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

No registrations found.

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

Summary

ID

NL-OMON23574

Source
NTR

Brief title
VR-CGT

Health condition

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

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

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen Hanzeplein 1 9713 GZ Groningen
Source(s) of monetary or material Support: Hersenstichting

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary outcomes include EMA level of social activities, proportion of time spent in social company, levels of distress, anxiety and depression.
Also, questionnaires and interview measures are used to assess paranoid thoughts and paranoid delusions, hallucinations, social anxiety, depressive symptoms, safety behaviors, worry, self-esteem, interpersonal sensitivity, cognitive schemas and cognitive biases. TiC-P and EQ-5D-5L measures are used to calculate cost-effectiveness and cost-utility.
In order to test differences between VRcbt and CBT in number of sessions needed to achieve clinically meaningful change, participants will complete short questionnaires on level of paranoid ideation before each session and therapists will rate participants' level of paranoid ideation after each session.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- IQ under 70
- Insufficient command of Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2019
Enrollment:	106
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

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

Study results

Summary results
N/A