ISRCTN24117387 https://doi.org/10.1186/ISRCTN24117387

Implementing multifactorial psychotherapy research in online virtual environments

Submission date
01/08/2014

Recruitment status
No longer recruiting

Registration date
26/08/2014

Overall study status
Completed

Last Edited
29/06/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Depression is a major global health problem. It is a widespread, long-lasting, disabling and recurrent disorder with a very high individual, societal and economic burden. It can cause major distress and disability for people with the condition. Although we have effective treatments for depression, such as antidepressant medication and cognitive behavioural therapy (CBT), there is considerable scope to improve these treatments, as only one-third of patients show good recovery after treatment. Moreover, traditional face-to-face psychotherapy can never be sufficiently widely available. The frequency of depression is such that it is not possible to treat all patients with traditional face-to-face therapy. Alternative ways of giving treatments are required to increase the availability and accessibility of therapy. One approach to achieve this is the use of online internet-based therapy, which has been shown to be effective for depression when supported by telephone or email contact, and which can be accessed easily. The purpose of this study is to understand how internet psychological treatments for depression work and to find out what elements are the active ingredients, and thereby, to enhance treatments for depression over time. The form of therapy we are testing is cognitive behavioural therapy, which involves trying to reduce depression through working on thoughts and actions. We hope to refine the most powerful elements within therapy to produce a better therapy that can help more people.

Who can participate?
Adult men and women who have symptoms of depression.

What does the study involve?
Eligible participants will be randomly allocated by chance to one of multiple variations of internet CBT, each of which have different combinations of treatment components within internet CBT. All participants will receive at least one of the treatment components within CBT, with regular support from an online therapist. Everyone will receive psychological treatment involving ingredients that we believe to be helpful. There is an equal chance of receiving each of the different variants of the therapy. We dont yet know which ingredients or combination of ingredients works best, which is why we are conducting this study. All participants will be allocated to a trained Psychological Wellbeing Practitioner (PWP) who will communicate by online written communications within the internet treatment platform. Participants will also be

able to send messages to the therapist. The therapy consists of components which typically take 1 hours work to complete and that are scheduled every 1-2 weeks. Participants will be asked to complete questions assessing mood and depression at the end of each module. The therapist will be in touch with participants to check on progress and give feedback and support on the completion of each module. The therapist will also send reminders if participants have not completed sessions. In total the internet therapy typically takes between 3-9 weeks to complete. Every online CBT session will include: overview, review of homework, psycho-education (in text, pictures and video format), practice of new skills (audio-recorded exercises), symptom measures, progress reports, session summary and printout.

What are the possible benefits and risks of participating?
Research has shown that internet treatments are effective in changing behaviour, bringing considerable benefits. Participants taking part in this study will therefore benefit from a psychological intervention that could reduce their levels of anxiety and depression. They will also have the benefit of attending a therapy remotely, as many do not have the time or flexibility to attend face-to-face support services. The risk associated with participating in this study is related to the severe levels of depression or anxiety that participants may still experience during the study. The direct risks of participation are minimal. It is possible that answering some of the questions or reading the feedback may be uncomfortable for some participants. If participants report suicidal thoughts, we will flag these up and specialist service will provide support, the participant will be referred to a secondary care mental health service, and participants will be encouraged to seek help from their local doctor or health service.

Where is the study run from?
Participants will be recruited from those referred into the Cornwall NHS Partnership Trust IAPT service (BEME), UK. They are also recruited from the rest of England through internet advertising.

When is the study starting and how long is it expected to run for?
May 2014 to April 2018

Who is funding the study?
The study is funded by Cornwall NHS Foundation Trust and South West Peninsular Academic Health Sciences Network, UK.

Who is the main contact?
Prof. Edward Watkins
e.r.watkins@exeter.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Ed Watkins

Contact details
Sir Henry Wellcome Building for Mood Disorders Research
University of Exeter
Exeter

United Kingdom
EX44QG
+44 (0)1392 724692
e.r.watkins@exeter.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Trial Protocol 30/07/2014 Version 1

Study information

Scientific Title
Implementing Multifactorial Psychotherapy Research in Online Virtual Environments 2 (IMPROVE-2)

Acronym
IMPROVE-2

Study objectives
Primary aim: to conduct a factorial study of components of cognitive behavioural therapy delivered over the internet with internet therapist support.
1.To assess the main treatment effect of individual components of cognitive behavioural therapy delivered in internet format on levels of depression as measured by the PHQ9.
2. To identify potential interactions between components of therapy in order to optimise the effectiveness of the CBT intervention for depression.
3. To operationalise the research into the effectiveness of components of CBT in an NHS setting, specifically within the BEME Improving Access to Psychological Therapies (IAPT) service for anxiety and depression in Cornwall.

It is hypothesized that the presence of treatment components (e.g., activity scheduling; thought challenging) will give significantly greater reductions in depression (improvement on PHQ-9) than the absence of the same treatment component (when aggregating across treatment cells). We hypothesize that following the Pareto principle, some but not all of the treatment components will have a significant main effect. We are also testing a subset of pre-specified interactions between treatment components.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Frenchay REC, 07/11/2014, ref: 14/SW/1091

Study design

Stratified block randomised single-blind 32-condition balanced fractional design. Randomisation will be minimized by severity of depression, antidepressant use, source of referral.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Available from the research team via a.newbold@exeter.ac.uk

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

Interventions
All participants will be randomised to receive at least one module of the internet cognitive behavioural therapy (CBT) intervention. Within this fractional factorial design, there is not a no-treatment control. The treatment consists of components which target each of seven aspects of the therapy. The treatment contents include text providing psycho-education and advice; pictures; video examples of individuals with depression using the treatment; questionnaires, rating scales, and online exercises and behavioural experiments including audio-recordings, which can be downloaded to be practiced in daily life. A number of questionnaires and exercises have built-in conditional feedback so a participant is automatically given feedback if an approach looked to be helpful, or if they report elevated suicide risk.

