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.

- Three groups of women will be recruited (18–35 years, regular natural cycles, no hormonal contraceptives) via targeted advertisements on social media and dedicated websites: 40 with ADHD on stimulants, 40 with ADHD not on stimulants, and 40 without ADHD.
- Participants provide consent for the screening procedures (checkmark); Screening information on age, sex assigned at birth, use of hormones, menstrual cycle information, and ADHD severity. All collected through Qualtrics. Data will be stored in spss/excel data format.
  - screening questions:
  - 1. Age (included if between 18 and 35)
    2. Sex assigned at birth and gender identity (exclude if male)
    a. What is your sex assigned at birth (male, female, intersex, prefer not to say)
    b. What is your current gender-identity (man, woman, non-binary, a gender not listed here, prefer not to say)
    3. Do you use hormones, including hormonal contraceptives and hormone replacement

therapy (excluded if yes)

4. Do you have a natural menstrual cycle? Excluded if no
5. Do you have hormonal disorders, including PCOS (excluded if yes)
6.
7. The Adult ADHD Self-Report Scale for DSM-5
8. Do you currently use medication for ADHD?
9. Where you diagnosed with ADHD? +When
10. Self-reported use of substances or online gaming (included if any of the behavior is reported to be weekly or more)
    a. Weekly alcohol use
    b. Weekly use of vapes or cigarettes
    c. Weekly use of cannabis
    d. Weekly use of other substances
    e. Weekly use of online games
11. For AFABs, the use of hormonal contraceptives and for natural cycling women, the menstrual cycle pattern average length, variation in cycle in the past X months, last start day of bleeding?
12. Parity and time since giving birth?

- Eligible participants will be forwarded to a second questionnaire to collect name, phone number and email address. This will be linked with the screening info with a random code. Personal data will be saved in an Excel form, saved in a different folder from screening data, on the research drive.
- Questionnaire data, all collected through Qualtrics: information on gender identity, addiction-related behaviour, ADHD diagnosis and treatment, reward-seeking behaviour:
    - 1. History of AD(H)D treatment
      a. Did you ever receive a diagnosis for AD(H)D
      b. If yes, how old were you
      c. Did you ever receive medication for the treatment of AD(H)D?
      d. If yes, what medication?
      e. If yes, how old were you when you first started using medication for AD(H)D?
      f. Are you currently using medication for AD(H)D?
      g. If no, when was the last time you used medication for AD(HD)
      2. Alcohol Use Disorder Identification Test (AUDIT)13
      3. Drug Use Disorder Identification Test (DUDIT)14
      4. Cannabis Use Disorder Identification Test (CUDIT)15
      5. Fagerstrom Test for Nicotine Dependence (FTND)16
      6. FTND for vapes and e-cigarettes17
      7. Gaming Use Disorder Identification Test (GADIT)18
      8. Multidimensional Scale of Perceived Social Support MSPSS21
      9. Country of birth, country of birth of parents
      10. Perceived social economic status22
      11. Social Media Disorder Scale (SMDS)25
      12. Conners' Adults ADHD Rating Scale self-report
      13. ADHD Rating Scale – past week

      14 Addiction related behavior in past week (weekly engagement in alcohol use, nicotine use, substance use, gaming, gambling, social media and binge eating.

      15. BIS/BAS20 adjusted to assess the current state

- Ecological Momentary Assessment Data collecterd through https://avicennaresearch.com/. only questionnaire data will be collected, no passive sensing.
    - Daily EMA will capture ratings of ADHD symptoms, reward and relief craving, and use of alcohol, nicotine/vapes, cannabis, other substances, and online gaming.

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 stored 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 operating procedure (SOP) documents are written to ensure that data collection is conducted according to standard procedures. A codebook file will be stored on the research drive to explain all variables in both the Qualtrics and Avicienna data
- All subject data will be saved under a subject number; the key will be saved in a separate document in the 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.
- This will be accompanied by a codebook that includes SOPs that explain 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 is used for the analyses

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

metadata will be added via the DataCite metadata standard.

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 who 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.

Files with personal data will additionally be encrypted and secured with a password that is only accessible to researchers who are currently working with the participant 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?

Data is owned by the Vrije Universiteit Amsterdam. PI Kaag controls access to the collected data.
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 (https://orcid.org/0000-0002-8394-6605)

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.

- Yes

Personal data such as names, addresses and other potentially identifiable information won't be made publicly available

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)?

Costs for projects under 500GB are covered by the VU.
The costs for using Avicenna are financed by the NWO XS fund by NWO (406.XS.25.03.021)