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Exploring the implementation of COMPASS digital cognitive behavioural therapy, into routine NHS care for adults with diabetes and comorbid psychological distress

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King’s College London

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Exploring the implementation of COMPASS digital cognitive behavioural therapy, into routine NHS care for adults with diabetes and comorbid psychological distress.

By

Emma Jenkinson

Thesis incorporating publications submitted for the degree of Doctor of Philosophy.

March 2024

Abstract

Psychological distress is common in adults with diabetes and is associated with poorer clinical outcomes and increased healthcare costs. Whilst previous work has indicated that psychotherapy treatments such as Cognitive Behavioural Therapy (CBT) are effective at improving some psychological outcomes in diabetes, the effect of this on diabetes-related distress is unclear. Furthermore, currently in England, the clinical need for effective psychological support within routine diabetes care is not met. Research indicates that internet-enabled CBT may provide an effective, accessible, and scalable model for providing psychological support for adults with diabetes in routine practice. However, more work is needed to explore how an internet-enabled CBT intervention can be implemented in routine psychological care for adults with diabetes. Therefore, this PhD investigated the implementation of a digital CBT intervention named COMPASS, designed to treat psychological distress in the context of Long-Term Conditions (LTC) into routine care for adults with diabetes and co-morbid psychological distress.

First, study 1 (presented in chapter 2) performed a systematic review with meta-analysis to explore the efficacy of CBT and third-wave CBT interventions on diabetes-related distress, for adults with diabetes. This review also explored the efficacy of these interventions on depression, anxiety, and glycated haemoglobin (HbA1c). The review also explored active intervention components that may be most useful in treating diabetes-related distress. The findings demonstrated that traditional CBT effectively improves diabetes-related distress and depression in adults with diabetes. Third-wave CBT for diabetes-related distress effectively improved anxiety, however more work is needed to confirm this. Furthermore, CBT interventions that had a digital component, included behavioural activation, and were delivered by a psychological practitioner bolstered treatment effectiveness. Preliminary evidence

indicated that studies which targeted diabetes-related distress as the primary outcome had larger treatment effects when compared with those that did not. This points to the potential benefit of COMPASS as a treatment for adults with diabetes and co-morbid psychological distress because of its tailored nature.

Study 2 (presented in chapter 4) used mixed methods and the RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) framework to explore the implementation of COMPASS for adults with diabetes and co-morbid psychological distress, within two distinct care pathways in England (Talking Therapies; primary care and a diabetes psychology clinic within a physical health service; secondary care). The findings of this study demonstrated poor reach, adoption, and implementation of COMPASS. This is despite preliminary treatment effects indicating that COMPASS may be effective at improving psychological outcomes, illuminating a research to practice gap. The study also identified key barriers and facilitators to the implementation of COMPASS from the perspective of adults with diabetes such as the importance of human contact in digital therapy, non-acceptability of digital interventions, a desire for COMPASS to include more self-management content. However, many of the barriers to the implementation of COMPASS identified in this study did not occur at the patient-level. For example, the route to mental health support prior to accessing COMPASS influenced the implementation of COMPASS. Hence, this study also identified contextual, service, and systemic level factors impacting implementation. Therefore, it was not possible to elucidate if the identified barriers and facilitators were unique to people with diabetes or if they were unique to COMPASS, a digital CBT treatment.

To explore this further and to attempt to contextualise the findings presented in study 2, a cross-sectional study was conducted using routinely collected Talking Therapies data.

Study 3 (presented in chapter 5) examined associations between having an LTC including diabetes (vs not having an LTC) on i) assessment attendance ii) treatment engagement (attending two or more treatment sessions) and iii) the intervention modality offered (i.e., digital vs face-to-face). Across the whole sample of 17,095 referrals to talking therapies, there were no significant differences between those with an LTC vs those who did not have an LTC in terms of attendance at assessments and treatment engagement. Across the whole sample, rates of internet-enabled treatment receipt were low. Regardless of LTC status receiving a digital treatment appeared to bolster engagement; however, adults who reported having a LTC were less likely to receive internet-enabled therapy in Talking Therapies. This suggests that barriers to engaging with COMPASS may not be wholly specific to living with an LTC such as diabetes. However, it appears that having an LTC may add an additional level of complexity which may reduce future implementation.

Finally, chapter 6, (study 4) examined the barriers and facilitators to implementing COMPASS, as perceived by in-service clinicians and wider stakeholders. The findings indicate recognition among stakeholders of the benefits of tailored digital interventions like COMPASS to increase access to psychological support for adults with diabetes and to assisting services to address clinical needs. However, several challenges to implementing COMPASS were identified, including concerns regarding its digital format and the complexities of integrating mental and physical health care within the current healthcare system. Negative attitudes surrounding digital treatment and integrated working, as well as deficiencies in clinician knowledge, confidence, and skills, were identified as barriers to implementation. Furthermore, structural obstacles such as inadequate funding, resources, and incongruence with existing care pathways and service objectives were highlighted.

