available as soon as article is published

5.5 In which repository will the data be archived and made available for re-use, and under which license?

Yoda

5.6 Describe your strategy for publishing the analysis software that will be generated in this project.

If applicable, R code will be published either with the article, or in the open science framwork.

6. Data management costs

6.1 What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable)?

There are no costs involved in storing the data during data collection in research drive or with archiving in Yoda, as the use up to 500Gb of storage per research project is free of charge.