Participant Information Sheet

You are invited to take part in a research study

Title of the study: Evaluating a Diabetes Specific Online CBT Intervention

Ieso Digital Health are running a study to evaluate an online, diabetes specific, cognitive behavioural therapy (CBT) intervention. This study has been funded by Roche Diabetes UK. If you have any questions about this study you can contact the Chief Investigator of this study Sarah Bateup on 0800 074 5560 or email at s.bateup@iesohealth.com.

Alternatively, you may contact the Clinical Leads at Ieso Digital Health, Jenny Schiller and Shazna Khanom at clinicalleadership@iesohealth.com or 01223 608760.

You are free to decide whether or not to take part in this study and if you decide to participate you may change your mind at any time.

Overview of the study

There is a strong evidence base that supports the effectiveness of cognitive behavioural therapy (CBT) for patients with a diagnosis of diabetes (type 1 and type 2) who also suffer from a common mental health disorder such as anxiety or depression. Both anxiety and depression can have a significant impact on a person's ability to manage their diabetes and therefore successful treatment of these common mental health conditions can positively affect a person's physical and mental health.

CBT is traditionally delivered face-to-face but currently there are not enough therapists to provide treatment for all the people who would benefit from it. New methods of delivering effective interventions are required. One method of delivering CBT is online therapist delivered CBT. Around 20,000 NHS patients have already had CBT using this online method and we know that people are just as likely to get better using online CBT as they are using face-to face methods. This study will help us understand whether online methods of delivering CBT help people who have diabetes and anxiety or depression. The findings from this study will help us understand how to enable more people to access effective treatments.

Why am I being invited to participate in this study?

Anyone, over the age of 18 who has type 2 diabetes, for 12 months or more, and has also experienced any symptoms of low mood or anxiety is invited to participate in this study.

What is CBT?

Cognitive behavioural therapy (CBT) is a talking therapy. It has been proved to help with a wide range of emotional and physical health conditions in adults and young people. CBT looks at how we think about a situation and how this affects the way we act. In turn, our actions can affect the way we think and feel. The therapist and patient work together to change the patient's behaviours, thinking patterns or both of these.

What do you need to know about the methods that will be used in this study?

If you decide to take part in this study you will be asked to complete some questionnaires that will help us understand how your diabetes is affecting you and whether you are suitable for this study. These questionnaires include:

- Patient Activation Measure (a short questionnaire which will assess your confidence in managing your health and healthcare)
- PHQ-9 (a short questionnaire that looks at symptoms of depression)
- GAD-7 (a short questionnaire about symptoms of anxiety)
- Diabetes Distress Scale and the Diabetes Quality of Life Scale (short questionnaires that ask about how diabetes is affecting your day-to-day living).

People who are suitable for this study will be those who have type 2 diabetes and have symptoms of anxiety and depression. People who are not suitable for this study will be offered advice and educational materials about wellbeing and diabetes. People who are suitable will be offered online CBT.

CBT will be delivered by British Association of Behavioural and Cognitive Psychotherapy (BABCP) accredited CBT therapists (see www.babcp.com for further details of accreditation). In addition, the therapists will have received additional training in delivering CBT to patients with type 2 diabetes.

CBT will be delivered individually, online, using synchronous written communication (similar to instant messaging) via the web-based platform developed and provided by the company Ieso Digital Health (see www.iesohealth.com). This means that the participants can be located in a place of their choosing whilst receiving therapy. Participants may also choose the day and time of day that they have their therapy appointments.

Participant and therapist will log on to the secure virtual therapy room at the agreed time. This can be done via a computer, tablet or smart phone. The session will take place in real time and progress in the same way as a face to face therapy session. The only difference would be that the method of communication will be through live written (typed) text. Participants will receive an evidence-based treatment which will consist of weekly therapy appointments lasting 60 minutes, with the same therapist. 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.

