The effect of Virtual Reality Exposure Therapy (VRET) on social participation in people with a psychotic disorder: a multi-site randomized controlled trial.

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The objective of the study is to determine if virtual reality exposure therapy (VRET) is an effective treatment for enhancing social participation in people with a psychotic disorder or generalized social anxiety disorder. The primary objective is...

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

Summary

ID

NL-OMON40358

Source
ToetsingOnline

Brief title
Virtual Reality Exposure Therapy in Psychosis

Condition

- Schizophrenia and other psychotic disorders

Synonym
Psychosis, Psychotic disorders - and also Social Anxiety

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW,Parnassia groep;GGZ-Delfland;GGZ-NHN;NutsOhra;Fonds Psychische Gezondheid

Intervention

Keyword: Exposure, Psychosis, Treatment, Virtual Reality

Outcome measures

Primary outcome

The main outcome will be social participation. Objective social participation is measured as the time spend in the company of other people and the type of people spend time with. Subjective social participation is measured as momentary paranoia, perceived social threat and event stress as experienced in situations with other people. Social participation will be measured by the PsyMate Experience Sampling Method before and at end of treatment, and at 3 months follow-up.

Secondary outcome

Quality of life, stigmatization, safety behavior, side-effects VRET, acceptability of VRET for patients and therapists, emotional and social wellbeing.

Medication adherence during participation in the study using the Brief Adherence Rating scale to control for medication effects.

Study description

Background summary

A large number of patients with a psychotic disorder live a life of limited participation in society, even if their psychotic symptoms have been treated successfully. An important factor in sustaining social isolation is that when

social anxiety and distrust increase, the patient has learned to flee the situation and as a consequence experiences a reduction in anxiety. This is a form of conditioned avoidance that doesn*t show reduction as an effect of antipsychotic medication. The evidence based psychological treatment for experiencing fear and paranoia in social situations is cognitive behavioral therapy (CBT) with exposure in vivo. This form of treatment in vivo has its limitations. First limitation is the lack of control over the real social environment. A second limitation is that exposure in vivo is expensive and not readily available in most Dutch mental healthcare institutes. Third limitation is that not al patients find exposure in vivo an acceptable form of treatment and either not seek treatment or drop-out when they learn what exposure entails. Virtual Reality Exposure Therapy (VRET) is an evidence based treatment for several anxiety disorders. It has the potential to be an affordable and accessible form of treatment to enhance social participation and wellbeing for patients suffering from a psychotic disorder and social withdrawal. In the virtual world, fear is experienced similar to the in vivo experience, though at the same time patients know they are using a computer simulation while safe in the therapist*s room.

Study objective

The objective of the study is to determine if virtual reality exposure therapy (VRET) is an effective treatment for enhancing social participation in people with a psychotic disorder or generalized social anxiety disorder. The primary objective is to determine the effect of VRET on social participation. Secondary objectives are to research the acceptability of VRET for patients and therapists, and to explore the influence of emotional factors as stigmatization and depression on social participation.

Study design

Single blind randomized clinical trial with 3-month follow-up.

Intervention

VRET treatment has a maximum of sixteen treatment sessions with a maximum of 60 minutes each. Existing CBT protocols will be adapted for VRET treatment in one area only: exposure in vivo will be replaced by virtual reality exposure. The rest of the treatment protocol will consist of well known, evidence based, CBT elements such as; providing treatment rationale, behavioral experiments, reducing safety behavior and attention training. Starting with exposure exercises for social situations lowest in patients anxiety hierarchy, followed by more anxiety provoking situations, will be the procedure in the VRET treatment. The exposure exercises will take place during the therapy session using the Virtual Reality system.

Study burden and risks

The patients will be interviewed and tested at 3 times (T0, T3, T6). This will take approximately 3 hours. The other tests (T1, T2) will be administered during appointed sessions. The patients will have a maximum of 16 sessions, with a maximum duration of 60 minutes each, during a 8-week timeframe. We expect patients to benefit from the therapy. We expect therapy to decrease social anxiety and paranoia and to increase
social participation for patients. It is possible some patients may experience simulator sickness symptoms during VRET. No major adverse events are expected or have been documented.

Contacts

Public
Vrije Universiteit

Lijnbaan 4
Den Haag 2512 VA
NL
Scientific
Vrije Universiteit

Lijnbaan 4
Den Haag 2512 VA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients first diagnosed with a non-affective psychotic disorder experiencing at least mild paranoia and/or social anxiety.

Exclusion criteria

IQ under 70
Insufficient command of the Dutch language
Epilepsy

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-04-2014
Enrollment:	160
Type:	Actual

Medical products/devices used

Generic name:	Sony HMZ-T1 (3D-viewer)
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	23-04-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL45965.029.13