

# VR-SOAP - Virtual Reality Treatment for improving SOcial Activities and Participation of young people with psychosis: a pilot study

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

## Summary

### ID

NL-OMON50129

### Source

ToetsingOnline

### Brief title

VR-SOAP: pilot

### 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:** Pilot study, Psychosis, 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 Methods (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 WHO DAS, PSP and PGGS. Furthermore, determinants of social interaction difficulties are measured with PANNS, BNSS, AQ, GPTS, SIAS, PSS, SERS, ISMI, BLERT, Hinting Task en SIAS.

## **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**

The objective of this study is to pilot this novel VR treatment for social interaction difficulties (VR-SOAP) in preparation of a subsequent randomized

controlled trial (RCT). The aim of the study is threefold: 1) to investigate the feasibility and acceptability of the therapy, 2) to evaluate and improve the treatment protocol using input from therapists and participants, 3) to explore sensitivity to change of outcome measures.

## **Study design**

Pilot study with a pre-test-post-test quasi-experimental design.

## **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 (social functioning). The VR-SOAP intervention will have four optional modules (1-4) and one fixed module (5): 1. Negative symptoms, 2. Social cognition, 3. Paranoid ideations and Social anxiety, 4. Self-esteem and Self-stigma, and 5. Communication and Interaction skills. In session 1 and 2 (introduction sessions) patient and therapist discuss the baseline assessment summary and formulate goals with regard to social contacts, leisure activities and/or social participation. Patient and therapist select two out of four optional VR modules (4 sessions each), depending on the perceived causes of the social interaction difficulties and the patient's goals. All patients will end with the Communication- and interaction skills module (4 sessions).

## **Study burden and risks**

Questionnaires and ESM are used at 2 times (baseline [T0] and end of treatment [T1]). The questionnaires will take approximately 165-175 minutes x 2 = 330-350 minutes. Optionally, an additional measurement takes place of approximately 40 minutes x 2 = 80 minutes. Patients will complete the ESM five times a day during two weeks (T0, T1). The diary will consist of 39 items and will take 3-4 minutes to complete per assessment (5 x 14 x 3-4 minutes x 2 = 420-560 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. No major adverse events are expected.

## **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.
- Reduced quantity or quality of social contacts, leisure activities or social participation, according to treating clinician and/or patient.
- Age 18-35.

### **Exclusion criteria**

- Estimated IQ <70.
- Insufficient command of the Dutch language.
- (Photo sensitive) epilepsy.

## **Study design**

## Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

## Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 27-07-2020

Enrollment: 12

Type: Actual

## Medical products/devices used

Generic name: Virtual Reality Social Worlds software

Registration: No

## Ethics review

Approved WMO

Date: 11-03-2020

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 10-06-2020

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	NL71197.042.19