

Virtual Reality treatment for improving SOcial functioning and Participation

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21243

Source

NTR

Brief title

VR-SOAP

Health condition

Psychosis (psychotic disorder).

Sponsors and support

Primary sponsor: University Medical Center Groningen (Hanzeplein 1, 9713 GZ Groningen).

Source(s) of monetary or material Support: NWO (Nederlandse Organisatie voor Wetenschappelijk Onderzoek)

Intervention

Outcome measures

Primary outcome

Feasibility and acceptability of the therapy (flow chart including the amount of patients that were invited to participate, the amount of patients that decided to participate, and reasons for not participating, drop-out and adherence rates). Also input from therapists and participants (questions about the length of sessions, order and structure of modules,

exercises, time spent in VR, acceptability, process of change, barriers and suggestions for further improvement etc.).

Secondary outcome

Sensitivity to change of suitable outcome measures: quantity and quality of social contacts, (leisure) activities and participation in daily life (measured with Experience Sampling Method [ESM]), level of functioning and determinants of social interaction difficulties (measured with questionnaires and interviews).

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 interaction difficulties. A novel VR treatment for this problem has been developed (VR-SOAP). The objective of this study is to pilot this novel VR treatment for social interaction difficulties in preparation of a subsequent randomized controlled trial (RCT). The aim of the study is threefold: 1) to determine 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. This study is a pilot study with a pre-test-post-test quasi-experimental design. Six patients will be included in the study.

Study objective

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. This impairment in social functioning can result in a lower quality of life and insecurity about the future. Current treatments have only moderate effects on social functioning. Virtual Reality (VR) has a great potential to improve training of social interaction difficulties. Therefore, we developed a new Virtual Reality intervention (VR-SOAP) for enhancing the social contacts, leisure activities and social participation of young people with psychosis. VR-SOAP is expected to be accepted by therapists and patients and that the treatment is feasible. This study aims to test this hypothesis.

Study design

All measures will be administrated at baseline (T0) and post-treatment (T1).

Intervention

VR-SOAP consists of 14 weekly sessions (60 minutes) focused on enhancing the quantity and quality of social contacts, leisure activities and participation of young people with a psychotic disorder. VR-SOAP has four optional modules (1-4) and one fixed module (5). In session 1-2 the patient and the therapist discuss the baseline assessment summary and formulate goals concerning social contacts, leisure activities and/or social participation. At the end of session 2, VR-SOAP is introduced. Patient and therapist select two out of four optional VR modules (four sessions each), depending on the perceived causes of the social interaction difficulties and the patient's goals: Negative symptoms (1), Social cognition (2), Paranoid ideations and Social anxiety (3), Self-esteem and Self-stigma (4). All patients will end with the Communication and Interaction skills module (5, 4 sessions), in which experiences, knowledge and skills from the other modules are integrated and applied.

Contacts

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Eligibility criteria

Inclusion criteria

DSM-5 diagnosis of schizophrenia spectrum or other psychotic disorder (1). Reduced quantity or quality of social contacts, leisure activities or social participation, according to treating clinician and/or patient (2). Age 18-35 (3).

Exclusion criteria

Estimated IQ <70, according to the treating clinician (1). Insufficient command of the Dutch language (2). (Photosensitive) epilepsy (3).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-07-2020
Enrollment:	6
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description

N/A

Ethics review

Positive opinion	
Date:	29-06-2020
Application type:	First submission

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

NTR-new NL8741

Other METc UMCG : METc 2019/562; ABR NL71197.042.19; UMCG 201900610

Study results

Summary results

N/A