Taken together, these studies contribute to the literature on the implementation of COMPASS an internet-enabled CBT intervention for adults with diabetes into routine care. The findings highlight both the significant barriers and facilitators associated with applying COMPASS in real-world practice settings. If these are not addressed, research will not translate into practice and clinical need will remain unmet. Therefore, future work should develop implementation strategies to overcome the barriers and enhance the facilitators identified in this thesis.

First author peer reviewed publications, or manuscripts under review

1. Jenkinson E, Knoop I, Hudson JL, Moss-Morris R, Hackett RA. The effectiveness of cognitive behavioural therapy and third-wave cognitive behavioural interventions on diabetes-related distress: A systematic review and meta-analysis. Diabet Med. 2022;39:e14948. doi: 10.1111/dme.14948
2. Jenkinson E, Hackett RA, Moss-Morris R, Wong G, Wheatley J, Cirkovic M, Hudson JL. Assessment attendance and treatment engagement with talking and internet-enabled therapies of people with and without a long-term physical health condition. An analysis of Talking Therapies service data. *BJPsych Open. 2024* [under review]

Non-first author publications during this thesis

1. Knoop, I., Picariello, F., Jenkinson, E., Gall, N., Chisari, C., & Moss-Morris, R. (2023). Self-reported symptom burden in postural orthostatic tachycardia syndrome (POTS): A narrative review of observational and interventional studies. *Autonomic Neuroscience*, *244*, 103052.

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Acknowledgements

My first acknowledgement must go to my supervisors: Dr Ruth Hackett, Dr Joanna Hudson, and Professor Rona Moss-Morris, thank you. I have always believed that I won gold when I started my PhD with you three. You are a true dream team and I feel very privileged to have been supervised by such intelligent, accomplished, inspiring, and supportive women in health psychology throughout my PhD. I have learned so much from each one of you that I will take forward with me, both professionally and personally.

A special mention must go to my primary and secondary supervisors Ruth and Jo. Thank you for being my guiding light for the last three years, I couldn't have completed this PhD without your wisdom and expertise. You are truly excellent, and I can't put into words how fortunate I feel to have worked so closely with you both. Thank you for your patience, encouragement, and belief in me, even when my own self-belief wavered.

To my friends and colleagues in the health psychology section, thank you for making coming to "the office" so enjoyable. I feel so lucky to have been surrounded by such a supportive and talented department of researchers, many of whom are now dear friends. Thankfully, I get to stick around and continue working with you all! A special shout out must go to the wider COMPASS team, especially Annie, Tash and Sophie thank you. I have learnt so much working in this team and consider it a huge honour to be surrounded by such intelligent and supportive early career researchers.

In true Emma style, I have more to say, and I could not submit this thesis without acknowledging my family and all friends who have supported me behind the scenes to get to this point. To my family, Mum, Dad and Josh… Thank you for your endless support, not just throughout this PhD but for the last 27 years. Thank you for reassuring me that I can do anything I set my mind to and for always reminding me never to not take life too seriously. To the 8RP girls, Anya, Nadia, Rosie, and Grace, I am so lucky to have lived with you throughout this journey. Thank you for listening to me express my every PhD thought, for wiping my tears on the stressful days, cooking my meals on the long days, and being front in line to cheer me on every day. Abbie, Catherine, Clara, I haven't forgotten you three... I am so appreciative of how much you have supported me in every way from our first day of the MSc in Health Psychology at Kings. Time really does fly! Thank you for encouraging me to purse this dream and for providing lots of love and laughter along the way.

Last but by no means least, thank you to all the people with diabetes, clinicians and stakeholders who participated in my research. Working with you has made me determined to advocate for better psychological care for people with diabetes and to support services to provide this. You are all truly inspirational.

Frequently used abbreviations

CBT Cognitive Behavioural Therapy

CI Confidence Interval

GAD-7 Generalised anxiety disorder 7 item scale

DDS-17 Diabetes Distress-17 Scale

DSM -5 - the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition

HbA1c Glycated haemoglobin

ICD International Classification of Diseases

LTC Long Term Physical Health Condition

MRC Medical Research Council

NHS National Health Service

NICE National Institute of Health and Care Excellence

PHQ-9 Patient Health Questionnaire-9 item Scale

PHQ-ADS Patient Health Questionnaire Anxiety and Depression Scale

SMD Standardised Mean Difference

UK United Kingdom

Chapter 1. Introduction to the literature

1.1 Chapter overview

This chapter will first introduce the clinical features and prevalence of diabetes. Next, the chapter will present an overview of three common psychological outcomes within diabetes; depression, anxiety, and diabetes-related distress and their associated clinical and economic implications. The chapter will conclude with a discussion surrounding the evidence base for psychological treatment, specifically Cognitive Behavioural Therapy (CBT) as an intervention to support the emotional wellbeing of people living with diabetes.

