ISRCTN12929657 https://doi.org/10.1186/ISRCTN12929657

Virtual Reality Exposure Therapy in Psychosis

Submission date
04/08/2014

Recruitment status
No longer recruiting

Registration date
08/09/2014

Overall study status
Completed

Last Edited
06/05/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
m.vander.gaag@vu.nl

Contact information

Type(s)
Scientific

Contact name
Prof Mark van der Gaag

Contact details
van der Boechorststraat 1
Amsterdam
Netherlands
1081 BT
+31 (0) 64 578 04 63
m.vander.gaag@vu.nl

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

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

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?
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
Protocol article	protocol	13/01/2016		Yes	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes