Sex and Gender differences in the treatment of alcohol use disorder

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Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON51556

Source
ToetsingOnline

Brief title
SEGA

Condition

- Psychiatric disorders NEC

Synonym
Alcohol addiction; alcohol use disorder

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: alcohol use disorder, gender, sex, stress

Outcome measures

Primary outcome

- Objective 1: The association between stressful events, craving and next day drinking as assessed using ecological momentary assessment.

Secondary outcome

- 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.

Study description

Background summary

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.

Study 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 burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Primary alcohol use disorder; starting treatment (either cognitive behavioral treatment or an online self-help program) to control drinking; Having a smartphone / tablet with internet access; Being between 18-64 years of age

Exclusion criteria

A current psychosis or history of psychosis
Acute suicidal ideation

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2022
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Date:	02-08-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL81985.018.22