

Virtual Reality Exposure Therapy in Psychosis

Submission date 04/08/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/09/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/05/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Paranoia is a mental condition where a person falsely believes that they are being persecuted by others and is deeply suspicious and mistrustful of those around them. Many paranoid patients live restricted lives; they find relationships difficult due to being so suspicious and unfriendly, suffer from social anxiety and tend to avoid all kinds of social occasions. Here, we want to see whether virtual reality technology helps to make paranoid patients feel more able to go outside and enjoy social occasions.

Who can participate?

All patients that experience fear and avoid going outside or travelling by public transportation, etc.

What does the study involve?

The patients are randomly allocated into one of two groups. Those in group 1 have up to 16 sessions of virtual reality exposure therapy over a 3 month period. Those in group 2 are placed on a waiting list for 6 months, after which they also receive the treatment. The amount of social participation (time spent with other people, including family, friends, colleagues and strangers) and feelings of paranoia experienced in social situations is measured. All participants are assessed at the start of the treatment, at the end of the treatment and 3 months after the treatment has ended.

What are the possible benefits and risks of participating?

There are no known serious risks. Some people feel sick (cyber illness) during the virtual reality exposure.

Where is the study run from?

VU University, Amsterdam (Netherlands) and the Parnassia Psychiatric Institute in the Hague (Netherlands)

When is study starting and how long is it expected to run for?

April 2014 to December 2015

Who is funding the study?

The NutsOhra Foundation (Netherlands)

Who is the main contact?
Professor Mark van der Gaag
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
001

Study information

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

Acronym
VRET.P

Study objectives
Virtual Reality Exposure Therapy will improve real life social participation in patients with a psychotic disorder experiencing paranoia and/or social anxiety symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee of VU Medical Center; 06/03/2014; NL45965.029.13 / 2014.015

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Psychotic disorders with continuing social withdrawal

Interventions

In both arms treatment as usual will be provided for the psychotic disorder for which the person sought help. In the first experimental arm there will be a maximum of 16 sessions (over three months) of Virtual Reality Exposure Treatment with a trained CBT therapist aimed at improving social participation. Treatment duration is three months, patients will be followed-up at 3 months. The second arm entails a waiting list for a period of six month, after which these participants will also get the VRET treatment.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Experience Sampling Method (ESM) on social participation.
2. Objective social participation is expressed as the amount of time spend with other people and the type of company (for example family, friends, colleagues or strangers).
3. Subjective social participation is expressed as momentary paranoia, perceived social threat and event stress as experienced in social situations.

All measures are measured at baseline, at end of treatment at 3 months, and at follow-up at 6 months.

Secondary outcome measures

1. Depression (BDI-II)
2. Stigmatisation and schemata (ISMI, BCSS)
3. Paranoia (GPTS)

4. Social interaction anxiety (SIAS)
5. Cognitive biases (DACOBS)
6. Safety behavior (Safety Behavior Questionnaire persecutory delusions)
7. Quality of life and cost-effectiveness (MANSA,TIC-P)
8. Presence and cyber sickness (SSQ, IPQ), measured at month 1 and at month 2 during treatment.
9. Psychosis (Positive and Negative symptom scales)
10. Social functioning (Social and Occupational Functioning Assessment Scales)

Overall study start date

01/04/2014

Completion date

31/12/2015

Eligibility

Key inclusion criteria

1. Aged 18 to 65 years, either sex
2. Fullfilling diagnostic criteria for a psychotic disorder
3. Experiencing at least mild paranoia and/or social anxiety as measured with the Green et al. Paranoid Thought Scales (GPTS) and Social Interaction Anxiety Scale (SIAS)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

160

Total final enrolment

116

Key exclusion criteria

1. IQ under 70
2. Insufficient command of the Dutch language
3. Epilepsy

Date of first enrolment

01/04/2014

Date of final enrolment

31/12/2015

Locations

Countries of recruitment

Netherlands

Study participating centre

van der Boechorststraat 1

Amsterdam

Netherlands

1081 BT

Sponsor information

Organisation

NutsOhra Foundation (Fonds NutsOhra) (Netherlands)

Sponsor details

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Sponsor type

Other

Website

<http://www.fondsnutsohra.nl>

ROR

<https://ror.org/04ev7sy32>

Funder(s)

Funder type

Other

Funder Name

Fonds NutsOhra (Netherlands)

Alternative Name(s)

NutsOhra Foundation, NutsOhra Fund, Stichting Nuts Ohra

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/01/2016		Yes	No
Results article	cybersickness results	01/03/2018	18/02/2019	Yes	No
Results article	main results	01/03/2018	18/02/2019	Yes	No
Results article	cost-effectiveness results	05/05/2020	06/05/2020	Yes	No