

A virtual reality game for patients with Obsessive-Compulsive Disorder: neuro-imaging

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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-OMON50305

Source

ToetsingOnline

Brief title

A virtual reality game for OCD: neuro-imaging

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: fMRI, neuro-imaging, OCD, virtual reality

Outcome measures

Primary outcome

Main study parameters involve (1) the VR-game output scores and (2) brain activity on fMRI and (3) Y-BOCS scores

Secondary outcome

Not applicable.

Study description

Background summary

Obsessive-compulsive disorder (OCD) is a chronic psychiatric disorder characterized by obsessions and repetitive compulsions. To date, a diagnosis of OCD is based on retrospective and subjective measures. There is a need for standardized and objective tools to improve diagnostics. Interestingly, virtual reality (VR) can be used to actively provoke and assess OCD specific symptoms in a controlled and standardized environment. In a former study, we showed a virtual reality game (VR-game) designed by our department is capable of inducing OCD symptoms of self-reported anxiety and compulsive behaviour in OCD patients. We will now investigate whether the VR-game is able to activate the pathophysiological substrate of OCD. This will support the objectivity and specificity of the use of the VR-game as a tool to examine OCD symptoms.

Study objective

The primary objective of this study is to investigate if the VR-game is able to activate the pathophysiological substrate associated with OCD in OCD patients, as opposed to healthy controls. The secondary objective is to investigate the correlation between the activity of the substrate and the severity of OCD.

Study design

We will perform a cross-sectional study including 9 OCD patients and 9 healthy controls. The participants will play the VR-game while time alterations in blood flow are visualized with fMRI. A comparison between OCD-patients and

healthy controls will be made. Some questionnaires to enable a psychiatric assessment of the participants and determine the severity of OCD will be obtained preceding the procedure.

Study burden and risks

The risk associated with participation can be considered negligible and the burden can be considered minimal. Total participation time is estimated around 3 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
- Use of psychiatric medication including tricyclic antidepressants, antipsychotics and benzodiazepines
- Mental retardation
- Use of medication potentially influencing cerebral blood flow and the cardiovascular system
- 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
- Irregular sleep/wake rhythm
- Contraindications for fMRI

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):	20-12-2017
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO	
Date:	18-01-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	20-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	25-06-2020
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

No registrations found.

In other registers

Register	ID
CCMO	NL59652.018.16