Plan Overview

A Data Management Plan created using DMPonline

Title: SEGA

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Project abstract:

Rationale: Alcohol use disorder (AUD) is one of the most prevalent psychiatric disorders in the Netherlands and characterized by high relapse rates: 50-60% of patients relapse within one year after detoxification. While the prevalence of AUD is 2-3 times higher in men (6.6%) than in women (2.3%), this gap is quickly closing. Moreover, the prevalence of AUD is suggested to be 3 times as high among gender minorities as compared to cisgender individuals. A central theory in addiction research is that compulsive alcohol use results from a shift in reward driven alcohol use to stress driven alcohol use. Recent studies suggest that women (and gender minorities) are particularly prone to stress-related relapse, whereas men are more prone to reward-related relapse, but empirical evidence of this hypothesis is scarce.

Objective: The main objective of this study is to investigate sex and gender differences in the prospective relationship between experienced stressors, craving and alcohol use during treatment and early recovery of AUD. The secondary objectives of this study are to investigate sex and gender differences in the clinical characteristics of AUD and to assess whether there are sex and gender differences in subjective and physiological alcohol cue reactivity at the onset of treatment and to explore how this is related to treatment outcome.

Study design: A longitudinal observational study

Study population: Individuals (18-64) with a primary diagnosis for alcohol use disorder, who will start cognitive behavioural treatment or an online self-help program to reduce or stop drinking

Main study parameters/endpoints:

- Objective 1: The association between stressful events, craving and next day drinking as assessed using ecological momentary assessment.
- Objective 2a: Subjective (craving) and physiological (heartrate variability) changes following a short 10-minute alcohol exposure paradigm in the first two weeks of treatment
- Objective 2b: sex and gender differences in clinical and social demographic characteristics, including alcohol use characteristics, comorbid psychiatric diagnosis, perceived social support and treatment satisfaction and positive health outcomes.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: We will follow AUD patients during treatment as usual (cognitive behavioral treatment or an online self-help program). The study will take place over a period of 16 weeks. In those 16 weeks participants will come to the research lab once, for a 90 minutes session, during which questionnaires are filled out and the participants undergo a 10-minute alcohol cue exposure session. During the exposure sessions participants will be exposed to pictures and videos of alcohol during which heartrate variability is continuously measured using an ambulatory monitoring system (VU-AMS). These exposure sessions may induce some level of stress, but are not perceived as adverse when properly supervised by a researcher. Additionally, participants are asked to fill out a short (6 questions) daily questionnaire on their smartphone to assess craving, affect, arousal, the occurrence of stressful events and previous day drinking (maximum duration of 2 minutes). Every four weeks an online questionnaire will be sent to assess alcohol use in the past 28 days (to make up for potentially missing data in the EMA assessment), treatment satisfaction and positive health outcomes. While the participants themselves will not have direct beneficial effects of the study, the knowledge resulting from this study has the potential to pave the way for the development of sex- and gender-specific treatment strategies for alcohol use disorder. The overall nature and extent of the added risk associated with participation in the current study is to be classified as negligible and the burden can be considered minimal.

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Copyright information:

SEGA

1. General features of the project and data collection

1.1 Project leader contact details

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1.2 I have composed my DMP with the assistance of a data stewardship (or management) expert. List his or her name, function, organisation/department, phone number and email address.

- The expert is connected to my department or institution (please explain his/hr expertise related to data stewardship)

Alex van der Jagt

1.3 In collecting data for my project, I will do the following:

- Generate new data

1.4 In my research, I will use:

- A combination of quantitative and qualitative data

1.5 I will be reusing or combining existing data, and I have the owner's permission for that.

- Yes, I have permission to use the data

1.6 In collecting new data, I will be collaborating with other parties.

- No

1.7 I am a member of a consortium of 2 or more partners. Clear arrangements have been made regarding data management and intellectual property. (also consider the possible effect of changes within the consortium on issues of data management and intellectual property)

