Preliminary study testing the ReCoVRY Virtual Reality-application as an adjuvant AUD therapy in the inpatient immediate post detoxification phase. A new Coaching Application based on Virtual Reality Exposure.

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This preliminary quasi experimental study aims to explore the experiences of patients using a newly developed VR application as an adjuvant in the treatment of AUD after clinical detoxification in DSM-5 diagnosed AUD patients. This study aims to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48455

Source
ToetsingOnline

Brief title
The ReCoVRY Virtual Reality-application as an adjuvant AUD therapy.

Condition

- Other condition

Synonym
alchol dependency, alcohol use disorder

Health condition

verslaving namelijk stoornissen in alcoholgebruik

Research involving
Human

Sponsors and support

Primary sponsor: Novadic-Kentron (Sint Oedenrode)
Source(s) of monetary or material Support: Novadic Kentron bekostigd de studie

Intervention

Keyword: Alcohol use disorder, Relapse prevention, Virtual Reality

Outcome measures

Primary outcome

In the present study a quasi-experimental study is proposed. This study provides more insights in the experience and acceptance of the use of an VR-application as an adjuvant in the inpatient treatment of AUD patients. The main study parameter is the experience and acceptance to use a VR app by AUD patient in an inpatient treatment program.

Secondary outcome

Furthermore the study will focus on the level of realism, operationalized in two different types of VR environments (360° recordings versus computer generated virtual worlds) that is experienced by the participants. In addition, the satisfaction and side effects as the level of self-efficacy and of craving experienced by the participants will be measured. The last two will be measured before and immediately after the VR-sessions. The dmCV (a hybrid measure of the SSQ and subjective symptoms of craving to differentiate from both) will be used for the exploration before (first base line measure) and after the three

sessions. The satisfaction will be measured only after the last session.

Study description

Background summary

Rationale: Alcohol Use Disorder (AUD) is a tremendous health challenge that affects the life of many people. For instance in the US over 15 million adults deal with an AUD (2015) and over five percent of the burden of disease and injury worldwide was attributable to alcohol consumption according WHO (WHO, 2012). Although treatment programs are available, about 6.7 percent received an AUD treatment (NIH, 2018). Treatment remains a challenge. According to Dutch research between 47-75% of AUD patients relapse in the first year after clinical detoxification (Snelleman et al., 2018). New digital technologies, such as Virtual Reality (VR), provide potential adjuvant treatment possibilities for AUD patients. VR is understood as an environment consisting of a mediated observation of solely virtual (digital) objects. It immerses users into virtual worlds as a multisensory and interactive experience, often supported by stereoscopic images, sound and body tracking (van Gisbergen, 2016). While being in the virtual world, the user feels a higher level of being present in the other world. VR creates patient contexts that are difficult or too expensive to simulate in clinics (Maples-Keller et al., 2017). Being in a sheltered and empowering VR environment, patients can explore challenging situations in a safe environment (Riva & Wiederhold, 2002). VR has successfully been used in psychiatry and psychology treatment programs for PTSD, phobias, and anxiety, but has not yet been developed and tested as an adjuvant tools in the immediate-post-inpatient-detoxification AUD therapy program ((Bordnick et al., 2008; Hone-Blanchet, et al. 2014; Ryan,et al., 2010; Son et al., 2015)).

Study objective

This preliminary quasi experimental study aims to explore the experiences of patients using a newly developed VR application as an adjuvant in the treatment of AUD after clinical detoxification in DSM-5 diagnosed AUD patients. This study aims to provide more insight in the experience and acceptance of using a VR-application in detoxification treatment. Furthermore, the study will focus on the effect of VR realism, operationalized in two different types of VR environments (360° recordings versus computer generated virtual worlds), negative effects of VR, satisfaction, and the intuition to use (attitude) towards the VR-intervention. In addition, the study will assess whether patients will experience strengthening of self-efficacy to stay abstinent in challenging and craving-induced environmental circumstances and the level of craving. When the outcomes are positive and this newly developed VR-software technology can be used by AUD DSM-5 patients and their therapists in the

immediate-post detoxification phase of an inpatient detoxification treatment program, a larger RCT study on long term effects will be developed.

Study design

it is an quasi experimental study that will compare three groups of 16 patients: (1) a group of AUD patients that will receive treatment as usual (TAU); (2) a group of AUD patients that will be exposed to Computer Generated Virtual reality environments and (3) a group of AUD patients that will be exposed to the same environments but recorded in 360°. The patients will receive VR as an adjuvant to the TAU AUD treatment in the last week of their stay in the inpatient detoxification unit. They will receive 3 VR sessions at day 1, 4 and 7. Prior to and immediately after each session patients will complete self-rating outcome measures. After the final session they will be asked to participate in an oral interview. The measurement instruments will address: (a) the experience of using the VR-application in AUD treatment (e.g., the ITC-Sense of Presence Inventory (ITC-SOPI); (b) the intention to use of the VR-application in AUD treatment (oral interview concerning (i) the accessibility; (ii) the affordability; (iii) the perceived usefulness; (iv) the perceived ease of use); (v) the motivation (c) possible VR negative effects (e.g., using the Simulator Sickness Questionnaire (SSQ); (d) Self-efficacy (using the Self-Efficacy scale for Drug Users-Revised (SELD-R); (e) and Craving (using among others the Visual Analogue Scale (VAS)).

Intervention

In the last week of their inpatient detoxification program patients of both the 360° and animated VR groups will have three 30 minutes VR session (day 1,4 and 7) in which they will be confronted with four different environments based on a general personal relapse prevention plan: a neutral environment, a green (safe) environment, a yellow (home) environment and orange (bar) environment. Craving levels and levels of self-efficacy will be measured prior and immediately after each session as well measures concering the patients' VR experience of the patients will be presented.

Study burden and risks

The patients burden will be the filling out of the questionnaires that will take 10 minutes before and 10 minutes at the end of each session also the session will take about 15 minutes. After the last session the patient will be interviewed for about 25 min. Total the patients burden will be around 2 hours and 10 min. In a pre-study patients were assessed in their immediate-inpatient-detoxification period. They could get acquainted with a forerunner of the VR -application and could address the side effects of application. They indicated there were no side effects but instead of side effects they experienced a high level of attraction because of a high fun

factor. So therefore we expect the burden and possible risks to be low.

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

a) Primary dependence of alcohol, (b) Age between 18 and 65 years and (c) Sufficient understanding of the Dutch language.

Exclusion criteria

(a) Severe psychiatric disorders like severe psychosis and suicidal ideations (issues); (b) severe poly-drug use (in such a way that it interfers with the

treatment); (c) severe physical diseases (cardiovascular diseases, COPD etc.),(d) mentally incompetent and (e) pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-07-2019
Enrollment:	48
Type:	Actual

Medical products/devices used

Generic name:	Virtual Reality application
Registration:	No

Ethics review

Approved WMO

Date:	09-07-2019
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	NL69690.029.19