Dynamic interactive Social Cognition Virtual Reality training (DiSCoVR): a pilot study

Published: 14-04-2016
Last updated: 17-04-2024

Primary ObjectiveIn preparation for a multicentre RCT we want to test the VR SCT for people with psychotic disorders in a feasibility study. We want to evaluate the feasibility and acceptability of VR SCT and improve the intervention protocol using...

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

Summary

ID

NL-OMON43774

Source
ToetsingOnline

Brief title
DiSCoVR

Condition

- Schizophrenia and other psychotic disorders

Synonym
Psychosis, schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: NWO;Knowledge innovation mapping (KIEM)

Intervention

Keyword: Psychosis, Social Cognition, Virtual Reality

Outcome measures

Primary outcome

The main goal of the pilot trial is to evaluate the feasibility and acceptability of the intervention and to evaluate and improve the intervention protocol. We will use feedback sessions questionnaires (completed by the therapist after each session) and post intervention evaluation questionnaires (for participants and for therapists), consisting of both quantitative and qualitative ratings to inquire about the intervention experience (e.g., was the treatment helpful, was it tolerable, was the number, frequency and duration of sessions appropriate). The following aspects will be examined with the questionnaires:

General

- Attrition rates

Participants

- Satisfaction with number and intensity of sessions
- Satisfaction with content of sessions
- Difficulty level appropriateness
- Satisfaction with VR technology (e.g., software and hardware)
- Experience (e.g., realism) of VR environments, avatars and narratives
- Strength of therapeutic alliance

- Subjective experience of training (e.g., helpfulness of training, applicability in daily life)
- Advantages and disadvantages of current approach

Training

- Protocol fidelity
- Satisfaction with number and intensity of sessions
- Satisfaction with content of sessions
- Difficulty level appropriateness
- Satisfaction with VR technology (e.g., software and hardware)
- Experience (e.g., realism) of VR environments, avatars and narratives
- Strength of therapeutic alliance
- Subjective experience of training (e.g., helpfulness of training, applicability in daily life)
- Advantages and disadvantages of current approach

Secondary outcome

To explore the efficacy of the intervention, we will examine the effect of VR SCT on several domains (see table 1 for an overview), as well as behaviour and performance during VR SCT (see table 2 for an overview).

Diagnostic Measures/ Symptoms

- Mini International Neuropsychiatric Interview Plus (MINI-plus): A structured clinical interview, used to determine diagnoses. Used to verify PD status if a diagnosis has not been verified in the past three years.

- Positive and Negative Syndrome Scale (PANSS): The PANSS is a semi-structured interview which uses self-report information and observation to assess positive symptoms (7 items), negative symptoms (7 items), and general psychopathology (16 items).
- Social Interactin Anxiety Scale (SIAS): Measures social anxiety verbally and non-verbally with a 20 item questionnaire
- Beck Depression Inventory (BDI): Measures the severity of depression with a questionnaire.
- Green Paranoid thought Scale (GPTS): Measures two dimensions of paranoid thinking with a 20 item questionnaire: ideas of social reference and ideas of social persecution.

Emotion Perception

- Bell-Lysaker Emotion Recognition Task (BLERT): An computerized affect recognition task to assess differentiation between six basic emotions in others (happiness, anger, disgust, sadness surprise and fear). Participants are shown video vignettes in which an actor expresses one of the six basic emotions and asked which emotion they recognize.
- Facial Expression of Emotion: Stimuli and Tests (FEEST): A computerized test which consists of 60 pictures portraying basic emotions (anger, disgust, fear, happiness, sadness or surprise), which the participant has to identify.
- Empathic Accuracy Task (EAT): This task consists of ten videos of people who discuss an autobiographical emotional event. Each person depicted in the videos has watched their own video and continuously rated their emotions while telling

the story on a 9-point scale. The participant has to rate the mood of the person in the video continuously on a 9 point scale. These two ratings are correlated to provide an index of empathy.

