ISRCTN57462718 https://doi.org/10.1186/ISRCTN57462718

Can we treat depression with self-compassion using virtual reality?

Submission date
10/06/2022

Recruitment status
No longer recruiting

Registration date
29/07/2022

Overall study status
Completed

Last Edited
28/06/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
New technologies provide more opportunities than ever before to work creatively with people affected by depression. One of these technologies is virtual reality (VR), which creates environments and scenarios that people can interact with as if they were real. Virtual reality can be used to help people experiencing depression explore and practise being more compassionate towards themselves.
Research shows that compassion plays an important role in general well-being and mental health, and that learning to be more self-compassionate can help people with depression to feel better. There are existing psychological therapies which aim to help people develop a more compassionate relationship with themselves. However, not everyone with depression finds it easy to access these therapies, partly because they are relatively time-consuming and expensive. Some people also struggle with parts of the therapy that involve remembering or imagining positive experiences of compassion from other people.
This study aims to find out if a new therapy that combines compassion-based therapies with VR technology is helpful and practical for people with depression who are registered with NHS psychology therapy services. This new virtual reality therapy is based on what is already known about depression, self-compassion, and how virtual reality affects the brain, mind, and body. It has been developed based on research in which practising self-compassion in virtual reality helped people to think more positively about themselves, and in the case of people with depression, helped them feel less depressed. People who have experienced depression have also been actively involved in creating this new virtual reality therapy.

Who can participate?
Adults over the age of 18 who are on the waiting list with Camden and Islington Psychological Therapies Services (iCope) for help with depression. The researchers will contact people who gave their consent to be contacted about relevant research studies when they registered with the iCope service to see if they would like to take part.

What does the study involve?
Everyone who decides to take part will be asked to fill some questionnaires at the start of the study and then again at two and six weeks later to measure changes in their depression and overall wellbeing during the study.

People will also be divided into randomly into two groups. One group will try out the new virtual reality therapy. The other group will not try out the virtual reality therapy but will fill out the same questionnaires. This group is included so that the researchers can compare the two groups and see if the virtual reality therapy made a difference to those who tried it.
The people in the virtual reality group will be offered four one-hour therapy sessions over the first two weeks of the study. These sessions will involve working one-to-one with a facilitator who will guide them through different activities both inside and outside of the virtual reality environment. They will wear a virtual reality headset and experience what it's like to be in a 'virtual body' that moves and speaks in real time. The virtual reality part of the sessions involves being compassionate to a virtual character who is upset, and then switching bodies with this character to see and hear their own compassionate response played back to them from the point of view of the upset character. People in this group will also do some brief exercises at home to think about and practise being self-compassionate.
At the end of study, everyone will be asked some questions about their experiences of taking part in the research. Everyone who takes part will stay on the waiting list for NHS therapy for their depression so that taking part will not affect how long they wait to start therapy.

What are the possible benefits and risks of participating?
People in the virtual reality group may benefit from trying a new type of therapy that has been shown in previous research to have a positive impact on people's wellbeing. As a result, they may become more compassionate and less critical towards themselves and find that their depression improves. Some people find that taking part in research like this gives them a sense of satisfaction knowing that they are helping to improve services for people like them. Therefore, people in both groups may feel satisfaction in helping to make more therapy choices available to other people with depression.
There are unlikely to be any major risks in taking part. Sometimes people get short-term side effects such as motion sickness or changes in vision when they use virtual reality, although this has so far not been the case with this virtual reality set-up, which is designed to make these side effects less likely. People may find that some of the questionnaires or activities involved bring up difficult or uncomfortable memories or feelings. The study has been designed with advice from people who have experienced depression to help make taking part as comfortable, safe, and accessible as possible.

Where is the study run from?
The study is being run by University College London (UCL) and takes place at the UCL University Clinic, which is a part of the Camden and Islington NHS Foundation Trust Psychological Therapies Service located on UCL premises.

When is the study starting and how long is it expected to run for?
March 2022 to June 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) Invention for Innovation (i4i) programme (ref: II-C8-0518-20002) (UK)

Who is the main contact?
1. Prof John King
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Study website
https://www.virtualcompassion.net

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
287198

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52630, II-C8-0518-20002, IRAS 287198

Study information

Scientific Title
Treating Depression with Self-Compassion using Virtual Reality: Feasibility and Acceptability Study (VRCom-F)

Acronym
VRCom-F

Study objectives
This study aims to test the feasibility and acceptability of a randomised control trial of delivering the scaled-up treatment within a clinical setting as an adjunct to psychological therapy. If successful, the results will also be used to generate an estimate of effect size to power an effectiveness trial determine the extent of clinical improvement associated with the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/06/2022, West Midlands - Edgbaston Research Ethics Committee (3rd Floor Barlow House, Minshull Street, Manchester, M1 3DZ, UK; +44 207 104 8070; edgbaston.rec@hra.nhs.uk), ref: 22/WM/0090

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Depression

Interventions
A two-arm randomised, single-site feasibility trial will be used to assess the feasibility and acceptability of an RCT of a brief immersive virtual reality (IVR) intervention for depression in a clinical setting (NHS psychological therapies service; IAPT).

