Evaluating a diabetes-specific online mental health support service - full protocol for Ethical Review

Full title: A pre-post intervention study to investigate the effectiveness of diabetes specific online therapist delivered cognitive behavioural therapy (CBT) for patients with Type 2 diabetes and with a comorbid axis I mental health disorder

Introduction

People with diabetes are more likely to experience issues with their mental health than the general population (1). Prevalence has been reported at around 25% of people with diabetes being affected by depression (2), and around 40% by anxiety (3). There is also some evidence to suggest that having depression can increase the risk of developing Type 2 diabetes (4, 5). As well as the impact that living with depression and diabetes has on quality of life (6), there is also an associated decrease in lifespan (7). Reports show that despite the acknowledgment of these risks, people with diabetes are often unable to access the support services that they require (8).

Cognitive Behavioural Therapy (CBT) has been shown to be effective for people with type 2 diabetes experiencing depression (9). However, as noted in (8), resources are stretched and not everyone has access to the appropriate support. Digital support may be able to bridge this provision gap by reaching a greater number of individuals. Whilst there is literature to support online interventions for diabetes (10) the methods described are either self-help methods or guided self-help; they are not therapist interventions.

Online and telephonic coaching interventions to support people with diabetes have been trialled (11, 12). These studies also observed changes in the Patient Activation Measure (PAM), a validated measure of confidence, skills and motivation relating to any condition. PAM has been demonstrated to predict certain health outcomes such as cholesterol and blood pressure in patients with diabetes (13). Despite the relatively large number of studies looking at PAM in diabetes (up to 80), there are very few focused on PAM, mental health and diabetes. There is a proposed link between PAM and mental health disorders (14), but this is not well established within a specific diabetes cohort. Understanding the link between PAM and mental health in diabetics may help development of new therapy pathways.

Aim of study

The primary aim of this study is to evaluate a new online therapy service for treating mental health problems, tailored for people with diabetes. The secondary aim of this study is to explore the relationship between patient motivation and engagement (as measured by the PAM score), anxiety and depression, and diabetes distress.

Study design

This study will use a pre-post treatment comparison design to determine the efficacy of a newly developed, diabetes-specific, online CBT programme. Participants will be recruited in England and as the therapy will be delivered online, this will be at a location convenient to the participant. There will be no formal control group, but a comparison data set will be evaluated in order to provide a reference for clinical outcomes in depression and anxiety in people with diabetes. Such data will be obtained from NHS mental health services providing psychological therapy in primary care, although it will not be possible to separate type 1 from type 2 diabetes patients. Such a comparison will, however, enable us to say whether the current therapy modality is broadly equivalent to standard care, and delivered with considerably higher accessibility.

Recruitment

People with Type 2 diabetes, who have been diagnosed for at least a year, will be informed about this study either by a health care professional (GP, specialist nurse, psychological therapist), or via a recruitment leaflet placed in their GP's surgery, or on the Roche Diabetes Care internet site, or on the Roche or Ieso blog or Facebook pages. This evaluation will aim to include 500 subjects within the therapy pathway. This will ensure that people with a range of mental health conditions and PAM scores are represented.

The following inclusion/exclusion criteria, assessed on recruitment and initial screening, will apply:

Inclusion criteria:
Diagnosed with Type 2 diabetes at least 1 year ago
Over 18 years of age at the time of recruitment
Able and willing to sign a consent prior to the study
Therapy will be provided based on set criteria, which define if a patient is a clinical case of depression (based on PHQ-9 score), anxiety (based on GAD-7 score) or an appropriate Anxiety Disorder Specific Measure.

Exclusion criteria:
People who are not suitable for CBT, eg patients with cognitive deficits from brain damage or dementia, and patients who do not wish to engage with the process eg by completing homework.
People who are already receiving psychological therapy.
People who do not have access to an Internet enabled device or have access to an Internet connection.
People who have a low level of literacy; those who cannot write or read emails or texts will be excluded from this study because they will be unable to utilise the intervention.
People 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.
People who do not speak English.
People who become unsuitable for treatment within the service. The normal IAPT (Improving Access to Psychological Therapies) exclusion criteria will be applied whereby someone who becomes actively suicidal or presents as a risk to others requires a referral on to a more specialised, secondary care service. In addition people 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 individuals will be excluded from this study and referred on to more specialised services.

