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Big White Wall Live Therapy RCT

Submission date
04/11/2014

Recruitment status
No longer recruiting

Registration date
10/12/2014

Overall study status
Completed

Last Edited
06/06/2018

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, generalised anxiety disorder, social anxiety disorder and panic disorder are common mental health disorders. People with common mental health disorders who choose to receive psychological support are normally treated in Improving Access to Psychological Therapies (IAPT) services. IAPT services provide evidence-based interventions (treatments) recommended by NICE, including Cognitive Behavioural Therapy (CBT). CBT is a type of talking therapy, which can help people manage their problems by changing the way they think (cognitive) and what they do (behaviour). CBT works by helping people make sense of overwhelming problems by breaking them down into smaller parts. Thoughts, feelings, physical sensations and actions are interconnected, often trapping people in a negative spiral. CBT helps people to stop these negative cycles. It aims to break down factors that are making the sufferer feel bad, anxious or scared so that they are more manageable. It can show people how to change these negative patterns to improve the way they feel. It has not yet been proven whether or not CBT works when delivered as a digital intervention, for example as a web-based treatment programme. Therefore, we would like to find out whether CBT delivered on an internet-platform ('Live Therapy' provided by Big White Wall), works as well as face-to-face CBT. We are carrying out a small study to work out whether a larger study comparing these two methods of treatment would be practical. We need to know whether our procedures for recruiting participants work well and find out about people's experiences of receiving CBT on an internet-platform.

Who can participate?
English-speaking adults (aged 18 years or over) who have entered either the Waltham Forest or Wandsworth IAPT service in order to receive treatment for depression or an anxiety disorder (generalised anxiety disorder, panic disorder, social anxiety disorder). They must also have private access to a computer and webcam.

What does the study involve?
Participants are randomly allocated to receive CBT in their local IAPT service (CBT-FtF) or CBT through an internet platform (Live Therapy, CBT-LT). In either case, they receive 12 weekly sessions of CBT for depression or anxiety. They are asked to complete questionnaires about their emotions and functioning after each session, as this is part of usual clinical practice. At the end of the treatment, they are asked to complete a questionnaire about their level of satisfaction with the care they are given. Six months after the treatment has ended, a member of the study team gets in touch with each participant and asks them to complete another

questionnaires about their emotions, functioning and satisfaction with the care they received. We are also interested in finding out what it was like to be part of this study, and we will be giving some of our participants the opportunity to describe their experiences and the ways in which the study and Live Therapy could be improved. This is done through an interview with a member of our research team, lasting about 60-90 minutes.

What are the possible benefits and risks of participating?
There are potential benefits of this research to the NHS and to wider society. By taking part in this study, participants will contribute to a better understanding and treatment of CBT delivered on an internet-based platform, which may help inform treatment options for people with depression and anxiety in the future. There are minimal risks in taking part in this study, as both CBT delivered face to face (CBT-FtF) and CBT delivered online as Live Therapy (CBT-LT) interventions will be delivered by qualified and experienced professionals used to working with people with common mental health problems.

Where is the study run from?
University College London, with collaboration from Waltham Forest and Wandsworth IAPT services (UK)

When is the study starting and how long is it expected to run for?
November 2014 to May 2016

Who is funding the study?
NHS England Regional Innovation Fund (UK)

Who is the main contact?
1. Professor Stephen Pilling
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Contact information

Type(s)
Scientific

Contact name
Prof Stephen Pilling

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomised controlled trial evaluating cognitive behavioural therapy delivered on an internet platform by Big White Wall

Acronym
N/A

Study objectives
The main aims of this study are to determine whether it would be feasible to conduct a large-scale trial comparing CBT delivered as Live Therapy (CBT-LT), one-to-one synchronous CBT delivered on a digital platform through video calling, audio or live text communication, with usual treatment, CBT delivered face-to-face (CBT-FtF) in NHS Improving Access to Psychological Therapies (IAPT) services, for depression, GAD, SAD and panic disorder.

This study will also compare clinical outcomes associated with CBT-LT and CBT-FtF, and will seek to determine whether CBT-LT is regarded as an acceptable treatment by patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Stanmore, 10/11/2014, ref: 14/LO/1720

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

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

Interventions
Participants are randomly allocated to receive one of two interventions:
1. CBT-FtF - CBT-FtF is face to face CBT that participants will receive, in an IAPT service, from a qualified CBT therapist. Participants will receive approximately 12 weekly sessions of CBT for either anxiety or depression. A study researcher will contact them 6 months after their treatment ends to collect follow up data.
2. CBT-LT - CBT-LT is CBT delivered over an internet platform (Live Therapy) by Big White Wall. Participants in this trial who receive Live Therapy will be able to log on to a secure website and choose a CBT therapist, who they can then communicate with using video, audio-only or text. They will be offered 12 weekly sessions of CBT for either anxiety or depression. A study researcher will contact them 6 months after their treatment ends to collect follow up data.

Intervention Type
Other

Primary outcome measure
The study includes participants with depression and anxiety disorders, and there are three primary outcome measures:
1. To assess depression: Patient Health Questionnaire (PHQ9)
2. To assess anxiety: Generalised Anxiety Disorder 7item scale (GAD7)
3. To assess functioning: The Work and Social Adjustment Scale (WSAS)
These measures will be compared across groups at baseline, treatment end (12 weeks) and 6 month follow up.

We will also measure client satisfaction with treatment (CSQ-8) at treatment end (12 weeks) and 6 month follow up.

Secondary outcome measures
N/A

Overall study start date
17/11/2014

Completion date
30/05/2016

Eligibility

Key inclusion criteria
1. English-speaking adults (aged 18 years or over) entering participating IAPT services via self-referral or GP referral
2. People who have been offered CBT at IAPT step 3 for symptoms associated with depression or a specific anxiety disorder (generalised anxiety disorder, panic disorder, social anxiety disorder)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Non-English speaking people
2. People with cognitive impairment
3. People currently receiving additional psychological treatment
4. People with drug and/or alcohol dependence
5. People with a diagnosis of a psychotic or bipolar disorder
6. People with a diagnosis of post-traumatic stress disorder or obsessive compulsive disorder
7. Individuals who have asked not to be approached for research

Date of first enrolment
17/11/2014

Date of final enrolment
30/05/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
London
United Kingdom
WC1E 7HB

Sponsor information

Organisation
North East London NHS Foundation Trust (UK)

Sponsor details
Research and Development Department
Maggie Lilley Suite
Goodmayes Hospital
Barley Lane
Goodmayes
Essex
England
United Kingdom
IG3 8XJ

Sponsor type
Hospital/treatment centre

Website
http://www.nelft.nhs.uk/

ROR
https://ror.org/023e5m798

Funder(s)

Funder type
Government

Funder Name
NHS England Regional Innovation Fund (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
HRA research summary			28/06/2023	No	No