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Differences in long-term outcome: face to face v internet enabled cognitive behavioural therapy (CBT)

Submission date	Recruitment status	[X] Prospectively registered
09/02/2016	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/02/2016	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/10/2018	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cognitive behavioural therapy (CBT) is widely recognised as being an effective treatment for anxiety and depression. CBT has traditionally been provided face-to-face. Technology is increasingly being used to deliver CBT, this enables patients to access treatment with a qualified therapist from home, via a computer, tablet or smart phone at any time of the day. One method of delivering CBT via a computer is by using , real time, written (typed) communication. This means that a patient and therapist meet for appointments in a secure, online therapy room. They communicate to one another by typing. In addition patients and therapists can also communicate between therapy appointments using a secure messaging system. One benefit of this method is that the patient has access to the transcripts of all their therapy sessions. This method of delivering CBT is called internet enabled CBT (IECBT).Over 7000 patients have had IECBT. The recovery rates for these patients have been reported to the NHS and these are the same as patients who have CBT face-to face. We therefore know that IECBT is just as effective as face-to face CBT. This study aims to help psychological therapists understand the longer term differences between face-to face CBT and IECBT. This will be very important for the development of services in the future.

Who can participate?
Patients in a South London psychological service will be invited to participate in this study.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are given access to IECBT. Those in group 2 are given access to face-to-face CBT. They are all given questionnaires to complete at every appointment in order to track their progress in therapy. Each participant is also contacted again 6 months after they have finished treatment. They are asked to fill in the questionnaires again and how much they remember about the treatment they had.

What are the possible benefits and risks of participating?
It is hoped that the findings from this study will help psychological therapy services widen access to psychological therapy and understand more about how to improve services so that more people can stay better for longer.

Where is the study run from?
Southwark IAPT Service, South London and Maudsley NHS Trust (UK)

When is the study starting and how long is it expected to run for?
August 2016 to September 2017

Who is funding the study?
Ieso Digital Health

Who is the main contact?
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Contact information

Type(s)
Public

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Study information

Scientific Title
Comparing outcomes in online, therapist-delivered and face-to-face cognitive behavioural therapy: a randomised controlled trial

Study objectives

1. There will be an insignificant difference in clinical improvement between face-to-face cognitive behavioural therapy (CBT) and internet enabled CBT (IECBT) at the end of therapy
2. Patients intervention arm (IECBT) will be more likely to retain gains made in therapy. Consistent with this hypothesis is the idea that learning underpins successful clinical outcomes and therefore patients who are able to recall the active ingredients of their treatment plan are also more likely to have sustained gains from therapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety disorders and depression

Interventions
Patients in a South London psychological service will be invited to participate in this study. These patients will have been referred for CBT by their GP for treatment for either anxiety or depression. Normally these patients would receive CBT face-to face in a clinic or hospital out-patient department. In this study the patients, will be allocated to a CBT therapist, as usual, but they will then be randomly assigned to either the:
1. Treatment arm - internet enabled cognitive behaviour therapy
2. Control arm - face-to face cognitive behaviour therapy
They will undergo treatment with the same therapist that they were allocated to.

If a patient is unhappy about the method of delivery they have been assigned to (either face-to face or IECBT) they can quickly be offered the alternative method. They will remain with the same therapist so this will not effect the continuity of their treatment. Patients who ask to be transferred to a different method will not be counted in the final data analysis for this study because this study is only interested in people who have had a full course of treatment in either face-to face CBT or IECBT.

All the patients who have completed treatment in this study (both face-face and IECBT) will be contacted 6 months after their therapy ended. The patients will be asked to complete the depression (PHQ-9) and anxiety (GAD-7) questionnaires again. This study wants to understand if there is any difference in longer term gains from CBT between face-to face CBT and IECBT. Patients will also be asked how much they remember about the treatment they had. It is anticipated that patients who have had IECBT are likely to remember more about their treatment than patients who have had face-to face CBT.

Intervention Type
Other

Primary outcome(s)
1. Severity of depression, measured using the Patient Health Questionnaire (PHQ-9)
2. Severity of anxiety symptoms, measured using the Generalised Anxiety Disorder Questionnaire (GAD-7)

Questionnaires to be completed at every appointment and again 6 months after they have completed the treatment.

Key secondary outcome(s)
Patient feelings about their relationship with their therapist, measured using the Working Alliance Inventory

Completion date
01/09/2017

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Patients (all genders) who are referred to to (or who self refer) to a South London NHS IAPT service
2. Patients who are aged 18 or older
3. Patients who have been assessed as suitable for high intensity cognitive behavioural therapy
4. Patients who have access to an Internet Enabled Device and are able to use the device to send and receive emails and access web based platforms

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients who are not suitable for CBT
2. Patients who do not have access to an Internet enabled device or have an Internet connection
3. Patients who do not wish to have at least one of their face-to face sessions recorded (audio

recording).
4. Patients who have a low level of literacy. Patients who cannot write or read emails or texts will be excluded from this study because they will be unable to utilise the intervention
5. Patients who are visually impaired and are unable to write on or read from a computer and do not have access to appropriate assistive technology for the visually impaired
6. Patients who do not speak English
7. Patients who become unsuitable for treatment within an IAPT service. The normal IAPT exclusion criteria will be applied whereby patients who become actively suicidal or present as a risk to others require a referral on to a more specialised, secondary care service. In addition patients who are experiencing symptoms of psychosis, hyper-mania, severe, cognitive impairment, severe personality disorder or severe learning disability are also deemed as being unsuitable for an IAPT service. These patients will be excluded from this study and referred on to more specialised services

Date of first enrolment
01/08/2016

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South London and Maudsley NHS Trust
Southwark IAPT Service
London
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Sponsor information

Organisation
Anglia Ruskin University

ROR
https://ror.org/0009t4v78

Funder(s)

Funder type
Industry

Funder Name
Ieso Digital Health

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request