Virtual Reality - Cognitive Behavioral Therapy for Depression (VR-CBT-D)

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24473

Source
Nationaal Trial Register

Brief title
VR-CBT-D

Health condition

Depressive disorder

Sponsors and support

Primary sponsor: GGZ Delfland
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Severity of depressive symptoms (item-total correlation of QIDS-SR)

Secondary outcome

Severity of automatic negative thoughts (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.
The current study is a first step to investigate whether VR, and more specifically challenging automatic negative thoughts and role-playing in a virtual world, is effective in a depressive disorder. This is a non-concurrent randomized multiple baseline single case experimental design (SCED) consisting of two phases (A and B).

Study objective

It is expected that
1. the VR-CBT-D treatment protocol reduces the severity of depressive complaints;
2. the severity of automatic negative thoughts decreases through VR-CBT-D and
3. a decrease in depressive symptoms is mediated by a decrease in the severity of the automatic negative thoughts (or possibly vice versa);
4. the degree of social avoidance decreases and
5. a decrease in depressive symptoms is mediated by a decrease of sociale avoidance (or possibly vice versa);
6. that patients will be at least reasonably satisfied with VR-CBT-D treatment and
7. the vr environment is experienced as realistic.

Study design

Primary outcome:
Severity of depressive symptoms, via item-total correlation of QIDS-SR (Quick Inventory of Depressive Symptomatology Self Report).
It concerns items 5, 10, 11, 13 and 14 of de QIDS-SR. These items are scored three times a week by the participants within the research protocol (from the assessment interview up to and including the closing interview) over the previous 24 hours. Depending on the duration of the baseline phase, this concerns a total of 27-33 measurement moments.

Secondary outcome:

1. Severity of automatic negative thoughts, via 5 items of ATQ-30 (Automatic Thoughts Questionnaire).
The five items on which the participant scores highest on the ATQ-30 (during the assessment interview) are completed three times a week up to and including the closing interview. Participants are asked to what extent the thought was present in the past 24 hours. When there are more than five highest scoring items, a random selection of five items is made. In total, the items are scored 27-33 times, depending on the duration of the baseline phase.

2. Extent of social avoidance behavior, via subscale Social Impairment BADS (Behavioral Activation for Depression Scale).
Three times a week, the items of the Social Impairment subscale are scored from the assessment interview (in total 27-33 measurement moments) and the question is asked to what extent the statement was true in the past 24 hours.

3. Sense of presence, via IPQ (Igroup Presence Questionnaire).
The questionnaire is administered at the end of the VR-CBT treatment sessions, so a total of four times.

4. Satisfaction with VR-CBT, via SRS (Session Rating Scale).
The SRS is completed at the end of each VR-CBT treatment session; a total of four times.

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-CBT-D). The treatment consists of five weekly sessions of 45-60 minutes.

Contacts

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Eligibility criteria

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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2020
Enrollment:	18
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-10-2020
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	NL8949
Other	METC Erasmus MC : MEC-2019-0744

Study results