Participants will also be encouraged to participate in between session practice tasks. These are a routine part of CBT as these can provide valuable opportunities of putting work done in session into practice. In the early stages of therapy practice tasks involve reading hand outs and information relevant to what was covered in the sessions. It would also include mood/thought/activity monitoring sheets that participants would be encouraged to complete, to get a better understanding of how problems present in day to day life and to gain insights into what factors maintain these problems. In later stages of therapy, the practice tasks may include specific CBT techniques taught in session, including thought challenging exercises, behavioural activation, confronting avoidance or other techniques specific to the problems discussed in session.

The amount of time that participants will spend on tasks outside of sessions each week will vary depend on the severity of the problem, however participants can expect to spend up to 30 minutes each day.

Participants will be asked to complete several questionnaires (including the PHQ-9, GAD-7 etc. and possibly some anxiety specific scales e.g. for post-traumatic stress disorder, health anxiety if applicable) before each treatment session and six months after treatment has been completed. It is anticipated that it will take no more than 5 minutes to complete the questionnaires on each occasion.

How your study data will be stored

All data will be held in accordance with the Data Protection Act 2018 and the General Data Protection Regulation (GDPR). In addition, the data that is collected for the purposes of this study will be stored securely, encrypted in transit and at rest, in compliance with Ieso Digital Health's policies and ISO27001 certification (international security standard).

Confidentiality

We would like to reassure you that we understand the privacy and confidentiality of your personal information and we take our responsibility to protect it very seriously. Information is only shared on a strictly 'need to know' basis, we have internal procedures in place so that only the minimum necessary information is used to conduct research on the most de-identified data possible, and everyone with access to any of your data will have a legal duty to keep it confidential. Your personal data will not be published or discussed externally for the purposes of this study.

Whilst the treatment is confidential, and we would never normally contact a person's GP without their express consent, participants should be aware that there might be occasions where we would

need to contact the person's GP. There are two main reasons that may prompt us to do this. One would be if the therapist assesses that the participant would be at risk of harm to themselves or pose a risk to others. The other reason would be if a participant became distressed during the course of treatment and the therapist assessed that there was a need for a referral to a more specialist service. In these rare instances the therapist would at first seek to gain consent from the participant to share information with the GP and the specialist service. Decisions to break confidentiality are rare, however when they do happen we have robust processes to ensure that the decision to share information is in the participants best interest. This decision will not be made by the therapist alone but will be made by the clinical team and overseen by the Senior Clinician.

What are the benefits of participating in this study?

People who participate in this study will be receiving a treatment that they may otherwise not be able to access. This treatment has been delivered to 30,000 NHS patients (these were people who were 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.

In addition, the findings from this study will help us learn whether many more people with diabetes and anxiety or depression could benefit from this way of delivering CBT.

What if I change my mind about participating in the study?

You can change your mind about participating in this study at any time. If you no longer wish to participate in this study you should phone Sarah Bateup (Chief Investigator of this study) on 0800 074 5560 or email at s.bateup@iesohealth.com.

Alternatively, you may contact the Clinical Leads at Ieso Digital Health, Jenny Schiller and Shazna Khanom at clinicalleadership@iesohealth.com or 01223 608760.

If you change your mind your data will be removed from the analysis in this study, however your information and health record will be retained as a resource that you can return to at any time you wish. This can help you remember coping strategies, techniques or processes that you learnt in therapy. We retain your clinical record by reference to the IGA Records Management Code of Practice for Health and Social Care guidance for managing health records https://digital.nhs.uk/information-governance-alliance and to support our legal obligations to be accountable for your care. The Code is based on current legal requirements and professional best practice. Our data retention practices are reviewed at least annually in conjunction with industry standards and best practice.

Who has reviewed this study?

All research studies are reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and has been given a favourable opinion

Complaints

If you have any complaints about this study you can contact the Investigator Sarah Bateup at s.bateup@iesohealth.com or by phone on 0800 074 5560.

If you wish to make a formal complaint, please submit to:

Email address: info@iesohealth.com

Postal address: Ieso Digital Health, Jeffreys Building, St Johns Innovation Park, Cowley Road, Cambridge CB4 1DS

If you are unhappy with the outcome of your complaint, you can contact the Independent Sector Complaints Adjudication Service (ISCAS):

70 Fleet Street
London
EC4Y 1EU

Tel: 020 7536 6091
Email: info@iscas.org.uk