Dynamic Interactive Social Cognition training in Virtual Reality (DiSCoVR) for people with a psychotic disorder

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The primary objective of the study is to determine whether DiSCoVR improves social cognition. We are interested in the effect of DiSCoVR on the following social cognitive domains:- Emotion Perception.- Social Perception.- Theory of Mind.The second...

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

Summary

ID

NL-OMON48817

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: KIEM-subsidie voor ontwikkeling van de Virtual Reality-software,GGZ Drenthe (Assen)

Intervention

Keyword: Psychosis, Social Cognition, Virtual Reality

Outcome measures

Primary outcome

The primary outcome variable of this study is social cognition:

- Emotion perception

- Social perception

- Theory of mind

Secondary outcome

Our main secondary outcome of interest is social functioning, measured in the daily life of the participant using Experience Sampling (ESM). For this purpose, participants are prompted to answer questions several times a day about their (social) activities and their assessment and experience of these activities.

We also study the following secondary outcomes:

- Information processing

- Social anxiety

- Self-esteem

- Depression

- Psychotic symptoms

- Stress

- Anxiety

Study description

Background summary

Understanding the social world in which we live, requires the ability to interpret emotions, intentions and behavior of other people. Deficits in social cognition, such as facial affect recognition (FAR), prosody and Theory of Mind (ToM), the ability to attribute mental states to oneself and others and to understand that others have beliefs, desires, and intentions that are different from one's own, are common in people with psychotic disorders (Savla, Vella, Armstrong, Penn, & Twamley, 2013). People with a psychotic disorder fail to use important communicative cues and do not properly consider social contextual information. This limits social functioning in work and relationships (Irani, Seligman, Kamath, Kohler, & Gur, 2012); it causes difficulties in finding and keeping a job, and establishing and maintaining relationships, as a result of which they can become socially isolated.
SCT is aimed at improvement of social cognition through drill and practice or strategy training. SCTs generally consist of different modules that focus on a specific aspect of social cognition (e.g., learning about emotions, understanding situations). Most SCTs feature a combination of repeated practice (restorative approach) and learning strategies to cope with deficits (compensatory approach) (Paquin, Wilson, Cellard, Lecomte, & Potvin, 2014). Social cognitive abilities are taught in a hierarchical manner, starting with fundamental skills (e.g., facial affect recognition) that are built upon with increasingly complex skills. Meta-analyses (Kurtz, Gagen, Rocha, Machado, & Penn, 2016; Kurtz & Richardson, 2012) have found that current SCT interventions for people with psychotic disorders have a moderate to large effect on performance on social cognition tasks.
The effects of SCT on daily life are most substantial when the intervention is combined with psychosocial rehabilitation (Kurtz & Richardson, 2012; Medalia & Saperstein, 2013). The stimuli that are typically used in training are distinct, however, from the dynamic, complex, interactive nature of real social interactions. Both FAR and ToM training are typically provided utilizing static pictures, text, comics or video clips. Thus, there is no opportunity for the participant to interact with the stimuli. Additionally, the tasks are isolated from other social and cognitive processes that occur simultaneously in real life situations, such as social context, conversations, body movements, background stimuli, limited time for responding before a situation changes, etc. Providing SCT directly in patients* daily lives might be more effective (i.e., having them practice with a therapist in real-life social interactions), but this is not practically feasible (Peyroux & Franck, 2014); it would require therapists to accompany patients in a variety of real-life social situations. Given the number of sessions typically needed, this is too time- and resource-consuming, and it is highly inefficient to wait for specific practice situations to occur. In addition, the presence of a