Study plan

On recruitment participants will have time to read detailed study information, including the study procedure and therapy duration, before consenting to take part. It will also explain the next steps if someone is not suitable for the therapy pathway.

Initially, all participants who meet the study criteria will be asked to complete the Patient Activation Measure (PAM) questionnaire. This will provide a baseline measurement for analysis. Once participants have completed the PAM, they will be directed to the therapy triage process to determine presence of depression, anxiety or both. This will be done via completion of a self-assessment questionnaire and questionnaires to identify depression and anxiety (PHQ-9 and GAD-7 respectively). If patients do not meet caseness thresholds on the PHQ-9 or GAD-7 (a patient is defined as above clinical caseness if their PHQ-9 score is ≥10 or their GAD-7 score is ≥ 8), but there is reason to believe that there is a mental health problem, patients will be asked to complete an anxiety disorder specific measure (ADSM) eg for PTSD, health anxiety etc to see if caseness threshold is reached on one of these measures. These scores will be the baseline measurements for the study and this information will form the basis of triage for

treatment suitability. The triage process will be carried out by a junior clinician at Ieso Digital Health, supervised by one of the clinical supervisors. All responses will be recorded securely on a specific study database.

Participants who are eligible for the full online therapy provision will be allocated to a British Association of Behavioural and Cognitive Psychotherapy or BABCP-accredited CBT therapist who has undertaken additional training in diabetes-specific CBT. Participants will be asked to complete the full Diabetes Distress questionnaire immediately before the first treatment session to obtain a baseline measurement.

People who do not exhibit "caseness" at the triage stage will be called to discuss their results with a trained therapist. It is widely recognised that people with a long-term physical health condition, including diabetes, can commonly experience symptoms such as low mood, worry and general distress. These commonly occurring symptoms can sometimes be misinterpreted as signs of a more severe mental health disorder. It is anticipated that some people with diabetes will misinterpret these symptoms and apply to the study; they will be provided with appropriate educational materials about mental health and reassured that they do not have an anxiety disorder or diagnosable depression and will be signposted to more appropriate support services where necessary. These individuals will not go on to receive further treatment or follow-up in this study.

If the participant has provided consent to inform their GP on the consent form, a letter will be sent to the GP to alert them of the study and engage their interest and involvement.

If the study identifies people who are at-risk to themselves, they would not be suitable for the online CBT intervention. These patients would immediately be sign-posted to the most appropriate service and the GP would be contacted. Ieso Digital Health has robust risk and safeguarding management protocols.

Therapy Intervention Details

Ieso therapy is delivered in line with NICE guidelines with duration and timing of sessions related to diagnostic need. Sessions last up to 1 hour and around 6-10 sessions are delivered over 8-12 weeks. Sessions are delivered by Ieso therapists who have undergone additional diabetes specific training.

When treating depressed or anxious diabetes patients, there are two major treatment goals:

1. Remission or improvement of depression or anxiety disorder, and
2. Improvement of quality of life and engagement with diabetes self-management activities.

CBT will be offered following a diabetes-specific treatment protocol delivered by BABCP accredited CBT therapists who have undertaken training in the diabetes specific CBT treatment protocol. Sessions will be reviewed by Ieso supervisors to ensure adherence to the protocol, fidelity to the CBT model and to provide specialist clinical supervision.

CBT will be delivered online using the Ieso platform. The treatment will consist of up to 10 CBT sessions with additional asynchronous, between session contact and homework (total up to 20 hours) using a disorder specific, evidence-based CBT protocol for depression or one of the 8 anxiety disorders. Disorder specific treatment will include diabetes-specific aspects in order to improve adherence to diabetes treatment and ability to cope with diabetes.

