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IMPROVE-1 Research Trial

Submission date
04/09/2013

Recruitment status
No longer recruiting

Registration date
23/09/2013

Overall study status
Completed

Last Edited
29/03/2017

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression is a major global health challenge: a widespread, long-lasting, disabling and recurrent disorder with an enormous 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 following treatment. Moreover, traditional face-to-face psychotherapy can never be sufficiently widely available to reduce the global burden of depression. 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 overcome difficulties for accessing treatment and increase treatment coverage. Many studies of CBT have been conducted but they have not determined how CBT works, that is, what are the active ingredients of therapy. Identifying the active ingredients of a therapy is an important step to refine the therapy and to improve its effect. 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?
Anyone over the age of 18, both male and female, with elevated symptoms of depression

What does the study involve?
Participants will be randomly allocated to one of multiple variants of internet CBT, each of which features different combinations of treatment components within internet CBT. All participants will therefore receive at least one of the many treatment components within CBT, supported by 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. All participants will be asked to agree to an online consent form before undertaking further assessment. After completing this consent, participants will be asked to provide basic

demographic data including their age, gender and ethnicity, before completing screening measures about symptoms. Each participant will be asked to confirm their interest in participation and will be asked to complete several more questions by email to confirm their suitability for the study. All participants will receive internet psychological treatment differing in the combination of treatment elements and will be allocated to a trained online therapist who will communicate by online communications within the internet treatment. Participants will be able to send messages to the therapist. The therapy is assembled in sections or modules, each of which typically takes 2-4 weeks to complete, including regular practice on the exercises and plans in each module, with the expectation of about one hour of work online per module. Participants will be asked to complete some questions assessing their 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 4-12 weeks to complete. A researcher from the team will contact participants by e-mail after 2 months and 3 months to check on how participants are doing and ask them to complete brief questionnaires about depression and anxiety.

What are the possible benefits and risks of participating?
Participants taking part in this study will 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 location flexibility to attend face-to-face support services. The risk associated with participating in this trial 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 encourage participants to seek help from their local doctor or health service.

Where is the study run from?
University of Exeter (UK)

When is study starting and how long is it expected to run for?
July to December 2013

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Prof. Edward Watkins
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Contact information

Type(s)
Scientific

Contact name
Prof Edward Watkins

Contact details

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University of Exeter
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Additional identifiers

Protocol serial number
IMPROVE Version 2 23rd August 2013

Study information

Scientific Title
Implementing Multifactorial Psychotherapy Research in Online Virtual Environments

Acronym
IMPROVE

Study objectives
To clarify uncertainties in the design and delivery of a Phase III fully powered, fractional factorial trial, the following questions will be investigated and rates estimated:
1. Is it feasible to recruit patients with depression from the internet using online advertising (estimated at 6 patients per week) and to retain patients through an internet delivered psychological treatment (estimated at 70% post-treatment retention)?
2. Is it feasible to deliver and implement a internet-delivered factorial design utilising multiple treatment cells with respect to randomisation, maintenance of participants in relevant treatment cells; fidelity of treatment delivery across multiple treatment cells?
3. What are preliminary estimates of potential confidence intervals for effect sizes per treatment component and for selected 2-way interactions on primary outcome measure of depression?

It is hypothesized that the presence of active 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 active treatment component (when aggregrating across treatment cells).

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Exeter, School of Psychology Ethical Committee, ref: 2012/59

Study design
Single-centre stratified block randomised single-blind 32-condition balanced fractional design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Moderate to severe depression

Interventions
All participants will be randomised to receive at least one module of the internet cognitive behavioral therapy (CBT) intervention. Within this fractional factorial design, there is not a no-treatment control. The treatment consists of modules each of which is split into 2-4 sessions a session is designed to take 20 minutes and is approximately one long webpage suitable for scrolling down. This organisation is designed to make the treatment easy to use and not too taxing, by breaking it into smaller chunks. The treatment contents include text providing psycho-education and advice; pictures; vignette examples of individuals with depression using the treatment (with some tailoring of examples based on participant gender); questionnaires, rating scales, and online exercises and behavioral 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 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 onto 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 module, 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 module and 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 6 12 modules, with an estimated average of 8-12 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
All participants will be asked to agree to an online consent form before undertaking further assessment. After completing consent, participants will be asked to complete screening questionnaires. This will include a short self report screening questionnaire on the inclusion criteria to determine eligibility, including the PHQ9, the GAD7 and whether they are receiving any other current psychological therapies. They will also be asked about diagnoses or symptoms relating to abuse of alcohol or illicit drugs, bipolar disorder or psychosis.
Participants will be asked to provide basic demographic data including their age, gender, ethnicity.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Rate of recruitment and patient flow
2. Retention and attrition through the treatment modules and number/percentage of participants retained through to follow-up assessment
3. Patient Health Questionnaire (PHQ-9) at baseline, 8 and 12 weeks

Key secondary outcome(s))
Generalized anxiety disorder-7 (GAD7) questionnaire at baseline, 8 and 12 weeks

Completion date
01/12/2013

Eligibility

Key inclusion criteria
1. Aged 18 or older as reported on mood screener
2. Access to internet and an email account that will be maintained and regularly checked for at least 12 weeks
3. Competent at reading and writing in English
4. Meeting caseness for major depression, as indexed by meeting standard cut-off scores on the Patient Health Questionnaire-9 (PHQ-9) (Kroenke, Spitzer & Williams, 2001) as follows:
4.1. A score of 2 or more (more than half the days) on one or both of the first two items measuring little pleasure in doing things or feeling down depressed or hopeless
4.2. A score of 2 or more on at least 5 of the PHQ9 items 1 to 9
4.3. A score of 2 or more on (very difficult) follow-up question 10 (how difficult have these problems made it for you to do your work, take care of things at home, or get along with people?)

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Co-morbid diagnoses of current and significant substance abuse or dependence, current psychosis, bipolar disorder. These are assessed by well-established screening questions within the internet mood screener followed up by relevant questions as necessary from the researcher
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 some intentions /plans for suicide

Date of first enrolment
10/07/2013

Date of final enrolment
01/12/2013

Locations

Countries of recruitment
United Kingdom

England

Australia

Canada

United States of America

Study participating centre
University of Exeter
Exeter
United Kingdom
EX4 4QG

Sponsor information

Organisation
University of Exeter (UK)

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) - University of Exeter Wellcome Trust Institutional Strategic Support Fund Seedcorn grant

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes