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Social cognitive therapy in virtual reality for early psychosis

Submission date	Recruitment status	[X] Prospectively registered
25/09/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/10/2017	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/04/2020	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Psychosis is a mental health condition that causes people to perceive reality differently. Many people with psychosis struggle to engage with traditional face-to-face treatments. This is especially true for service users who have difficulties with social cognition (how people make sense of the social world) and social functioning (how people get along with others and engage in day-to-day activities). Therapies designed to improve social cognition and social functioning usually involves working with people individually or in groups. However, many services users find it difficult to attend face-to-face therapy; for example, when motivation to leave the house is low. New technologies like 'virtual reality' (VR) and 'virtual worlds' are an exciting new area of development with huge potential to help service users with psychosis overcome some of their anxieties about attending face-to-face therapy, at least in the initial stages, as VR therapies can be delivered at a person's home (a less threatening environment). The research team through a consultation process with service users, researchers and computer designers created a virtual world to deliver an existing social cognition training package. The adapted training package are tested with a small number of service users who had a first episode of psychosis and are in stable condition. The aim of this study is to find out if it is feasible the study is, how acceptable the package is to service users in order to plan a larger study to test if the VR training package improves service user's social skills and social functioning.

Who can participate?
Adults aged 18 to 45 years old who are service users with diagnosis of first episode psychosis.

What does the study involve?
Participants receive a social cognition interaction training programme using virtual reality environment. The participant joins a therapy group with three more people. A week before the therapy starts, participants are trained to use the VR environment. Participants attend the group sessions from home on a date and time agreed, twice a week for four weeks. After eight sessions the research team contact participants to schedule a visit and ask them to complete the same questionnaires and tests they completed before the start of the therapy. 10 participants are asked for an exit interview to talk about their experience in the study. After the study, participants continue under the care of their care coordinator and team. Participants are followed up to examine if they have gained skills to understand and respond to social situations.

What are the possible benefits and risks of participating?
Participants may benefit from the therapy as it is an opportunity to improve skills and confidence in social situations. There is a great potential to improve reach and reduce treatment costs by using virtual reality. There are some individual risks with participating in this study. Participants will potentially share sensitive information during online therapy. This is because the virtual reality version of the SCIT therapy will be developed in Second Life®, an online platform. The research team has made adjustments to the environment to guarantee safety and privacy during online therapy. Participants may share confidential information during assessments. Every effort will be made to preserve confidential information. An identification number will be assigned to individuals and will be kept separate from personal information. Participants may feel distress during assessments or therapy sessions. This is an expected reaction of being in therapy. Parts of the clinical assessment interview and therapy may be upsetting for some participants. The interview or participation in the study may be stopped and consent may be withdrawn by either the researcher or participant at any time if it is deemed too distressing for the individual. Participants will have a list of contact details for seeking help in a crisis (e.g. calling Crisisline, the Samaritans or go to A&E). This information will be also displayed in the VR environment in Second Life®. However the VR environment is not an emergency tool, it is not monitored for 24 hours a day. Content in the VR environment is for information purposes only and the therapy is meant to help self-manage. Also, participants may lose connection during the therapy sessions. Failure to connect or losing connection whilst attending group therapy can be distressing for participants. In order to address this issue, connectivity will be assess before starting therapy. A mobile telephone line will be available to participants one hour before each session and until the end of the session.

Where is the study run from?
Avenue Clinic (UK)

When is the study starting and how long is it expected to run for?
February 2016 to October 2018

Who is funding the study?
MQ: Transforming Mental Health (UK)

Who is the main contact?
Dr Alba Realpe
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Contact information

Type(s)
Scientific

Contact name
Dr Andrew Thompson

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
35917

Study information

Scientific Title
Virtual reality as a method of delivering social cognitive therapy in early psychosis

Acronym
VEEP 1

Study objectives
This study is a proof-of-concept trial that aims at answer the following research questions:
1. Is it possible to adapt part of a face-to-face delivered SCIT programme to a virtual reality environment?
2. Is this adapted intervention feasible and acceptable to deliver to a first episode psychosis (FEP) group?
3. Does the virtual world environment improve later uptake of social cognition training and other psychological interventions?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Non-randomised; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Mental Health, Primary sub-specialty: Psychosis; UKCRC code/ Disease: Mental Health/ Organic, including symptomatic, mental disorders

Interventions
A proof-of-concept single-centre trial of an adapted intervention to virtual reality for patients experiencing their first episode of a psychotic disorder. Feasibility, acceptability and usability of the platform as well as intention to engage in further therapy is assessed using mixed methods (including validated questionnaires and individual interviews).

Social Cognition Interaction Training programme (SCIT) is delivered. This intervention targets dysfunctional social cognitive processes, including problems with emotion perception and Theory of Mind, hasty judgment making, and biased social attributions. SCIT is group psychotherapy for individuals with psychotic symptoms. SCIT is a type of Cognitive Behavioural Therapy (CBT). The SCIT is a three stage, manualised group intervention specifically comprising: (i) emotion recognition training; (ii) recognizing attributional styles and (iii) skills integration. This version of the SCIT intervention is abbreviated and comprises eight sessions of 45 minutes twice weekly in a virtual reality environment. There is no control group. The purpose of this therapy is to help people gain skills to understand and respond to social situations. Situations like having conversations with family, friends, co-workers, and people in general. Teaching materials include slide presentations, videos, games, and group discussions.

