

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

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24473

Bron

Nationaal Trial Register

Verkorte titel

VR-CBT-D

Aandoening

Depressive disorder

Ondersteuning

Primaire sponsor: GGZ Delfland

Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2020
Aantal proefpersonen:	18
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 05-10-2020

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8949
Ander register	METC Erasmus MC : MEC-2019-0744

Resultaten