Components chosen reflect both traditional elements within CBT (thought challenging, behavioural activation) and innovative elements emerging from Prof Watkins research (concreteness training, compassion work), each hypothesized to specifically target distinct mechanisms of therapy.

All components involve brief weekly prescribed therapist online support because supported internet-interventions outperform unsupported ones, with improved retention and adherence. The support takes the form of the therapist reading the answers, exercises, and plans from the patient at the end of each module and then writing a response to the patient providing encouragement, support, guidance on plans and exercises, and feedback. This written support is then accessible by the patient when they next log on to the treatment platform. The patient is not able to progress to the next session without completing a module and reading the feedback. Patients receive an email whenever there is feedback for them to read.

A consistent formatting, structure and organisation occurs in each component, such that whilst involving distinct elements they are interchangeable within the overall treatment package, and able to coherently fit together. The assumption is that each treatment component its homework will take 1-2 weeks to complete. The final section of each module always involves questionnaires to assess progress and symptoms (PHQ-9, GAD-7), and plans for making specific timetabled

homework. The first session of each module always involve reflection on the last session, how homework went, and any questions for the therapist. In practice, this organisation means that each participant will be allocated between 1-7 components of therapy with an estimated average of 3-9 weeks to complete.

The treatment components investigated within the factorial design are:
1. Functional analysis
2. Relaxation
3. Identifying and challenging negative thoughts
4. Activity scheduling and reducing avoidance
5. Concreteness training
6. Absorption training
7. Compassion training
These are arranged across 32 treatment arms within the fractional factorial design.

Consent and screening
Participants identified as relevant by screening on the PHQ-9 will be asked to give consent to be contacted by the research team using the contact details they provide as part of treatment as usual in the NHS IAPT service or in an online format. Participants will also be asked to give consent to be interviewed for eligibility for the trial. Participants will be screened by the research team using a telephone-based structured diagnostic interview to confirm eligibility. After completing the two-stage screening procedure those eligible (and who have completed the introductory session online) will be invited to confirm consent to take part in the trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
As of 27/09/2016:
Patient Health Questionnaire (PHQ-9) which will be rated at baseline, 3 months from randomisation and 6 months post- treatment

Initial
Patient Health Questionnaire (PHQ-9) which will be rated at baseline, 20 weeks from randomisation and 6 months post- treatment

Secondary outcome measures
As of 27/09/2016:
Generalized anxiety disorder-7 (GAD7) questionnaire will be rated at baseline, 3 months from randomisation and 6 months post-treatment

Initial
Generalized anxiety disorder-7 (GAD7) questionnaire will be rated at baseline, 20 weeks from randomisation and 6 months post-treatment

Overall study start date
25/05/2014

Completion date
30/04/2018

Eligibility

Key inclusion criteria
1. Aged 18 or older
2. Access to internet and an email account that will be maintained and regularly checked for at least 3 months (changed from 20 weeks on 22/09/2016)
3. Competent at reading and writing in English
4. Receiving treatment within BEME Cornwall IAPT service. Those living elsewhere in England can take part as long as they are registered with a UK GP (sentence added 27/09/2016)
5. Meeting caseness for depression, as indexed by a score of 10 or more on the Patient Health Questionnaire-9 (PHQ-9) (Kroenke, Spitzer & Williams, 2001)
6. Completion of the introductory module of the therapy
7. Signed consent to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1056

Total final enrolment
767

Key exclusion criteria
1. Identification of comorbid severe or enduring mental health problems other than depression such as current alcohol or drug abuse problems, psychosis or bipolar disorder, either during routine screening by the NHS IAPT service, by online mood screener, or via research structured diagnostic interview at initial assessment.
2. Persistent self-injury requiring clinical management/therapy
3. Unable to engage with internet treatment for physical, practical or other reasons (e.g., very disabling physical or mental health problem, unable to comprehend materials, poor reading)
4. Formal concurrent face-to-face psychotherapy/counselling including computer-based CBT; IAPT treatments
5. Elevated levels of suicide risk as indicated by reporting suicidal ideation and intentions/plans for suicide

Date of first enrolment
07/07/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sir Henry Wellcome Building for Mood Disorders Research
Exeter
United Kingdom
EX4 4QG

Sponsor information

Organisation
University of Exeter (UK)

Sponsor details
c/o Gail Seymour
Research and Knowledge Transfer
The Innovation Centre
Rennes Drive
Exeter
England
United Kingdom
EX4 4RN
+44 (0)1392 726621
g.m.seymour@exeter.ac.uk

Sponsor type
University/education

Website
http://www.exeter.ac.uk

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
Cornwall NHS Foundation Trust (UK)

Funder Name
South West Peninsular Academic Health Sciences Network (UK)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/05/2022

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
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/10/2016		Yes	No
HRA research summary			28/06/2023	No	No
Results article		28/06/2023	29/06/2023	Yes	No