After consent has been signed, a researcher asks the participants complete a series of questionnaires and video tests. The participant joins a therapy group with three more people. A week before the therapy starts, participants are trained to use the VR environment. Participants attend the group sessions from home on a date and time agreed, twice a week for four weeks. After eight sessions the research team contact participants to schedule a visit and ask them to complete the same questionnaires and tests they completed before the start of the therapy. 10 participants are asked for an exit interview to talk about their experience in the study. After the study, participants continue under the care of their care coordinator and team.

Intervention Type
Behavioural

Primary outcome measure
Feasibility, acceptability and usability of the platform as well as intention to engage in further therapy are assessed using mixed methods including attendance records, validated questionnaires and individual interviews at the end of the intervention (i.e. soon after the end of the eight sessions).

Secondary outcome measures
1. Social Function, Quality of Life and Behavioural Change Intention are measured using the Personal and Social Performance Scale (PSP), EuroQual 5-D scale, Theoretical Domains Framework – Domain Four (TDF – D4) and Theoretical Domains Framework – Domains Eight and Nine at baseline and end of intervention

2. Social Cognition is measured using the Social Cognition Screening Questionnaire (SCSQ), the Bell Lysaker Emotion Recognition Task (BLERT), the Hinting task, the Cognitive Style Questionnaire – Short Form (CSQ-SF) and the Awareness of Social Inference Test (Part III: Social Inference—Enriched) - (TASIT) at baseline and end of interventions
3. Demographics, using Basic demographic information, including educational and employment data, will be collected as well as information about service use at baseline
4.Psychosis diagnosis is assessed using the Clinician diagnosis will be recorded from the notes based on the categories from the DSM-IV at baseline and end of intervention
5. General psychopathology is measured using the Brief Psychiatric Rating Scale (BPRS) and the Duration of Untreated Psychosis (DUP) as measured routinely by clinicians at baseline and end of intervention
6. Neuocognitive variables are measured using the National Adult Reading Test (NART) and the Trail Making Test at baseline and end of intervention

Overall study start date
01/02/2016

Completion date
01/10/2018

Eligibility

Key inclusion criteria
1. Males and Females
2. Adults between 18 and 45 years old
3. Any service users with a diagnosis of first episode psychosis treated by the Early Intervention for Psychosis team

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 20; UK Sample Size: 20

Total final enrolment
20

Key exclusion criteria
1. In the acute phase of a psychotic episode (i.e. under care of the acute (inpatient) services or the crisis team)
2. < 18 years, as they cannot access the ‘Second Life’ under the rules of this platform (Linden

Labs)
3. Lack of fluency in English (spoken and written), since this is required to complete the assessments and follow intervention instructions
4. A known diagnosis of a moderate intellectual disability due to some of the content delivered during the intervention requiring a certain level of understanding

Date of first enrolment
15/11/2017

Date of final enrolment
15/05/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Avenue Clinic
Manor Court Avenue
Coventry and Warwickshire Partnership NHS Trust.
Nuneaton
United Kingdom
CV11 5HX

Sponsor information

Organisation
University of Warwick

Sponsor details
Research & Impact Services
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Sponsor type
University/education

ROR

https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
MQ: Transforming Mental Health

Alternative Name(s)
Mental Health Research, MQ: Transforming Mental Health, MQ

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results from the feasibility trial will inform a grant proposal to investigate the efficacy of the modified intervention in an appropriately powered (informed by the pilot study) study (e.g. NIHR HTA). Dissemination plans will involve describing the co-design process and the results of the feasibility study to a wide array of stakeholders; members of the research team have active roles in national mental health bodies. Locally, through collaboration with the West Midlands CLARHC (Co-Investigator MB is the lead for the mental health stream) research findings will be disseminated to wider patient, carer and professional groups.

The research team has access to wide range of media channels through Warwick University Public Relations Department and has previously been able to use this to access a wider public audience in research findings (including the BBC and time magazine). Findings will also be disseminated through the MQ Mind the Gap newsletter and any MQ public engagement events if this was possible/appropriate.

Intention to publish date
01/02/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from principal investigator, Dr Andrew Thompson (Andrew.D.Thompson@warwick.

ac.uk). The sponsor, The University of Warwick, has defined a scheme for the classification of information and how it should be handled and transferred according to its requirements for confidentiality, integrity and availability. All data sharing in this study will follow this guidance. Any requests from external parties to share data will be discussed and agreed within the Study Management Group and the approval will be formally minuted. The data sharing agreement will then be completed by the requester and signed as approved by all the required signatories prior to the collation and transfer of any data.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/03/2020	15/04/2020	Yes	No