therapist changes the situation, which further limits real-life training.
A promising solution may be to provide SCT using Virtual Reality (VR).
The defining characteristic of VR is the experience of a sense of presence in an interactive three-dimensional world. A computer generates an image, which is presented to the user through a screen or a head-mounted display. The virtual world changes according to the participant*s movements and actions, because a tracker feeds back the user*s position and orientation to the computer to update the image. The result is an interactive experience that elicits psychological and physiological responses remarkably similar to those in the real world (Veling, Moritz, & van der Gaag, 2014). This considerable ecological validity offers a unique possibility to explore interactions between individuals and complex everyday environments in an experimentally controlled way. It allows practicing social cognitive skills in interaction with (virtual) others.
VR may solve current problems in SCT, because it is sufficiently realistic and interactive to induce genuine psychological reactions (Veling, Moritz, et al., 2014), yet is controllable, which facilitates structured training of social cognitive skills (such as FAR and ToM) in dynamic daily life situations. In VR, specific situations or scenarios can be customized, repeated and varied, and it allows direct feedback. VR has been shown to be feasible and effective for treatment of mental disorders (e.g., anxiety; Opri* et al., 2012), and it is a safe and valid way to study psychotic disorders (Veling, Moritz, et al., 2014).(Veling, Moritz, et al., 2014). Pilot studies showed promising treatment effects, including improvement of social skills in psychotic disorders (Park et al., 2011; Rus-Calafell, Gutiérrez-Maldonado, & Ribas-Sabaté, 2014). These studies did not specifically target social cognition, however. A study (n=8) by Kandalaft, Didehbani, Krawczyk, Allen and Chapman (2013) found significant improvements on several social cognitive domains and social functioning after a VR SCT for young adults with autism spectrum disorders. The extent to which a specialized social cognition training is effective for people with a psychotic disorder remains unknown, however. One case study (n=2) is available (Peyroux & Franck, 2016), in which two participants received a VR SCT. Substantial improvements in a variety of social cognitive and functional domains were observed. However, since this study included only two participants, it serves mostly as an indication rather than confirmation of the efficacy of VR SCT.
In recent years, our collaborating research group has developed and tested VR social environments for research of psychotic disorders (Brinkman et al., 2011; Veling, Brinkman, Dorrestijn, & van der Gaag, 2014). These environments (café, bus, supermarket and street) were used to study social behavior in VR (Counotte et al., 2017; Geraets et al., 2017; Veling, Pot-Kolder, Counotte, van Os, & van der Gaag, 2016). Additionally, the virtual environments were successfully utilized to provide a VR treatment targeting paranoia and social anxiety in people with a psychotic disorder (Pot-Kolder, Veling, Geraets, & van der Gaag, 2016). The café, supermarket and street worlds served as a basis for developing the VR SCT environments.
In the previous year, we have conducted a pilot study on the

acceptability and feasibility of this VR SCT, called DiSCoVR (Dynamic Interactive Social Cognition training in Virtual Reality, registered under: NL55477.042.16). Preliminary analysis on the first twelve participants shows that they enjoyed the intervention, thought it was moderately useful for daily social contact, enjoyed the combination of VR and a therapist, and judged the difficulty level of the intervention to be adequate. At the time of writing, two of the twenty-one currently included participants have dropped out. Preliminary testing suggests that DiSCoVR significantly improves emotion perception and self-esteem. Our next step is to test DiSCoVR in a larger study, to be able to draw conclusions on its efficacy on daily life social functioning and social cognition.

Study objective

The primary objective of the study is to determine whether DiSCoVR improves social cognition. We are interested in the effect of DiSCoVR on the following social cognitive domains:
- Emotion Perception.
- Social Perception.
- Theory of Mind.

The second objective of DiSCoVR is to investigate the impact of DiSCoVR on social functioning. Additionally, the effect of DiSCoVR on secondary domains of interest is investigated, including self-esteem, depression and social anxiety.

Study design

The study will be a multicenter Randomized Controlled Trial with two groups: a group receiving the VR SCT, DiSCoVR, and an active control group, virtual reality relaxation therapy (VRelax), matching the intervention as closely as possible in terms of visits, content and attention received. Participants will be randomly allocated to one of these groups. Both the intervention and the active control conditions consist of sixteen 45 to 60-minute sessions, provided over the course of eight weeks. Social cognition and social functioning will be assessed at three points in time: at baseline, post-treatment, and at three months after completing either DiSCoVR or VRelax. These assessments will be performed by research assistants who are blind to the participant's study condition. The DiSCoVR group will receive one additional assessment, between sessions 1 and 2. In this assessment, a VR task and two questionnaires will be completed.

Intervention

The SCT consists of sixteen sessions, which last 45-60 minutes each. During these sessions, participants in the VR SCT group 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 behavior of the participant in the virtual environment and provide feedback on the utility and functionality thereof (e.g., gaze, interactive behaviors). 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).
6. Reporting (e.g., session content, duration, protocol deviations).