Theory of Mind

- The Awareness of Social Inference Task III (TASIT): Video vignettes of everyday social interactions. Assesses detection of lies, sarcasm, understanding of intentions and beliefs.
- Faux Pas Test (FP): administered to assess participants* ability to understand others* perspectives, thoughts and feelings, and recognition and use of social rules. Ten stories are read to the participant, of which five contain a *faux pas* (breach of social rules). Participants are asked to indicate whether a faux pas has occurred and if so, what, who, and why. Two additional questions are asked to assess empathy (how is X feeling) and comprehension (a factual detail from the story).

Social Functioning

- Personal and Social Functioning Scale (PSP): structured interview which inquires about various domains of daily life functioning (e.g., work, friendships, self-care).

Neurocognition

- Trailmaking Test (A and B) (TMT-A&TMT-B): To assess processing speed (TMT-A)

and mental flexibility (switching between two mindsets; TMT-B). In this task, numbers (TMT-A) or numbers and letters (TMT-B) are printed in circles, scattered across a page. Participants connect these numbers in correct order (TMT-A). In TMT-B, participants also have to concurrently connect letters in alphabetical order (i.e., 1-A-2-B-3-C-4-D etc).

- Nederlandse leestest voor volwassenen: measures premorbid intelligence level (IQ).

- Rapid visual information processing: a sensitive measure of sustained attention. Outcome measures for this test include response accuracy, target sensitivity, and reaction times.

Simulator sickness questionnaire (SSQ)

-Measures simulator sickness on symptom level, is administered before and after the VR exposure.

Eye Tracking

- The Oculus Rift DK2 virtual reality headset used in this study has an integrated eye tracking system (the Eye Tracking Upgrade Package of SensoMotoric instruments (SMI)) which. The SMI eye tracker delivers eyeball position, gaze vectors and size values for both eyes at 60Hz, fixation and saccades can be determined.

Heart Rate

- Hearth rate variation will be measured by electrocardiogram (ECG).

Manipulation check

A manipulation check at the end of the first VR session will assess basic memory encoding of the scenes as included in the VR exposure (i.e., scene feature recall and spatial and temporal ordering of the features depicted in the scenes and emotional reactions during the exposure (i.e., state anxiety and dissociative experiences).

- State Anxiety Inventory (SAI): State anxiety will be assessed with the State Anxiety Inventory. The SAI reflects one half of the State-Trait Anxiety Inventory and contains 20 items measuring current anxiety level. Responses to each item range from 1 (not at all) to 4 (very much so). Overall scores range from 20 to 80, and the higher the score, the greater the level of anxiety. This measure was selected due to its psychometric properties and pragmatic value and to assess the degree participants experienced state anxiety during the VR exposure.

- Clinician Administered Dissociative States Scale (CADSS): The CADSS measures state dissociation was developed to assess alterations in levels of state dissociation in a clinical population. Twenty-three self-report items are scored on a 5-point scale ranging from 0(not at all) to 4 (extremely). Overall mean scores range from 0 to 4, with higher scores indicating higher levels of state dissociation, including the symptom areas depersonalization, derealization, and amnesia. The CADSS self-report items have satisfactory reliability and validity.

- Feature binding: Scene feature recall and spatial and temporal ordering of the features depicted in the scenes will be assessed with a free recall task

and a relocation task. Virtual scenes from the VR exposure session will be played back to the participants and they will be asked to indicate the correct temporal order of the scenes and relocate specific features (e.g., avatars) in the correct spatial location within a given scene (Kessels, Postma, & de Haan, 1999).

