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

Published: 18-04-2019
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To 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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON48557

Source
ToetsingOnline

Brief title
VR CBT for psychosis

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychosis, psychotic disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: CleVR,Hersenstichting

Intervention

Keyword: Cognitive Behavioral Therapy, Paranoid delusions, Psychosis, Virtual Reality

Outcome measures

Primary outcome

Primary outcome is level of paranoid ideations in daily life social situations, measured with ecological momentary assessments (EMA) at semi-random moments ten times a day during seven days, before and after treatment.

Secondary outcome

Mean scores before and after treatment on GPTS, SIAS, PSYRATS, SBQ, PSWQ, SERS, IPSM, BCSS and DACOBS will be compared between conditions.

Cost-effectiveness analyses (CEA) will be conducted using TiC-P and EQ-5D-5L questionnaires.

For determining number of sessions needed for achieving clinically meaningful changes, scores of patients on VAS items (based on GPTS, EMA and ORS), and scores of therapists on the GCI will be compared per session between conditions.

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.

Study objective

To 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.

Study design

Single-blind randomized controlled intervention study.

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 with social situations in daily life, including the use of exposure and behavioral experiments.

Study burden and risks

Participants will be interviewed and tested at 3 times (T0, T3, T6). This will take approximately 1.5 hours. They will also complete diary questionnaires 10 times a day during 7 days, which takes 2-3 minutes. Also, self-report questionnaires (15 minutes) will be administered weekly after appointed sessions. The patients will have a maximum of 16 sessions, with a maximum duration of 60 minutes each, during a 8-12 week timeframe. We expect patients to benefit from the therapy in both conditions. It is possible some patients may experience simulator sickness symptoms during VRcbt. No major adverse events are expected or have been documented.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

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

Exclusion criteria

- IQ under 70.
- Insufficient command of Dutch language.
- Received Cognitive Behavioral Therapy for paranoid delusions in past 12 months.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2019
Enrollment:	106
Type:	Actual

Medical products/devices used

Generic name:	Virtual Reality Social Worlds software
Registration:	No

Ethics review

Approved WMO Date:	18-04-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-09-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-11-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-06-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL66850.042.18