IAPT services operate a stepped care model, with cases triaged for low versus high intensity treatment. Our participants will be recruited from the low-intensity stream, in which patients typically engage with brief (up to 6 weeks) courses of treatment. The waiting times for different treatments vary but can be up to several months. At initial assessment, a risk assessment is performed and participants are given self-help resources and details of how to access support while on the waiting list.

We plan to recruit 50 adults currently registered a single-site London NHS IAPT service while they are on the waiting list for treatment as usual (TAU) within the service. Participants will be randomly allocated to either the intervention (IVR) or waitlist (WL) control arms on a 1:1 basis, stratified by sex after completing baseline assessments. All study appointments will be held at the UCL Clinic, part of the Camden and Islington Psychological Therapies Service located on UCL premises. We expect study duration per participant to last for approximately 6 to 8 weeks. All participants will engage in TAU within IAPTs after the study. Based on our previous work with the Trust IAPT services, and recent consultation regarding referral rates in the Trust, we estimate that the number of eligible and interested participants approached will meet the capacity at which we are able to enrol participants. We estimate we will be able to enrol approximately 2-4 participants a week, which ourselves and the Trust believe will be attainable in practice.

At their initial appointment, all participants will take part in baseline assessments comprising of mental health measures and specific questionnaires relating to self-compassion and self-criticism. Those in the IVR arm will be invited to attend four treatment sessions over two weeks (1 training and introductory session; 3 active treatment sessions including some post-intervention assessments at the final session) and a follow-up assessment at four weeks after the final treatment session (6 weeks after randomisation). Those in the WL arm will only need to attend follow-up assessment appointments held approximately two weeks and six weeks after randomisation. After completion of the follow-up assessments (6 weeks after randomisation) all participants will continue TAU within the Trust. If participants provide their additional consent, we will also analyse PHQ-9 scores (a measure of depression symptoms) collected as a routine assessment in their subsequent TAU (post-TAU follow-up).

Study assessments will involve a combination of standardised questionnaires and qualitative interviews. A full list of assessments and timepoints can be seen in the Assessment Schedule. We will measure a range of clinical and psychological outcomes including depression and anxiety symptoms and diagnosis, quality of life, self-compassion, self-criticism and emotional processing at baseline and follow-up. We will also engage in qualitative research with participants about their experience of taking part in this RCT to inform subsequent research. Acceptability and adherence in the intervention will be assessed quantitatively using the TAAS (Milosevic et al., 2015) and by engaging in qualitative research with participants (both completing and dropping out).

As this is a feasibility study, the focus of the results will be on the estimates of the treatment effects, acceptability and feasibility of conducting the RCT rather than statistical significance and as such no hypothesis testing will be undertaken. No interim analyses will be undertaken.

Due to the nature of the intervention/study, it is not possible to blind participants and researchers in this study. However, the trial statistician will remain blind throughout the duration of the study, until the blinded analysis detailed in the statistical analysis plan has been conducted and reported to the study team.

Formal power calculations are generally not undertaken in feasibility studies. The sample size is based on the precision needed for estimates to inform the conduct of a potential future definitive RCT, for which sufficient participants should be recruited to determine factors such as attrition and recruitment rates. Sample sizes between 24 and 50 have been recommended (Julious et al., 2005; Sim & Lewis, 2012), thus the feasibility trial will involve randomisation of 50 participants (approximately 25 to intervention and 25 to control). This sample size balances feasibility testing (rates of recruitment and retention, and any delivery issues with the proposed intervention and the research methods) and checking assumed statistical parameters for the further study. We are already confident from our small-scale pilot that accrual rates will be strong and are more concerned with completion rates. Based on NIHR guidance (NIHR, 2019), If we recruit 50 people, we can estimate a completion rate of 80% to within an exact 95% confidence interval of 69-91%. At this sample size the relative gain in precision for the pooled estimate of standard deviation is less than 10% for each five participants added per group (Teare at al., 2015). This sample is also sufficient to permit more detailed exploratory analysis of clinical effect to allow us to develop an analytic approach which can be formalised prior to future research.

If this study is successful, the results of this study will enable us to generate an estimate of effect size to power a subsequent larger RCT of the effectiveness of the IVR intervention. An RCT was selected to build on our previous clinical study which did not include a control group, given that RCT's are the gold standard for gathering data to support clinical evidence and potential translational research. However, should the feasibility study indicate that a different trial design/methodology would be more appropriate to investigate the effectiveness of the intervention, this will be taken into account in designing subsequent research. As part of the study protocol, we detail a series of Stop/Review/Go criteria. These will allow critical assessment of the feasibility of delivering the study as designed in this protocol. Criteria will be considered holistically along with other information gathered as part of the study to make an informed decision about continuation. A number of criteria indicating stop will likely require a re-definition of the study approach, potentially requiring further feasibility work to be conducted.