- No, I am not working with 2 or more partners

1.8 I can give an estimate of the size of the data collection; specifically, the number of participants or subjects (“n=”) in the collection and its size in GB/TB

- Not yet (please explain)

Approximately 200 participants will be collected. The EMA data and survey data will be a few MB;the physiological data approximately 1 GB

1.9 The following end products I will make available for further research and verification (please elaborate briefly)

- (Several versions of) processed data

Data will be made available, anonymized, upon request

1.10 During the project, I will have access to sufficient storage capacity and sites, and a backup of my data will be available. (please elaborate briefly)

- Yes, I will make use of my institution's standard facilities for storage and backup of my data

Data will be stored during the data collection in research drive. When all data is analyzed and published, the raw data will be saved on another encrypted server.

2. Legislation (including privacy)

2.1 I will be doing research involving human subjects, and I am aware of and compliant with laws and regulations concerning privacy sensitive data.

- Yes, I will involve human subjects in my research. I will comply with the Algemene Verordening Gegevensbescherming (AVG)
- The Wet Medisch-Wetenschappelijk Onderzoek met Mensen (WMO, or Medical Research (Human Subjects) Act) applies to my project; I will have it reviewed by a Medical Research Ethics

Committee. In addition I will comply with the Kwaliteitsborging Mensgebonden Onderzoek (Quality Assurance for Research Involving Human Subjects)

The study is approved by the METC of the Amsterdam UMC:
NL81985.018.22 SEGA-studie

2.2 I will be doing research involving human subjects, and I have (a form of) informed consent from the participants for collecting their data.

- Yes (please describe the form this consent takes)

Clients at the Jellink will be contacted if they consented to be approached for research, by a Jellinek Employee (either the main investigator, the junior researchers on the projects or the students). Participants that are recruited elsewhere, register themselves and thereby consent to be contacted by the researcher.

After a telephonic interview to explain study procedures, participants are scheduled for a session at the VU. here study procedures are explained again, after which participants sign written informed consent. They have the option to indicate whether we are allowed to use their data for other research purposes and whether they want to be contacted for future research.

2.3 I will be doing research involving human subjects, and I will protect my data against misuse.

- Yes, the data will be pseudonymised. (please explain how this will be done, and by which organisation) and

All data will be stored under a code; The code-name combination will be stored on the research drive and is only accessible to the researchers and students who need to contact participants for interviews. After participants participated in the study, the key will only be visible to the main researcher.

2.4 I will stick to the privacy regulations of my organisation

- Yes

3. Making data findable

3.1 The data collection of my project will be findable for subsequent research. E.g., on a catalogue, a web portal, or through the search enginge of the repository (note: this is key item 3, which you should report to ZonMw at the end of your project).

- No, I have not yet chosen an archive or catalogue/web portal

Anonymized data will be availble upon request. It will be explored if and how we can make the data available in a search engine.

3.2 I will use a metadata scheme for the description of my data collection (note: this is key item 7, which you should report to ZonMw at the end of your project).

- No, I have not yet chosen a metadata scheme

Anonymized data will be available upon request. It will be explored if and how we can make the data available in a search engine.

3.3 I will be using a persistent identifier as a permanent link to my data collection (note: this is key item 1, which you should report to ZonMw at the end of your project).

- No, I will not be using a persistent identifier (please explain)

Anonymized data will be available upon request. It will be explored if and how we can make the data available in a search engine. If we decide to make the data available through a search engine, we will be using a DOI code.

4. Making data accessible

4.1 Once the project has ended, my data will be accessible for further research and verification.

- Yes, after an embargo period (please explain)

Anonymized data will be available upon request. It will be explored if and how we can make the data available in a search engine.

4.2 Once the project has ended, my data collection will be publicly accessible, without any restrictions (open access).

- No, there will be access restrictions to my data collection (please explain)

not all data will be made publicly accessible, as it is highly sensitive data and could theoretically be identifiable. hence only fully anonymized data will be made available, for those participants that consented to it. Anonymized data will be available upon request. It will be explored if and how we can make the data available in a search engine.