Participants will be asked about healthcare utilisation between therapy sessions, including changes or events relating to medication use, GP visits, diabetes clinic visits, non-routine hospital visits, and hospital admissions.

The psycho-education section of the CBT provision (sessions 1–3) includes information about the association of mood and activities and the development and maintenance of depression and/or anxiety. In addition, patients will learn about the link between diabetes and mood and ways to influence impaired

mood with cognitive techniques. Furthermore, patients will be encouraged to explore diabetes-specific goals, such as blood glucose management and self-management checks with their specialist diabetes nurse/clinician. Patients will be asked to identify behavioural goals with their CBT therapist, in order to improve glycaemic control. This will include such factors as diet, weight loss and exercise. Individual goal achievement will be collaboratively reviewed in further sessions and possible barriers to the goal attainment will be identified and modified if possible. Change mechanisms including values based behavioural activation, problem solving and cognitive reattribution strategies will be used to enable patients to identify and modify perceived barriers to various aspects of self-management and to enhance coping skills. Later sessions will focus on beliefs, fears and predictions relating to diabetes complications. All patients will develop a collaborative relapse prevention plan (therapy blueprint) which will include regular access to the Ieso therapy site and to the therapy materials used in sessions with their therapist.

Therapy is expected to be delivered over a period of up to 12 weeks. All participants will be contacted 6 months post-treatment and asked to complete primary and secondary outcome measures.

Outcome Measures

Primary:

The following will be measured at baseline, before each therapy session, immediately at the end of the course of therapy, and at a 6-month follow-up call: PHQ-9 (depression) and GAD-7 (anxiety); if appropriate ADSM (anxiety-disorder specific measure e.g. for post-traumatic stress disorder, health anxiety etc).

Secondary:

The following will be measured at baseline, before each therapy session, immediately at the end of the course of therapy, and at a 6-month follow-up call: PAM (patient activation measure), DDS (Diabetes Distress Scale) and ADDQoL (Audit of Diabetes Dependent Quality of Life).

Data Analysis

Data analysis will only be carried out on patients who have completed two or more therapy sessions.

Clinical recovery will be defined as: where a patient starts out in therapy as a clinical case on at least one of the primary outcome measures (greater than or equal to 10 on PHQ-9 and greater than or equal to 8 on GAD-7) and their post intervention scores fall out of caseness on both measures at the end of treatment. The recovery rate for a group of patients will be calculated as the number of patients recovered, divided by the number of patients at caseness at initial assessment.

Reliable Improvement will be defined as: where a patient starts out in therapy as a clinical case (greater than or equal to 10 on PHQ-9 or greater than or equal to 8 on GAD-7) and their post intervention scores fall greater than or equal to the measurement error of the questionnaire i.e. by at least 6 points on the PHQ-9 scale or at least 4 points on the GAD-7 scale. The improvement rate for a group of patients will be calculated as the number of patients improved, divided by the number of patients who have completed two or more therapy sessions.

Patients who simultaneously improve and recover will be classed as reliably recovered. The overall percentage of patients who recover, improve and reliably recover, according to the above metrics, will be calculated.

Although inferential analysis of comparative clinical effectiveness will not be possible in the present study due to the lack of a control group, we hope to access IAPT data in diabetes patients who have

received standard IAPT CBT (generally face-to-face) to reference clinical outcomes from this study using online CBT. We will compare averages for the same time period, using a multivariate rejection sampling algorithm. Logistic regression analyses will be performed to identify significant predictors of recovery and improvement in diabetes patients receiving online CBT.

Pre- and post-treatment values for all outcome measures, including secondary outcome measures, will be compared using a paired t-test.

In order to understand if there are significant predictors of recovery and improvement in diabetes patients receiving online CBT, based on patient demographics and service variables, logistic regression analyses will be performed. Variables to be studied will include PAM scores, different levels of severity of mental illness, different mental illness diagnoses (eg depression, anxiety, PTSD, social anxiety etc) and different demographic variables. Service variables, pertaining to a patient's course of treatment, will also be studied, including waiting times between various stages in the patient journey, treatment duration and number of scheduled appointments the patient failed to attend.

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