A virtual reality game for patients with Obsessive-Compulsive Disorder

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Observational invasive

Summary

ID

NL-OMON44773

Source
ToetsingOnline

Brief title
A virtual reality game for OCD

Condition

- Anxiety disorders and symptoms

Synonym
compulsion disorder, neurotic anxiety

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: OCD, virtual reality

Outcome measures

Primary outcome

Main study parameters involve

(1) the VR-game subjective and objective output scores, in relation to

autonomic variables

(2) including heart-rate variability, skin conductance, ECG and ICG

Secondary outcome

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Study description

Background summary

Obsessive-compulsive disorder (OCD) is a chronic debilitating psychiatric disorder associated with significant impairment in social and occupational functioning. Severity of OCD symptoms is currently assessed through a clinician-rated questionnaire, the Yale-Brown Obsessive Compulsive Scale (Y-BOCS). However, using the Y-BOCS for the assessment of OCD symptom severity has important limitations that may under- or overestimate OCD symptom severity. First, retrospective assessment of symptom severity is subjective to the patient*s memory or actual state of mind. Second, the assigned Y-BOCS score is subjective to the interpretation of the clinician.
Interestingly, virtual reality (VR) can be used to create a controlled and standardized environment in which current symptom severity can be assessed without the limitations of a retrospective questionnaire. VR is a relatively new technique, starting to be implemented in the diagnostic and treatment process of diverse mental disorders. In this research project we will investigate a virtual reality game (VR-game) for OCD. This VR-game is interactive and designed to provoke and assess OCD symptoms in a controlled and standardized way. If OCD symptom severity can be assessed in this VR-game, subjective and retrospective limitations will resolve, leading to more accurate, efficient and objective OCD diagnostics.

Study objective

The main goal of this study is to validate the VR-game as a tool to provoke OCD symptoms and assess OCD symptom severity.
The first objective is to investigate whether the VR-game is able to provoke OCD symptoms in OCD patients.
The second objective is to investigate whether the VR-game is able to assess OCD symptom severity.

Study design

This study will be performed in two groups of participants. The groups consist of OCD patients and healthy controls.
Both groups will participate in a cross sectional study where VR-game output scores are studied in relation to the autonomic effects.

Study burden and risks

The risk associated with participation can be considered negligible and the burden can be considered minimal. Total participation time is 2 hours.

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

Diagnosis of primary OCD by DSM-IV criteria
Age between 18-65

Exclusion criteria

Severe neurological disorders and cardiovascular disorders.
Severe comorbid axis I disorders
Alcohol or substance abuse during the last 6 months
Use of alcohol or benzodiazepines in the 24 hours prior to investigation or recreational drugs in the 72 hours prior to investigation
Abnormal hearing and uncorrected vision

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-02-2014
Enrollment:	70

Type:	Actual

Ethics review

Approved WMO
Date: 31-01-2014

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO
Date: 02-06-2014

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO
Date: 06-07-2016

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO
Date: 10-11-2016

Application type: Amendment

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

ID: 24956
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL46697.018.13

Register	ID
OMON	NL-OMON24956