A symptom provocation study in contamination-based obsessive-compulsive disorder using augmented reality

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The main objective of this study is investigating whether augmented reality can provoke symptoms in patients with contamination-based OCD by evaluating how this AR HMD symptom provocation compares to a traditional symptom provocation.

Ethical review Approved WMO **Status** Will not start

Health condition type Anxiety disorders and symptoms

Study type Interventional

Summary

ID

NL-OMON47525

Source

ToetsingOnline

Brief title

AR OCD symptom provocation study

Condition

Anxiety disorders and symptoms

Synonym

Anxiety, contamination fear

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: augmented reality, obsessive-compulsive disorder, symptom provocation

Outcome measures

Primary outcome

- AR HMD task, the main study parameters consist of self-reports measured by a VAS and physiological recordings of heart rate and Skin Conductance level (SCL) measured by the VU-AMS.
- Traditional Symptom Provocation task, the main study parameters consist of self-reports measured by a VAS and physiological recordings of heart rate and Skin Conductance level (SCL) measured by the VU-AMS.

Secondary outcome

N/A

Study description

Background summary

Traditional symptom provocations are an effective means for assessing symptoms. In order to further optimize traditional symptom provocations, researchers have recently proposed the use of virtual reality (VR) as a device that can be used to present dynamic stimuli. Virtual reality can be defined as a stereoscopic, computer-generated reality that enables an individual to experience all three dimensions of a virtual scene from any perspective, i.e. the first or third person perspective. In order to accomplish this, the participant wears a headset, known as a head-mounted display (HMD), which displays content that envelops their entire field of view. While this method is promising, there is a significant and inherent caveat in this design. While remaining tethered to a stationary desktop computer in order to conduct a symptom provocation, clinicians will remain unable to comprehensively understand the manifestations of these symptoms in real world settings. In order to circumvent these issues, the present research proposes to introduce a novel approach, which can be

defined as stereoscopic augmented reality with a head-mounted display for exposure based treatments. Augmented reality (AR) with a head-mounted display enables an individual to experience stereoscopic computer generated images that are overlaid into the viewer*s natural environment. The present study will therefore seek to clinically validate the use of this technology as a tool for being able to successfully elicit symptomatic responses in patients with contamination-based OCD.

Study objective

The main objective of this study is investigating whether augmented reality can provoke symptoms in patients with contamination-based OCD by evaluating how this AR HMD symptom provocation compares to a traditional symptom provocation.

Study design

This is a pilot study with behavioral outcome measures.

Intervention

Augmented Reality exposure

Study burden and risks

The risk and burden associated with participation can be considered minimal. There will be a total of 1 Traditional Symptom Provocation and 1 AR HMD symptom provocation per individual, each of which takes ~1 hour to complete. Furthermore, structured diagnostic interviews for psychiatric disorders and personality questionnaires in addition to self-report questionnaires will be administered.

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

The recruitment of participants takes place as follows. Practitioners at the department of Psychiatry will inform OCD-patients currently being treated or are currently waitlisted for treatment within our institution about our study. If someone is willing to participate in the study, we will personally visit with them at the Psychiatry department to inform them of the entire procedure. Moreover, they will receive an information letter by email that reviews all of the information again in detail in order to ensure that they have the opportunity to fully understand the procedure. If they are still interested in participating, they will sign an informed consent and we will perform screening for inclusion and exclusion criteria. Demographics and clinician-related questionnaires (Y-BOCS, GAF, HAM-D, HAM-A. BABS) will be administered to make sure that the individual can participate. If a participant meets any of the exclusion criteria, then they are excluded from participating in this study.;Inclusion criteria for OCD group:

- -Men and women.
- -Age between 25-65.
- -Recent DSM-V diagnosis (mild, moderate, and severe) of obsessive-compulsive disorder with a primary diagnosis of contamination fear.
- -Currently in treatment or are waiting for treatment in the AMC department of Psychiatry

Exclusion criteria

Exclusion criteria for OCD participants:

- A primary DSM-V diagnosis for any disorder(s) besides contamination-based obsessive-compulsive disorder or other subtype of obsessive-compulsive disorder.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled Primary purpose: Treatment

Recruitment

NL

Recruitment status: Will not start

Enrollment: 16

Type: Anticipated

Medical products/devices used

Generic name: Oculus Rift DK2

Registration: No

Ethics review

Approved WMO

Date: 29-03-2019

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 NL58465.018.18