Real time telemonitoring of physiological processes and self-reported craving processes in alcohol addiction

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON43159

Source
ToetsingOnline

Brief title
Craving monitoring study

Condition

- Other condition

Synonym
Alcohol addiction OR Alcohol dependence

Health condition

alcohol verslaving

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Craving monitoring, Ecological Momentary Assessment, Electrodermal activity, Heart Rate

Outcome measures

Primary outcome

The main study parameters are self-reported alcohol craving, self-reported

(re)lapse, Blood alcohol concentration, Electrodermal activity, Blood volume

pulse.

Secondary outcome

The second study parameters are negative affect, stress, alcohol permitted,

alcohol available, severity of nicotine craving and social activities.

Study description

Background summary

Alcohol abuse is a major societal challenge. It is currently the fourth leading unhealthy lifestyle behaviour contributing to morbidity and mortality and has devastating effects on individuals and their families. Despite the availability of different treatment options, many clients fall back into their addictive behaviour. Such relapse is typically preceded by internal (e.g. stress) or external influences such as exposure at a party. Unfortunately, these critical moments typically occur in-between counselling sessions and when (online) support is not readily available. Moreover, many clients do not recognize such early responses in time and fail to take necessary precautions. As such, to improve addiction treatment, the client would need to be supported at his/her most vulnerable moments at whatever time and place. Therefore the aim of this project is to research the possibility of a remote monitoring system that can determine craving based on self-reported and physiological data. This system unobtrusively monitors, with wearable bio-sensors, the clients physiological

craving responses in everyday life, jointly with an app to monitor self-reported psychological craving thoughts.

Study objective

The primary objective of the study is to assess whether or not physiological craving can be determined as different fluctuations prior to subjective craving or (re)lapse events when compared to non-events. The study has two secondary objectives: 1) to study the predictive value of self-reported alcohol craving to (re)lapse and whether these relations are moderated by own believe in the effectiveness of own coping skills; 2) to investigate whether negative affect, stress, alcohol permitted, alcohol available, severity of nicotine craving and/or social activities predicts subjective alcohol craving or (re)lapse.

Study design

An observational study, with an Intensive Repeated Measures in Naturalistic Settings Case-study design where participants are monitored with wearable bio-sensors and fill out questionnaires approximately six times a day for a total of 100 days. Additionally, participants fill out questionnaires at the baseline of the study and at the end of the study they take part in a semi-structured interview.

Study burden and risks

A participant attends a briefing, which entails filling out a baseline questionnaire and getting instructions on the experiment with an investment of 90 minutes, during the experiment they keep an Electronic diary were they fill out 5 questionnaires with 4 questions which take 2-3 minutes and at the end of the day the participant fills in a daily diary, which costs 8-15 minutes depending on the amount of craving moments and drinking behaviour during that day. Once a week a participant is asked to fill in an additional questionnaire with five questions, with a time investment of 3-5 minutes. Expected effort is 21-35 minutes a day over the whole 3 month period. It is assumed that during the course of the experiment the participant will get used to the questions and therefore be able to answer the questions quicker. In a debriefing session of 90 minutes at end of the experiment the experiences of participant will be discussed in a semi-structured interview.
Participants are free to collaborate in the study. They may quit the study without reason and without consequences. At the end of the experiment a participant can receive a short report of their personal data, showing them insight into their craving, mood and the other parameters collected in this experiment. This will not be a medical report, only a global overview of the results of the individual participant. A possible side effect of the study, is reactivity, the possibility that research methods themselves affect behaviour under study (Shiffman, 2009a). The participant might become more aware of their

craving, mood and believe in own coping strategies during the day, causing them to change behaviour which already might lead to less (re)lapse.
This awareness can also be a risk causing rumination, sadness or even (re)lapse. However, throughout the entire study, participants are enrolled in a treatment of Tactus addiction care meaning that they always have (online) sessions with a therapist during the study.

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

Moderate or sever alcohol use disorder according to de DSM-5 en under treatment at Tactus Addiction Care.

Exclusion criteria

Multiple user (except for nicotine)
Diagnosed with a psychiatric disease, suicidality, schizophrenia or panic disorder

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-11-2016
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	27-09-2016
Application type:	First submission
Review commission:	METC Twente (Enschede)

Approved WMO

Date:	01-11-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NL58392.044.16