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Virtual reality group therapy for depression

Submission date	Recruitment status	[X] Prospectively registered
25/08/2020	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/09/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/03/2021	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Non-attendance to group therapy is a significant issue for patients with depression. To improve access to group therapy, the NHS has recommended the use of digitally enabled therapies such as mobile application-based self-help. These therapies aim to reduce the cost of services, time and travel associated with treatment, and the perceived stigma of having to go to a treatment centre.

Virtual reality is a technology that allows users to experience computer-generated environments within a controlled setting. Users can access these computer-generated environments by inserting their smartphone into a head-mounted display (goggles), e.g. Samsung Gear VR. This technology is a feasible, acceptable, and cost-effective tool in the treatment of several different mental health disorders.

In this study, virtual reality will be used to deliver and receive group therapy remotely. The patients and the therapist will access the group at home using a goggle with smartphone insertion and an online application called vTime (vTime, Limited, 2018). During group therapy, the therapists and the patients would be anonymous and represented by an avatar (an abstract character). The Virtual Reality Group Therapy sessions will consist of 3 patients and one therapist. The treatment will consist of 8 sessions delivered once a week for 45 minutes.

This study aims to assess the functionality, feasibility and acceptability of the Virtual Reality Group Therapy intervention.

Who can participate?
Adult patients that have a diagnosis of mild to moderate depression

What does the study involve?
The Virtual Reality Group Therapy will consist of 8 sessions delivered once a week for 45 minutes. A single sample of 6-8 participants will be asked to complete the same questionnaires and measures at the start and end of the trial. Then, to assess the feasibility and acceptability of theVirtual Reality Group Therapy sessions, the participants will be invited to take part in a semi-structured interview.

What are the possible benefits and risks of participating?
Possible benefits include:
1. Improved accessibility/convenience as participants would receive treatment remotely from home. The remote nature of the treatment might especially benefit patients who struggle to leave the house due to physical disabilities (e.g. bedbound or wheelchair using patients, who lack the motivation to leave the house, who work during service hours, and who live in remote locations.
2. Patient engagement during treatment as during Virtual Reality Group Therapy, the therapists and the patients would be anonymous and represented by an avatar. This could potentially improve therapeutic engagement. Avatars increase the anonymity of patients, reduce the perceived stigma of attending group treatment, and limit the non-verbal cues received from other group members. All of this contributes to patients having more open and honest conversations in the group, leading to better therapeutic engagement.
3. Potential cost-savings of virtual treatment as Virtual Reality Group Therapy would be delivered remotely, so therapists would no longer need large buildings with multiple rooms to provide group therapy, and patients would no longer have to pay for travel. As a result of the remote nature of the treatment, patients may no longer be limited to services offered in their Borough, but could also access specialised services delivered in different Boroughs. This could potentially lead to distributing specialist resources across the country.

Possible risks include:
1. Cyber-sickness as during treatment, patients will be asked to join a virtual environment by wearing a head-mounted-display (goggle) with a mobile phone insertion. The HMD is a Conformite Europeene (CE) marked consumer product that is widely available in stores; therefore, it conforms with health and safety standards. If used for very long durations, virtual reality could induce cybersickness, which is a form of motion sickness with symptoms such as nausea and disorientation. To reduce risks of cybersickness, the virtual reality treatment sessions have been limited to 45 minutes. Furthermore, the virtual environments selected for therapy are serene locations which patients will experience seated. These factors will further reduce any possibility of cybersickness.

This treatment will be delivered remotely; patients will access this treatment online from home. Similar to all treatments offered online, there is an issue of managing any patient risk remotely (e.g. self-harm or suicide). The study eligibility criteria have been designed to limit any risks that may arise during treatment. The intervention will be delivered by a senior group therapist who has experience providing online treatment. The therapist is fully trained in risk management and NHS Trust safety policies. Risks such as suicide will be checked before each session, and if the therapists identify a need, a follow-up call will be given to the patient to manage the risk.

Where is the study run from?
The study will be run from the Unit for Social and Community Psychiatry (UK). The unit is jointly operated by Queen Mary University of London and East London NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
From October 2020 to March 2021

Who is funding the study?
This study is funded by East London NHS Foundation Trust (UK) as part of the researchers PhD

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
287460

Study information

Scientific Title
Virtual Reality Group Therapy for Depression: A proof of concept feasibility study

Acronym
VRGT

Study objectives
1. To assess the functionality of the Virtual Reality Group Therapy intervention
2. To assess the feasibility and acceptability of the Virtual Reality Group Therapy intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending, ethical approval will be sought from a Health Research Authority Research Ethics Committee by October 2020

Primary study design
Interventional

Study design
Single-centre interventional proof-of-concept trial repeated measures design

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild to moderate depression

Interventions
Virtual reality will be used to deliver and receive group therapy remotely. The patients and the therapist will access the group at home using a head-mounted display with smartphone insertion and an online application called vTime (vTime, Limited, 2018). During group therapy, the therapists and the patients would be anonymous and represented by an avatar (an abstract character). The VRGT sessions will consist of 3 patients and one therapist. The treatment will consist of 8 sessions delivered once a week for 45 minutes.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Occulus Gear VR

Primary outcome(s)
1. Functionality and feasibility of the intervention calculated using the following:
1.1. Recruitment rates collected using an excel recruitment spreadsheet at the end of recruitment.
1.2. Treatment attendance rates collected using treatment adherence log between baseline and 8 weeks
1.3. Reasons for drop-out collected using treatment adherence log between baseline and 8 weeks
1.4. Interest in VR treatment collected using interest in VR questions at baseline/enrolment and 8 weeks
1.5. Therapeutic relationship using the Working Alliance Inventory at 8 weeks or point of drop-out.
1.6. Acceptability using a client satisfaction questionnaire at 8 weeks or at point of drop out.
2. Self-reported measure of depression measured using the Patient Health Questionnaire-9 (PHQ-9) will be collected at baseline, before each treatment session at 1, 2, 3, 4, 5, 6, 7, and 8 weeks, and post-intervention after 8 weeks.

Key secondary outcome(s)
1. User experiences of VRGT explored qualitatively through interviews at 8 weeks

Completion date
29/03/2021

Eligibility

Key inclusion criteria
1. Referral from primary care for the treatment of mild to moderate depression (stepped 2).
2. No history of ongoing suicidal attempts or current tendency towards self-harm
3. Able to understand written and verbal English
4. Eligible for group therapy
5. Aged ≥18 years
6. Access to a smartphone
7. Access to Wi-Fi at home
8. Has an email account
9. Capacity to give consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Unwilling or unable to give consent
2. Having a diagnosis of depression with psychotic symptoms (ICD-10: F32.3 and F33.3)
3. Associated diagnosis of an organic or neurodevelopmental disorder
4. Participation in another trial

Date of first enrolment
10/10/2020

Date of final enrolment
10/11/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Newham Talking Therapies
Vicarage Lane Health Centre

10 Vicarage Lane
Stratford
London
United Kingdom
E15 4ES

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
East London NHS Foundation Trust

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date