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

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25755

Source
Nationaal Trial Register

Brief title
VR for OCD

Health condition

obsessive-compulsive disorder

In dutch: obsessieve-compulsieve stoornis

Sponsors and support

Primary sponsor: AMC Amsterdam
Source(s) of monetary or material Support: AMC Amsterdam

Intervention

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 the VR-game 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 substrates of OCD. This will support the objectivity and specificity of the use of the VR-game as a tool to provoke and assess OCD symptoms.

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.

We will perform a cross-sectional study including 27 OCD patients and 27 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.

Study objective

The primary objective of this study is to investigate if a specifically designed VR-game is able to activate the pathophysiological substrate associated with OCD in OCD patients, as opposed to healthy controls. This will be investigated by visualizing brain activity using fMRI while participants play the game. We hypothesize increased VR-game output scores and increased brain activity within the orbitofrontal cortex, anterior cingulate cortex and the amygdala in OCD patients and relative to healthy controls.

The secondary objective is to investigate the correlation between the degree of activation of the pathophysiological substrate and the severity of OCD in OCD patients.

Study design

Subjects will participate only once, participation will take 3 hours.

Intervention

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. In the VR-game OCD patients encounter 15 OCD-specific items like running gas, an open window and a dirty toilet. They are asked to rate their emotional responses, subdivided in anxiety, tension, uncertainty and urge to control on a 0-10 visual analogue scale. Subsequently they are expected to intervene in the OCD-specific item and rate their emotional responses again afterwards. Thereafter, OCD patients have the option to perform compulsive behavior (e.g. checking or repeating the intervention) followed by another rating of their emotional responses (for an overview, see figure 1).

Contacts

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Eligibility criteria

Inclusion criteria

- Diagnosis of primary OCD by DSM-IV criteria,

- Age between 18-65

- Written informed consent of the subject

Exclusion criteria

- Severe neurological disorders (including seizures) 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 including schizophrenia like disorders and bipolar disorder

- Alcohol or substance abuse (including benzodiazepines) 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 (e.g. regular nightshifts or cross timeline travel)

- Contraindications for fMRI

Study design

Design

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

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-05-2017
Enrollment:	54
Type:	Unknown

Ethics review

Positive opinion

Date:	12-04-2017
Application type:	First submission

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
NTR-new	NL6240
NTR-old	NTR6420
Other	METC AMC : 2016_297

Study results