Study description

Background summary

Rationale: People with psychosis commonly experience deficits in social cognition and social functioning. Social cognition training (SCT) has been shown to have beneficial effects on social cognition tasks, but generalization to social functioning in daily life is limited. Current SCT stimuli do not seem to be ecologically valid, and patients cannot practice skills in dynamic social interactions. We propose that this problem could be solved by providing SCT in Virtual Reality (VR). VR allows for practice of skills in situations resembling real life, yet is safe and controllable. We want to pilot this new intervention in preparation for a randomized controlled trial (RCT).
Objective: The primary objective is to determine the feasibility and acceptability of VR SCT in people with psychotic disorders. Secondarily, we want to study behavior during VR SCT and explore the effect of VR SCT on behaviour, social cognition and physiological measures.
Study design: This study is a pilot study with a patient group with a psychotic disorder (PD) and a healthy control group (HC). PD will receive the intervention, baseline and post-intervention assessment will be obtained. HC will perform a baseline measure.
Study population: PD consist of 25 individuals with a psychotic disorder and social cognition problems, age 18-65, recruited from the department of psychiatry of the UMCG and GGZ Drenthe. Twenty-five HC, age 18-65, will be recruited from employees of the UMCG and the University of Groningen.
Intervention: The VR SCT consists of sixteen sessions, which last 60 minutes each during an 8-week timeframe. During sessions, participants explore virtual environments developed to train social cognitive skills. The intervention consists of three modules: facial affect recognition, emotion recognition within a context, and theory of mind & interaction training.
Main study parameters/endpoints: Primary outcome: Acceptability, utility and feasibility of the intervention, measured using questionnaires and interviews. Secondary outcome: social cognition, neurocognitive and psychophysiological outcome measures.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: PD will be interviewed and tested at baseline and post intervention, with an average total duration of approximately three hours for each measurement. The intervention will take sixteen hours in total (sixteen sessions of 60 minutes each). We expect patients to benefit from the therapy by increasing social cognitive skills. Some patients might experience simulator sickness symptoms during the therapy. No major adverse events are expected or have been documented. HC will perform the baseline measure which will take approximately 3 hours in total and one VR SCT session of 60 minutes.

Study objective

Primary Objective
In preparation for a multicentre RCT we want to test the VR SCT for people with psychotic disorders in a feasibility study. We want to evaluate the feasibility and acceptability of VR SCT and improve the intervention protocol using input from experts and participants experience.

Secondary Objective
To explore suitable outcome measures and the effects of VR SCT on social cognition, physiological measures.
To study behaviour and physical measures (e.g. interpersonal distance, eye movement and hearth rate) during VR SCT in healthy controls (HC) and patient with a psychotic disorder.

Study design

This pilot study will be a clinical trial with an experimental group of individuals with a psychotic disorder group (PD) and HC. PD receive the VR SCT intervention and they will complete a baseline and post-intervention assessment.

HC only have one assessment (no intervention). During this measurement baseline tasks similar to PD baseline tasks will be assessed and in addition one session of VR SCT will be completed. During this session data of HC is collected on heart rate, eye tracking and performance on emotion recognition. This data is necessary to establish watching behaviour, hearth rate and emotion recognition performance in HC because no reference data of healthy people is available yet for VR SCT tasks.

Intervention

Virtual Reality set-up
Virtual environments have been developed with Unity3D software by CleVR BV. VR is offered using the Oculus Rift HMD (first consumer version) with a resolution of 1080x1200 per eye, with 110 degrees diagonal Field of View, and build in

6-DOF (Degrees of Freedom) tracking. Participants can move through virtual worlds using a joystick. The built-in tracker responds to the participant*s head movements, showing them in the virtual world (e.g., if the participant looks down in real life, their gaze in the virtual world will be shifted downward as well). The therapist controls this PC and the VR software. He or she is at all times in control of the VR intervention, and able to change or stop the virtual environment immediately if necessary. The VR program that is currently in use can project four different virtual environments: a bus, a shopping street, a store and a café. The therapist can control the content of the virtual environment in several ways, e.g., the amount of avatars walking around, the emotions that they show and the level of difficulty of exercises.

VR SCT
The SCT consists of sixteen sessions, which last 60 minutes each. During these sessions, PD participants navigate virtual environments developed to train social cognitive skills. The VR SCT is provided by a therapist, that is, a psychologist or other mental healthcare professional who has been trained to apply the treatment protocol. This therapist has the following tasks :

1. Operating the VR system and assisting the participant in the use of the VR technology (as explained above).
2. To tailor the training (e.g., difficulty level) to the abilities and needs of the participant.
3. To formulate strategies with the participant which they can use in the exercises, and to evaluate the performance of the participant during the exercises and tweak their strategies accordingly.
4. To observe the behaviour of the participant in the virtual environment and provide feedback on the utility and functionality thereof (e.g., gaze, interactive behaviours). For example, if a participant avoids eye contact with avatars, a therapist may comment on this and encourage participants to explore facial features to improve affect recognition.
5. To control the dialog function in the latter part of the training (explained below).