4.3 I have a set of terms of use available to me, which I will use to define the requirements of access to my data collection once the project has ended (please provide a link or persistent identifier; also note that this is a key item 4, which you should report to ZonMw at the conclusion of your project).

- Not yet, my institution will draft a set of terms of use with the help of a legal advisor

4.4 In the terms of use restricting access to my data, I have included at least the following:

- Conditions related to data security
- Agreements on methodology
- Collaboration in using the data set, including agreements on publication and authorship
- The sharing of data for commercial purposes, taking into account the provisions of state aid law
- Whether or not the data set may be linked with another data set (for reasons of privacy)
- The manner in which the data set can be accessed
- The approval of the participants allows for further research using this data set

During data collection, only researchers who need to access data and/or personal information will be given access, after signing a contract of confidentiality. Data will be saved at the research drive and won't be saved on local computers etc.

All involved researchers will work using a protocol that gives a step-by-step approach to collect and store the data.

5. Making data interoperable

5.1 I will select a data format, which will allow other researchers and their computers (machine actionable) to read my data collection (note: this is key item 5, which you should report to ZonMw at the end of your project).

- Yes (please specify)

If data is made available (either upon request or in an openly accessible archive), processed data will be shared in a CSV file. Physiological data will first be processed to get mean scores.

5.2 I will select a terminology for recording my data (e.g., code, classification, ontology) that allows my dataset to be linked or integrated with other datasets (note: this is key item 6, which you should report to ZonMw at the conclusion of your project).

- Yes, metadata standard (please specify)

All data will be accompanied by a file that explains all variable names and values.

5.3 I will be doing research involving human subjects, and I have taken into account the reuse of data and the potential combination with other data sets when taking privacy protection measurements.

- Yes, the participants have given their permission for reuse of the data, and the data have been pseudonymised

It is optional for participants to give consent for sharing their data for other purposes. Only the data of participants who gave consent will be shared with others.

6. Making data reusable

6.1 I will ensure that the data and their documentation will be of sufficient quality to allow other researchers to interpret and reuse them (in a replication package).

- I will document the research process (please explain)
- I will perform quality checks on the data to ensure that they are complete, correct and consistent (please explain)
- In addition, I will take further quality assurance measures (please specify)
- I will document the software used in the course of the project (please specify)

The project will be preregistered at the Open Science Framework, which will include a detailed step-by-step description of the research process (how is data collected), the processing of the data including quality checks (how did we get from raw to processed data), and quality assurance (which cut-off values do we use to exclude data, for example, physiological data due to incorrect labeling of heartbeats or artifacts). The software used for these analyses (e.g., R, VU-DAMS) will be described in that same protocol.

6.2 I have a number of selection criteria, which will allow me to determine which part of the data should be preserved once the project has ended. (see also question 1.9 and 6.1)

- No

6.3 Once the project has ended and the data have been selected, I can make an estimate of the size of the data collection (in GB/TB) to be preserved for long-term storage or archival.

- Yes (please specify)

The raw data (physiological and survey data) and processed data will approximately be 1GB.

6.4 I will select an archive or repository for (certified) long-term archiving of my data

collection once the project has ended. (note: this is a key item, which you should report to ZonMw at the conclusion of your project)

- Yes, and this archive meets certification criteria and intends to get certified (please explain how your data will remain accessible and reusable in the long term)

Data will be archived in Yoda

6.5 Once the project has ended, I will ensure that all data, software codes and research materials, published or unpublished, are managed and securely stored. Please specify the period of storage.

- Yes, in accordance with VNSU guidelines (please specify the number of years)

data will be stored for 10 years

6.6 Data management costs during the project and preparations for archival can be included in the project budget. These costs are:

- Unknown (please explain)

We do not have a specific budget, but this falls under administrative time. Approximately 1 hour per month.

6.7 The costs of archiving the data set once the project has ended are covered.

- Not yet (please explain)

As we have not yet decided where to archive the data, we are unsure about the costs