Virtual Reality cognitive behavioral therapy for paranoid delusions - a randomized effect study

Gepubliceerd: 23-05-2019 Laatst bijgewerkt: 18-08-2022

Seventy percent of patients with schizophrenia and other psychotic disorders has paranoid delusions. Paranoid delusions are associated with great distress, hospital admission and social isolation. Cognitive behavioral therapy (CBT) is the main...

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

Samenvatting

ID

NL-OMON23574

Bron
NTR

Verkorte titel
VR-CGT

Aandoening

Virtual Reality, Schizophrenia, Psychosis, Cognitive Behavioral Therapy, Exposure Therapy

Virtual Reality, Schizofrenie, Psychose, Cognitieve Gedragstherapie, Exposure Therapie

Ondersteuning

Primaire sponsor: Universitair Medisch Centrum Groningen Hanzeplein 1 9713 GZ Groningen
Overige ondersteuning: Hersenstichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome is level of paranoid ideations in daily life social situations, measured with ecological momentary assessments (EMA). EMA is a structured diary method in which individuals are asked in normal daily life to report their momentary thoughts, feelings and symptoms, as well as the (appraisal of the) social context.

Toelichting onderzoek

Achtergrond van het onderzoek

Seventy percent of patients with schizophrenia and other psychotic disorders has paranoid delusions. Paranoid delusions are associated with great distress, hospital admission and social isolation.Cognitive behavioral therapy (CBT) is the main psychological treatment, but the median effect size is only small to medium. Virtual reality (VR) has a great potential to improve psychological treatment of paranoid delusions. Preliminary studies suggest that VR based CBT (VRcbt) for paranoid delusions may be more (cost-)effective than standard CBT. The aim of this project is to test this hypothesis.
In a multicenter Randomized Controlled Trial (n=106), this study will investigate if VRcbt is more (cost-) effective than standard CBT for treatment of paranoid delusions and improving daily life social functioning of patients with schizophrenia and related psychotic disorders. In both conditions participants will receive maximum 16 sessions of treatment.

Doel van het onderzoek

Seventy percent of patients with schizophrenia and other psychotic disorders has paranoid delusions. Paranoid delusions are associated with great distress, hospital admission and social isolation. Cognitive behavioral therapy (CBT) is the main psychological treatment, but the median effect size is only small to medium. Virtual reality (VR) has a great potential to improve psychological treatment of paranoid delusions. Preliminary studies suggest that VR based CBT (VRcbt) for paranoid delusions may be more (cost-)effective than standard CBT. The aim of this project is to test this hypothesis.

Onderzoeksopzet

All measures will be administered at baseline (T0), after treatment (T3) and 6 months after treatment (T6), by raters who are blind for the treatment allocation of the participants.

Onderzoeksproduct en/of interventie

VRcbt consists of maximum 16 sessions in virtual social situations that trigger paranoid

ideations and distress, delivered in an 8-12 week time frame. Standard CBT also consists of maximum 16 sessions, aiming at reappraisal of the meaning of paranoid beliefs to reduce distress and improve coping in daily life, including the use of exposure and behavioral experiments.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- DSM-5 diagnosis of schizophrenia spectrum or other psychotic disorder.
- At least a moderate level of paranoid ideations (GPTS >40).
- Age 18-65

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- IQ under 70
- Insufficient command of Dutch language

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2019
Aantal proefpersonen:	106
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	23-05-2019
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	NL7758
Ander register	Medisch Ethische Toetsingscommissie van het Universitair Medisch Centrum Groningen : METc 2018.425; ABR NL66850.042.18; UMCG 201800564

Resultaten

Samenvatting resultaten
N/A