The intervention consists of three modules: facial affect recognition, emotion recognition within a context, and theory of mind & interaction training.

1. Facial affect recognition training. Participants walk around the virtual environment and encounter virtual characters (avatars) who show dynamic facial emotions. Participants will be trained to recognize these emotions by using strategy coaching (i.e., helping the participant to choose the most appropriate strategy to complete a task), practice, and attentional direction to salient features (i.e., the face and mouth, which provide important affective cues). Participants are encouraged to explore the avatars* facial features, and identify the emotion that they portray out of six basic emotions (happiness, surprise, fear, disgust, anger and sadness). Participants choose the correct emotion by selecting it with their joystick in a multiple-choice menu that is

shown in their field of vision. In the FAR training, we will expose patients to facial emotions and train them in emotion recognition, starting with basic emotions in a one-on-one standing situation, and gradually increasing difficulty, allowing them to practise: mixed and subtle emotions; more avatars simultaneously; walking and talking avatars; and complex, distracting situations in which facial emotions should be recognized quickly.

2. Emotion recognition within contexts. The general aim of this module is similar to the first, but in this part of the training, emotions will be placed into narratives. These narratives are provided by pre-written scenarios that are structured as a data tree.

Participants start in a basic scenario. Making a choice or giving an answer to a quesiton results in the selection of one of the data branches. If an inappropriate or incorrect answer is chosen, participants are given hints (e.g. exaggerated emotions or statements that convey emotional information more clearly) and given another opportunity to provide an answer. Thus, the flow of the narrative is dependent on the choices made by the participant, in order to make the training more naturalistic and interactive and tailored to the capacities of the participant. The questions that are asked and the answers will be presented and answered within the VR environment, to preserve a sense of immersion and presence in the virtual world.

3. Theory of Mind & interaction training. The goal of this module is for participants to learn to interpret the motivations, thoughts, intentions and implied meanings of the avatars. As in the second module, participants will encounter scenarios involving the avatars. In module 3, the emphasis is thus no longer on recognizing emotions but rather understanding the mental states underlying them. Another important difference is that in module 3, participants are no longer passive spectators: they engage in interactions with the avatars. If a mental state is misunderstood, avatars will give more obvious hints; correct answers are *rewarded* with positive reactions from the avatars. For example, if a participant reassures an avatar, the avatar may react with *Thanks, that really makes me feel a lot better* and smile at the participant. We will use a variety of tree-structure scenarios, including true belief situations (understanding what another person correctly believes) and false belief scenarios (understanding that others can have erroneous beliefs about reality and inhibiting one*s own perspective). For an example of such a scenario, see Appendix 1. The flow of the narrative is again based on the input provided by the participant. Participants are allowed to answer freely. In the data tree, these answers are categorized in a finite amount of descriptions (1: the participants answers adequately; 2: the participant answers inadequately (e.g., starts talking about a completely different subject); 3: the participant barely answers or affectively *flat*, e.g., *I don*t know* or *I don*t care*). The therapist selects the category that best fits the answer given by the

participant.

Study burden and risks

Some participants might experience mild cyber sickness. Symptoms are similar as those of motion-induced sickness, but fortunately they tend to be less severe and have a lower incidence. Some research suggests that the simulator sickness sensations can be at least partially explained by overlap with anxiety symptoms, since studies showed no increase of simulator sickness symptoms after exposure to VR and higher cyber sickness scores in patients with psychosis before but not after exposure in relation to healthy controls.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria for participants with a psychotic disorder:
1) Diagnosis of a psychotic disorder, determined by a structured interview (SCAN/ SCID/ M.I.N.I./ M.I.N.I. plus interview) in the previous three years
2) Age 18 - 65.
3) Indication of impaired social cognition by the treating therapist;Inclusion criteria healthy controls:
1) Age 18 - 65.

Exclusion criteria

1) An estimated IQ below 70.
2) Substance dependence.
3) Insufficient proficiency of the Dutch language.
4) Presence of a relevant psychiatric or neurological disorder such as autism, dementia, epilepsy or organic brain damage.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	14-04-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-06-2017
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	NL55477.042.16

Study results

Date completed:	17-08-2021
Actual enrolment:	47