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Evaluating a diabetes-specific online cognitive behavioural therapy intervention

Submission date
18/08/2018

Recruitment status
No longer recruiting

Registration date
22/10/2018

Overall study status
Completed

Last Edited
18/07/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Approximately 3.2 million people in the UK have a diagnosis of type 2 diabetes. It is estimated that that this number is likely to rise in the next 10 years. People who have diabetes are twice as likely to suffer from anxiety or depression. Mood disorders such as anxiety or depression can make it harder for people to manage their diabetes and this can lead to further complications such as worsening of their physical health and poor quality of life.
People who have diabetes and another condition like anxiety or depression tend to respond well to evidenced based psychological therapies such as cognitive behavioural therapy (CBT). All the studies so far have focused on face-to-face CBT or self-help methods. Whilst face-to-face CBT can be highly effective, there are not enough therapists to provide treatment for number of patients who need it. Therefore, other methods of delivering CBT are required.
Online CBT, delivered by qualified therapists, using written (typed) conversation (see www.iesohealth.com) has been demonstrated to be equally effective as face-to-face CBT for patients with anxiety and depression and we need to know whether this method will be just as effective when patients have anxiety and/or depression as well as diabetes. Online methods have a lot to offer, they enable patients to access therapy from home (or any other place of their choosing) at any time and on any day of the week. This study aims to look at whether CBT delivered online in this way is equally as effective as face-to-face CBT at:
1. Reducing the symptoms of anxiety and depression
2. Enabling people to manage their diabetes more effectively
3. Reducing the distress that can sometimes be associated with having a diagnosis of diabetes

Who can participate?
Adults with a diagnosis of type 2 diabetes for at least 12 months who feel they may be anxious or depressed

What does the study involve?
Participants will receive an online course of CBT with accredited therapists. There will be weekly 60 minute therapy appointments with between session practice tasks. There will be no limit in the number of sessions participants can receive, but most people receive 6-8 sessions. Participants will be able to contact their therapist between sessions to discuss their progress or explore any difficulties they may be having.

The sessions will involve working with a therapist to understand how specific situations, sensations, symptoms or feelings can affect the way we think and what choose to do, or not do. The therapist supports the person to work towards personalised goals and to learn to manage uncomfortable or unpleasant symptoms.
Therapy is expected to be delivered over a period of around 12 weeks. Before receiving the treatment and 6 months afterwards, participants will be asked to complete questionnaires relating to diabetes management, depression and anxiety.

What are the possible risks or benefits of participating?
The possible benefit of participating in this study is that participants will be receiving a treatment that they may otherwise not be able to access. This treatment has been delivered to 30,000 NHS patients (patients who are anxious or depressed but not specifically with a focus on diabetes) and it has been demonstrated to be equally effective as face-to-face CBT.
Whilst the treatment is confidential and we would never contact a person's GP with their express consent, participants should be aware that occasionally a therapist may assess that a person is at risk to themselves or others. In these rare cases we would need to ensure the person was referred to the most appropriate service and the person's GP would be informed.
There are no known risks to participants taking part in this study.

Where is the study run from?
Ieso Digital Health, Cambridge (UK)

When is the study starting and how long is it expected to run for?
August 2018 to July 2022

Who is funding the study?
Roche Diabetes Ltd (UK)

Who is the main contact?
Sarah Bateup
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
DIAB1

Study information

Scientific Title
A pre-post intervention study to investigate the effectiveness of diabetes specific online therapist delivered cognitive behavioural therapy for patients with Type 2 diabetes and with a comorbid axis I disorder

Study objectives
The primary research question is how effective is an online diabetes-specific CBT intervention in helping patients manage symptoms of co-morbid anxiety and depression?
The secondary objective of this research is to look more closely at the relationship between mental health conditions, diabetes, and a patient motivation and engagement score. We would like to find out whether improvements in mental health are also linked with improvement in an individual's engagement with their diabetes using this score.

