

VR-SOAP - Virtual Reality treatment for improving SOcial Activities and Participation of young people with psychosis.

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To test the effect of a novel VR treatment for social interaction difficulties (VR-SOAP) on quantity and quality of social contacts, leisure activities and social participation of young people with a psychotic disorder. Furthermore, to investigate...

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

Summary

ID

NL-OMON54752

Source

ToetsingOnline

Brief title

VR-SOAP 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: NWO,CleVR

Intervention

Keyword: Psychosis, Randomized controlled trial, Social functioning, Virtual Reality

Outcome measures

Primary outcome

Primary outcome is quantity and quality of social contacts, leisure activities and participation, measured with Experience Sampling Method (ESM). Patients will complete ESM at semi-random moments, prompted by a signal on their phone (five times a day during a period of two weeks).

Secondary outcome

Secondary outcome is the level of functioning, measured with SFS. Furthermore, determinants of social interaction difficulties are measured with PANSS, BNSS, BLERT, Hinting, GPTS-R, SIAS, SERS-SF, ISMI and DAQ.

Study description

Background summary

Young people with a psychotic disorder have the same social goals as their healthy peers, but their social networks are smaller, they participate less often in leisure activities and are less successful in work and education. Causes of these problems are multifaceted, but culminate in difficulties with interacting in daily life social situations. Current treatments have only moderate effects on social functioning. Virtual reality (VR) has a great potential to improve training of social interactions difficulties. We have developed a VR treatment for this problem. In this study it will be investigated if this treatment helps.

Study objective

To test the effect of a novel VR treatment for social interaction difficulties (VR-SOAP) on quantity and quality of social contacts, leisure activities and

social participation of young people with a psychotic disorder. Furthermore, to investigate the level of functioning and determinants of social interaction difficulties.

Study design

Single-blind randomized controlled trial with cross-over.

Intervention

VR-SOAP is a VR treatment of 14 weekly sessions, focusing on enhancing quantity and quality of social contacts, leisure activities and participation of young people with a psychotic disorder. The VR-SOAP intervention will have four optional modules (1-4) and one fixed module (5): 1. Neurocognition and negative symptoms, 2. Social cognition, 3. Paranoid ideations and Social anxiety, 4. Self-esteem and Self-stigma, and 5. Communication and Interaction skills. VR-SOAP is compared with VRelax, VR video relaxation in combination with stress management psycho-education. The VRelax intervention also consists of 14 weekly sessions.

Study burden and risks

Questionnaires and EMA are used at 3 times (baseline [T0], end of treatment [T1], six months after start treatment [T2]). The questionnaires will take approximately 145-155 minutes. Patients will complete the EMA five times a day during two weeks. The diary will consist of 35 items and will take 3-4 minutes to complete per assessment (5 x 14 x 3-4 minutes = 210-280 minutes). The patients will have 14 sessions (maximum 60 minutes), during a 4 month timeframe. We expect patients to benefit in the VR-SOAP condition. It is possible some patients may experience simulator sickness symptoms during VR-SOAP/VRelax. No major adverse events are expected.

Contacts

Public

Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Scientific

Universitair Medisch Centrum Groningen

Hanzeplein 1

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

- DSM-5 diagnosis of schizophrenia spectrum or other psychotic disorder.
- Reduced quantity or quality of social contacts, leisure activities or social participation, according to treating clinician and/or patient.
- Age 18-40

Exclusion criteria

- Estimated IQ <70.
- Insufficient command of the Dutch language.

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: Recruiting

Start date (anticipated): 23-04-2022

Enrollment: 116

Type: Actual

Medical products/devices used

Generic name: Virtual Reality Social Worlds software

Registration: No

Ethics review

Approved WMO

Date: 07-10-2021

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 05-01-2022

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 14-04-2022

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 01-12-2022

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 08-03-2023

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Not approved
Date: 14-04-2023
Application type: Amendment
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO
Date: 14-05-2024
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

ID: 27237

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL69628.042.21