DiSCoVR consists of three modules, targeting different domains of social cognition: emotion perception; social perception & ToM; and social interaction training. At the end of each session, participants are given an (optional) homework assignment, which are intended to promote the use of the intervention*s techniques in daily life.

Module 1: Emotion Perception (sessions 1-5)
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. Homework exercises during this module include recognizing emotions in the home environment, so that participants learn to employ FAR strategies in their daily lives.

Module 2: Social Perception & ToM (sessions 6-9)
In this part of the intervention, participants witness conversations between avatars. The goal of this module is to place emotions into a narrative. By introducing context, participants are taught to consider situational information in order to judge the thoughts, emotions and behaviors of others.

The social scenarios generally include multiple versions and/or endings, in which many factors are equal but one crucial factor differs: e.g., an avatar is having a good day or a bad day, which is reflected in their reactions. At different points during the scenario, the participant is prompted to assess the emotions and/or thoughts of the avatar. If the participant gives a wrong answer, the avatars will more explicitly state their thoughts, intentions and/or emotions, after which participants are prompted to try again. Participants analyze social situations by assessing (the relations between) thoughts, emotions and behavior. Using this *GGG-model* (gedachten, gevoelens, gedrag), participants learn to understand why others act in a certain way and how mental states are influenced by situations and other people. At this stage in the intervention, homework exercises consist of assessing thoughts, behavior and emotions of participants themselves and others in their daily environments.

Module 3: Social Interaction Training (sessions 10-16)
In the final module, participants learn to apply the techniques and strategies they acquired in the first two modules. They practice in one-on-one role play interactions in the virtual environment. The therapist interacts with the participant through an avatar, using a transformed voice. Since the participant is wearing the VR headset and noise cancelling headphones, it appears to them that they are interacting with a virtual person. Role play situations are tailored as much as possible to the participant*s goals; however, occasionally, standard scenarios are used, for example, in case participants do not contribute situations they*d like to practice with. To help participants determine how to react in a social situation, participants use a series of steps: 1) determine your own thoughts, emotions and behavior (GGG); 2) determine the other person*s thoughts, emotions and behavior (GGG); 3) list the possible ways you could react; 4) evaluate how desirable each option is (and, if possible, practice it by role playing); and 5) choose the reaction with the most desirable outcome. In the final part of the intervention, participants use this series of steps in difficult social situations they encounter in their daily lives.

The control condition also consists of 16 weekly one-on-one sessions of 60 minutes with a therapist. It is matched to the DiSCoVR condition for therapist contact and use of VR. VRelax is relaxation therapy using 360 degrees videos in VR (www.vrmentalhealth.org). The videos are played using a Samsung Gear VR head-mounted display, powered by a Samsung Galaxy smartphone. Several environments are available, including swimming with dolphins, a beach and a forest. Relaxation exercises such as progressive muscle relaxation and guided meditation are embedded in the videos. Participants can look around in 360 degrees by moving their head. The Gear VR registers head movement and adjusts the image accordingly. Participants can navigate between environments and activate relaxation exercises by looking at hotspots within the videos.

Study burden and risks

Participation in the study implies the following time investment:
- Three measurements of approximately two hours each
- 30 minutes per day of experience sampling, for a week, at all three measurement occasions.
- 16 hours of therapy
- For DiSCoVR participants, an extra assessment of 30 minutes.

We do not anticipate any adverse side effects of participation. Some people may experience cyber sickness when they use VR. The symptoms of this resemble motion sickness, including dizziness and nausea. After removing the VR headset, cybersickness usually passes quickly. Importantly, cybersickness also appears to be caused or exacerbated by stress and / or anxiety. With repeated (gradual) exposure, it is less likely that participants will suffer from cybersickness.
To prevent cyber sickness, the protocols are structured in such a way that the time in VR is gradually increased.

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

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
4. Written informed consent.

Exclusion criteria

1. An estimated IQ below 70, and/or a diagnosis of intellectual disability.
2. Insufficient proficiency of the Dutch language
3. Epilepsy.

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:	Recruitment stopped
Start date (anticipated):	09-04-2018
Enrollment:	100

Type:	Actual

Ethics review

Approved WMO Date:	13-12-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-05-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	09-10-2019
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	NL63206.042.17

Study results

Date completed:	01-10-2022
Actual enrolment:	83