Virtual Reality - Cognitive Behavioral Therapy for Depression (VR-CGT-D): The effect on depressive symptoms, automatic negative thoughts and social avoidance

Published: 10-02-2020
Last updated: 10-04-2024

The study is a first step towards investigating whether VR, and more specifically changing automatic negative thoughts (ANT) and doing role play in a virtual world, is effective in treatment of a depressive disorder.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON48286

Source
ToetsingOnline

Brief title
VR-CBT-D

Condition

- Mood disorders and disturbances NEC

Synonym
Depression, Major depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Delfland (Delft)
Source(s) of monetary or material Support: GGZ Delfland

Intervention

Keyword: Automatic negative thoughts, Depression, Social avoidance, Virtual Reality

Outcome measures

Primary outcome

Primary outcome is the severity of depressive symptoms (item-total correlation of QIDS-SR).

Secondary outcome

Secondary outcomes are the severity of ANT (5 items of ATQ-30) and the extent of social avoidance behavior (subscale Social Impairment BADS). It is also examined whether these independent variables have a mediating role in the severity of depressive symptoms. Exploratory research is conducted into the extent to which the VR environment is perceived as realistic (IPQ) and patients are satisfied with VR (SRS).

Study description

Background summary

Although cognitive behavioral therapy (CBT) is an effective psychotherapy for depression, previous research shows that only 40-60% of patients with depression benefit from CBT. The CBT techniques aimed at challenging automatic negative thoughts and reducing (social) avoidance behavior in the current form may not work sufficiently enough. Innovations such as Virtual Reality (VR) can change this. VR is already regularly applied in treatment practice, but the effectiveness in treating depression has not yet been investigated.

Study objective

The study is a first step towards investigating whether VR, and more specifically changing automatic negative thoughts (ANT) and doing role play in a virtual world, is effective in treatment of a depressive disorder.

Study design

It is a nonconcurrent randomized multiple baseline single case experimental design (SCED) consisting of two phases (A and B). The primary outcome measure (severity of depressive symptoms) is measured regularly, with a total of 27-33 measurement moments.

Intervention

After a randomized baseline waiting list period, ranging from 4-6 weeks, each participant follows the same intervention according to the VR-CBT treatment protocol for depression (VR-CGT-D). The treatment protocol consists of five weekly sessions of 45-60 minutes.

Study burden and risks

Filling in the questionnaires adds extra time (3-3.5 hours) to the regular duration of treatment. In addition, a number of participants will have to wait longer with the start of the intervention than others due to randomization (although the waiting list period within the study will usually be shorter than the regular waiting time for treatment). All participants receive evidence-based CBT for depression, to which VR is added. Regular CBT interventions, namely changing negative thoughts and doing role plays, are performed in a virtual environment. The largest symptom reduction is expected within 4 weeks. In the unlikely event of no positive treatment effect, participants can quickly follow another therapy, given the relatively short-term intervention. No serious side effects are expected.

Contacts

Public
GGZ Delfland (Delft)

Sint Jorisweg 2
Delft 2612 GA
NL
Scientific
GGZ Delfland (Delft)

Sint Jorisweg 2

Delft 2612 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Major depressive disorder according to the Diagnostic and Statistical Manual, 5th edition
- Age between 18 and 65 years.
- In possession of a smartphone with internet access.
- Proficiency in the Dutch language (spoken and written). Participants must be able to follow therapy in Dutch and read Dutch questionnaires.

Exclusion criteria

- An acute risk of suicide, estimated by the practitioner by means of a suicide assessment.
- A co-morbid psychotic disorder.
- Co-morbid alcohol and / or drug dependence.
- Mental retardation.
- Participation in other psychological treatments during the research.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-07-2020
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO Date:	10-02-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-10-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL70992.078.19