Intervention Type
Behavioural

Primary outcome measure
Feasibility and acceptability of a full RCT. This will be assessed by:
1. Recruitment rates
2. Eligibility rates
3. Willingness to be randomized rates
4. Retention rates
5. Ease of delivery. This will be assessed by engaging in qualitative research with those involved in recruitment and treatment to examine issues of implementation and practicality.
6. Acceptability of the intervention and adherence to the intervention protocol. This will be

assessed by 1) using the Treatment Acceptability/Adherence Scale questionnaire (TAAS, Milosevic et al., 2015) mid-way through the intervention (end of session 2 out of 4) and 2) engaging in qualitative work with participants (both completing and dropping out).

Secondary outcome measures
1. Depression symptoms are measured using the Patient Health Questionnaire–9 (PHQ-9; Kroenke et al., 2001) at baseline, post-intervention (2-weeks after baseline), follow-up (6-weeks after baseline) and after treatment as usual (optional assessment).
2. Anxiety symptoms are measured using the General Anxiety Disorder–7 questionnaire (GAD-7; Spitzer et al., 2006) at baseline and follow-up (6-weeks after baseline).
3. Quality of life is measured using the Recovering Quality of Life (ReQoL-20, Keetharuth et al., 2018) and EuroQol Health and Well-being (EQ-HWB-S, EuroQol Research Foundation) questionnaires at baseline and follow-up (6-weeks after baseline).
4. Self-Compassion and Self-Criticism are measured at baseline, post-intervention (2-weeks after baseline), follow-up (6-weeks after baseline) using the Self-Compassion and Self-Criticism Scale (SCCS, Falconer et al., 2015). Other aspects of self-compassion and self-criticism are also measured at baseline and follow-up (6-weeks after baseline) using the Fears of Compassion Scale (FCS, Gilbert et al., 2011), the Types of Positive Affect Scale (TPAS; Gilbert et al., 2008) and the Forms of Self-Criticising/Attacking & Self-Reassuring Scale (FSCRS, Gilbert et al., 2004).

Overall study start date
25/03/2022

Completion date
14/06/2024

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 15/05/2024:
1. Adults aged 18 years or older
2. Registered with Camden & Islington IAPT services (Islington site) for low-intensity psychological therapy for depression
3. Clinical caseness of depression (PHQ-9 ≥ 10)
4. Willing and has capacity to provide written informed consent
5. Sufficiently fluent in English to complete assessments and intervention
6. Double vaccinated against Covid-19
7. Able to commit to attend the appointment schedule

Previous participant inclusion criteria:
1. Adults aged 18 years or older
2. Registered with Camden & Islington IAPT services (Islington site) for low-intensity psychological therapy for depression
3. Diagnosis of depression (PHQ-9 score of 10+ and ICD-10 diagnosis of F32 depressive episode on the CIS-R)
4. Willing and has capacity to provide written informed consent
5. Sufficiently fluent in English to complete assessments and intervention
6. Double vaccinated against Covid-19
7. Able to commit to attend the appointment schedule

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Total final enrolment
25

Key exclusion criteria
Current participant exclusion criteria as of 15/05/2024:
1. Current drug or alcohol dependence
2. Individuals at current risk of suicide or self-harm
3. Individuals with severe depression (PHQ-9 score of 20+)
4. IAPT clinician deemed participation not appropriate
5. Defined as clinically extremely vulnerable (at high risk of serious illness from coronavirus)
6. History of seizures, brain injury or epilepsy
7. Uncorrected hearing or vision impairment
8. Head or neck injury, or individuals suffering from musculoskeletal problems
9. Individuals with vestibular/balance issues
10. Individuals engaging in any concurrent psychological treatments or mental health research

Previous participant exclusion criteria:
1. Current drug or alcohol dependence
2. Individuals at current risk of suicide or self-harm
3. Individuals with severe depression (ICD-10 F32 diagnosis of severe depressive episode and/or PHQ-9 score of 20+)
4. IAPT clinician deems participation not appropriate
5. Defined as clinically extremely vulnerable (at high risk of serious illness from coronavirus)
6. History of seizures, brain injury or Epilepsy
7. Uncorrected hearing or vision impairment
8. Head or neck injury, or individuals suffering from musculoskeletal problems
9. Individuals with vestibular/balance issues
10. Individuals engaging in any concurrent psychological treatments or mental health research during the course of the study

Date of first enrolment
17/04/2023

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
iCope Psychological Therapies Services
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ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We plan to publish the results in a suitable peer-reviewed journal(s) in line with NIHR's Open Access Policy by mid 2025. More broadly, key findings will be disseminated through our project website https://www.virtualcompassion.net, and promotion of research at conferences and via the wider media.

Intention to publish date
30/12/2025

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	25/05/2022	28/07/2022	No	Yes
HRA research summary			28/06/2023	No	No