Ethics approval required
Old ethics approval format

Ethics approval(s)
We are applying for ethical approval via IRAS (project ID 252123), approval has not yet been granted

Study design
Interventional non-randomised pre-post study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 Diabetes with co-morbid anxiety disorder and/or depression

Interventions
Participants will receive an evidence-based cognitive behavioural therapy (CBT) treatment which will consist of weekly therapy appointments lasting 60 minutes. CBT will be delivered online, using synchronous written communication via the web based platform developed by the company Ieso Digital Health (see www.iesohealth.com). It will be delivered by British Association of Behavioural and Cognitive Psychotherapy (BABCP) accredited CBT therapists. The therapists will provide treatment online using synchronous written communication (typed). The therapy provided will be identical to traditional face-to- face CBT in that it will use evidenced based disorder specific treatment protocols with fidelity to the CBT model. The treatment will be delivered individually.
Participants will also be encouraged to participate in between session practice tasks, which are a routine part of CBT. Average treatment durations are 7 treatments sessions over a period of two months, although patients who require more sessions (in order to gain benefit) will be provided with more sessions.
CBT will be provided following a disorder specific treatment protocol for patients with an anxiety disorder or depression and a diagnosis of type 2 diabetes. Participants will receive all elements of the treatment although this may be moderated to meet their individual needs. For example, some patients may find working behaviourally more helpful than working with cognitions. These types of moderations are very normal when delivering CBT.
The therapists' ability to deliver the interventions with fidelity to the CBT model and adherence to an evidence based protocol will be assessed by a team of clinical supervisors at Ieso Digital Health. This is assessment is possible because the intervention is delivered online using synchronous written communication and therefore each therapy appointment is recorded as a transcript. It is therefore possible to quality check the intervention provided to every participant. Fidelity to the treatment model will be assessed using the standardised and validated tool 'Cognitive Therapy Scale- Revised' (CTS-R). The CTS-R is routinely used in research settings to ensure that that the intervention provided is CBT and not another type of therapy. The CTS-R is also routinely used in higher education settings as a formative and summative assessment of trainees' ability to deliver CBT. The CTS-R is a 12 item scale where each item is scored on 0-6 Likert scale where 0 is incompetent and 6 equates to expert skill. The final score is reported as a total percentage. A score of 40% is considered to be competent.

Intervention Type
Behavioural

Primary outcome(s)
The following are assessed at the baseline, post-intervention and at the 6 months follow-up:
1. Depression, assessed using the Patient Health Questionnaire (PHQ-9)
2. Anxiety, assessed using the Generalised Anxiety Disorder Assessment (GAD-7)

Key secondary outcome(s))
The following are assessed at the baseline, post-intervention and at the 6 months follow-up:
1. Patient activation level and knowledge, skill and confidence in measuring their long-term

health condition, assessed using the Patient Activation Measure (PAM) via telephone
2. Distress (emotional burden, regimen distress, interpersonal distress and physician distress), assessed using the Diabetes Distress Scale (DDS)

Completion date
31/07/2022

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Diagnosed with type 2 diabetes at least 12 months prior
3. Co-morbid anxiety disorder and/or depression

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
102

Key exclusion criteria
1. Unsuitable for cognitive behavioural therapy
2. Unable to access an Internet-enabled device or no access to an Internet connection
3. Low level of literacy
4. Visually impaired and unable to write on or read from a computer, and unable to access appropriate assistive technology for the visually impaired
5. Unable to speak English
6. Unsuitable for treatment within a primary care psychological therapy service:
6.1. Patients who become actively suicidal or present as a risk to others will be referred to a more specialised, secondary care service
6.2. Patients experiencing symptoms of psychosis, hypermania, severe cognitive impairment, severe personality disorders or a severe learning disability are also unsuitable for the study and will be referred to more specialised services
7. Already involved in a different research project
8. Undergoing any other mental health therapy at present

Date of first enrolment
01/12/2019

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ieso Digital Health
The Jeffreys Building
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Sponsor information

Organisation
Roche Diabetes Care Ltd

ROR
https://ror.org/024tgbv41

Funder(s)

Funder type
Not defined

Funder Name
Roche Diabetes Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to patient privacy and commercial confidentiality concerns.

IPD sharing plan summary

Not expected to be made available

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
Protocol file	version 7	26/02/2019	18/08/2022	No	No
Statistical Analysis Plan	version 2.0	13/07/2020	18/08/2022	No	No