Virtual reality as a treatment for alcohol use disorder

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51954

Source
ToetsingOnline

Brief title
VR as a treatment for alcohol use disorder

Condition

- Other condition

Synonym
alcohol addiction, Alcohol use disorder

Health condition

Middelgerelateerde en verslavingsstoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia (Den Haag)
Source(s) of monetary or material Support: Ministerie van OC&W,Antes

Intervention

Keyword: Addiction, Alcohol use disorder, Virtual reality, VR CET

Outcome measures

Primary outcome

The main parameter is subjective craving. Subjective craving will be measured with questionnaires and participants will be asked to fill in the ASI, Mate CRIMI: verlangen and VAS before each treatment session. After the treatment session participants will be asked to fill in the VAS again. Three months after the last session participants will be asked to answer all the questionnaires mentioned above once more.

Secondary outcome

Secondary parameter will be physiological craving and self-efficacy, measured by self-report. The non-invasive physiological measures are heart rate variability and skin conductance, which will be measured with the Biopac software. Third, after each virtual reality session, participants will be asked to fill in the therapy evaluation scale to investigate how participants experienced the virtual reality cue exposure therapy. Also, alcohol relapse will be monitored through self-report and routine urine drug monitoring.

Study description

Background summary

The abuse of substances is a major, global problem, although it is most prominent in western, developed countries (WorldHealthOrganisation, 2018). It is a problem in terms of the huge financial costs due to medical care, criminality and loss of productivity (see for example: Bouchery et al., 2011). Moreover, the enormous emotional burden suffered by addicted individuals and their environment, cannot be expressed financially.

Relapse in substance use is a common problem among alcohol and drug addicts. Therefore, many researchers have devoted themselves to developing new interventions to treat addiction problems in order to reduce relapse (Marissen et al., 2005). Substance abuse disorder (SUD) patients are known to have 50-80% relapse into substance abuse after a period of abstinence. Craving almost always precedes a relapse and is therefore seen as an important contributor to the relapse in previous substance abuse (McKay, 1999).

In recent years, virtual reality (VR) has gained ground within mental health care research, showing that the treatment of anxiety disorders with VR can be successful (Freeman et al., 2017). However, whether VR can contribute to the treatment of SUD is still largely unclear.

Lee et al. (2007) showed that craving decreased after 8 sessions of VR-CET in which 8 participants were exposed to alcohol related context and cues in VR-CET scenarios. Lee et al. (2007) therefore suggest that virtual reality may increase the effectiveness of cue exposure therapy and contribute to a decrease in craving for alcohol. In addition, they hypothesize that virtual reality may not only be useful in treating alcohol dependence but can also serve as an evaluation tool to identify high-risk patients (Lee et al., 2009). In addition, research by Son et al. (2015) shows that virtual reality treatment in alcohol addicts after 10 sessions contributes to a slowdown in brain metabolism, suggesting a decrease in craving for alcohol. However, they conclude that further studies into this form of therapy (VR CET) and the long-term effects of this needs to be further investigated. In their systematic review of 8 alcohol studies with VR Durl et al. (2018) conclude that although VR has shown positive results in alcohol studies it remains underutilized, among other things because of the high costs. They also conclude that further longitudinal empirical research is needed as only one study thus far looked into longitudinal effects. A meta-analysis (Ghita & Gutierrez-Maldonado, 2018) of thirteen studies in which virtual reality was used as a diagnostic tool and for treating craving in people familiar with alcohol abuse shows that virtual reality can be used to provoke craving and that VR CET can be used to reduce craving.

Study objective

The main goal of the study is to examine if cue-exposure therapy through virtual reality (VR CET) can contribute to decreasing subjective craving in patients who suffer from alcohol use disorder (AUD). Further, the questions will be addressed whether; 1. VR CET results in a decrease in physiological

craving, 2. To what extent do physiological measurements of craving and subjective craving correspond 3. And if it results in an increase of self-efficacy.

Study design

Participants will be recruited in the day treatment department for Addiction and Personality disorders of Antes, located in Rotterdam. They will be interviewed and asked to fill in questionnaires. During their virtual reality treatment participants will be monitored physiologically. Records will be kept of moment of discharge from treatment, as well as the reason for discharge. The outcomes of routine (drug) urine analyses will be recorded alongside of self-report on relapse in drug use. Three months after initial assessment, participants will be interviewed again to investigate the level of experienced craving in the last month and the use of addictive substances in the last three months.

Intervention

During the VR CET participants will receive an hour of VR CET twice a week for 5 subsequent weeks, 10 hours in total. The regular CBT protocol for addiction care will be used as a guideline, in which the following components will be addressed: 1. Handling risk situations, 2. Dealing with craving, 3. Refusing alcohol in social situations. During VR CET these parts will be addressed with the use of virtual reality to practice these skills in a virtual world.

Study burden and risks

The participants will be exposed to a relatively new developed virtual reality cue-exposure treatment (VR CET) in the period after detoxification. Positive treatment outcomes of virtual reality in the field of anxiety disorders are known and first results of addiction studies show that AUD patients had a decreased brain metabolism that implies a regulating effect on the limbic system and reduces alcohol craving after 10 sessions of virtual reality therapy (Son et al., 2015). Despite several positive results further research in the field of virtual reality and substance use disorders is needed, because treatment through virtual reality is not yet solidly proven to be effective in the treatment of alcohol use disorders. Therefore, t further research is needed on VR therapy focused on craving in AUD. During the VR CET patients will be exposed to alcohol related stimuli. This might cause a (temporary) increase of craving or in the most adverse situation even increase chances of relapse in alcohol abuse. However, in case of increased craving participants will be actively treated with regards to regulating their craving through stimulus respons prevention techniques. They will be offered the same relapse prevention as during standard cognitive behavioral treatment, in which attention will be paid to self-control measures, an emergency plan and insight into the pattern

that precedes relapse.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Alcohol use disorder

Exclusion criteria

Severe interfering psychiatric disorders (acute mood disorders, acute psychotic disorders and neuropsychiatric disorders).

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2022
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	CleVR VR CBT system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-06-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-03-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL76721.078.22