1.2 About Diabetes in adults

Diabetes, or Diabetes Mellitus as it is scientifically known, is an overarching term for a group of metabolic disorders characterised clinically by hyperglycaemia (high blood glucose levels) (American Diabetes Association, 2014). Hyperglycaemia in diabetes results from the progressive loss of pancreatic beta cell mass and/or function (American Diabetes Association, 2014). This can be represented through deficits in insulin secretion, insulin action or both (American Diabetes Association, 2014; ElSayed et al., 2023). Typical symptoms of hyperglycaemia include polydipsia (excessive thirst), polyuria (excessive urination), polyphagia (excessive hunger), weight loss, blurred vision, and susceptibility to infection (American Diabetes Association, 2014; ElSayed et al., 2023). Despite the clinical characterisation of diabetes through hyperglycaemia, it is important to note that hypoglycaemia (low blood glucose levels) also occur in diabetes. Hypoglycaemia is defined by the National Health Service (NHS) as occurring when glucose in the blood is too low (below 4mmol/l) (NHS UK, 2023). Typical symptoms of hypoglycaemia include slowed cognitive function, sweating, fatigue, quickening of heart rate, and in severe cases loss of consciousness (American Diabetes Association, 2014). Type 1 diabetes and type 2 diabetes are the most common types of diabetes worldwide (American Diabetes Association, 2014; ElSayed et al., 2023). Discussions of other types of diabetes including gestational diabetes, genetic defects in β-cell function or insulin action, diseases of the exocrine pancreas (e.g. pancreatitis), endocrinopathies (e.g. Cushing's syndrome), drug, chemical or infection induced diabetes are beyond the remit of this thesis (see American Diabetes Association (2014) for a review of these). Therefore, throughout this thesis the term 'diabetes' will be used to refer only to type 1 diabetes and type 2 diabetes unless otherwise specified.

1.2.1 Type 1 diabetes

Type 1 diabetes is an autoimmune condition. Most cases of type 1 diabetes result from autoimmune destruction of beta (**β**) cells in the pancreas (American Diabetes Association, 2014). The speed at which **β**-cells are destroyed varies across individuals. However, the destruction of beta cells in the pancreas leads to absolute insulin deficiency, meaning that people living with type 1 diabetes require lifelong exogenous insulin therapy. Within the United Kingdom (UK), type 1 diabetes accounts for approximately 8% of all cases (Whicher, O'Neill, & Holt, 2020). Type 1 diabetes is more commonly diagnosed during early adolescence although it can affect people at any age. There is currently no cure for type 1 diabetes thus its management is lifelong. Additionally, the cause of type 1 diabetes is currently unknown. However, research suggests that factors such as genetics and viral infections (e.g. Human Enteroviruses) likely play a role in the aetiology of type 1 diabetes although these factors are still poorly defined and evidence is currently inconclusive (American Diabetes Association, 2014; ElSayed et al., 2023).

1.2.2 Type 2 diabetes

Type 2 diabetes is a progressive condition. Unlike type 1 diabetes, type 2 diabetes is not caused by destruction of **β** -cells but instead a dysfunction of the pancreatic **β** cells (American

Diabetes Association, 2014). Therefore, the requirement for exogenous insulin therapy to survive is not necessary, at least initially. Loss of function in **β** -cells results in difficulties producing and/or secreting insulin and insulin resistance (American Diabetes Association, 2014; Eizirik, Pasquali, & Cnop, 2020). Insulin resistance is the process by which cells in the body do not respond properly to insulin that your body is making, and therefore, is unable to moderate levels of blood glucose properly. This leads to rising blood glucose levels. Additionally, impairments in insulin secretion and/or production may also contribute to rising blood glucose levels. Often people with type 2 diabetes will have a combination of insulin resistance and impairments in the secretion and/or production of insulin (Eizirik, Pasquali, & Cnop, 2020). Within the UK, type 2 diabetes accounts for approximately 90-95% of all cases (Whicher, O'Neill, & Holt, 2020). Although the specific aetiologies are not known, there are numerous established modifiable risk factors for type 2 diabetes (Diabetes UK., 2023a). These include, living with overweight or obesity (Ntuk et al., 2014), having a sedentary lifestyle (Hu, 2003), smoking, or increased rates of hypertension (high blood pressure). Non-modifiable risk factors include older age, having a family history of type 2 diabetes, and ethnicity. Specifically, individuals from an African-Caribbean or South Asian heritage are two-four times more likely to develop type 2 diabetes than their white European counterparts (Ntuk et al., 2014; Whicher, O'Neill, & Holt, 2020).

1.2.3 Prevalence of diabetes

Diabetes is a substantial public health challenge both nationally and internationally. Estimates from the International Diabetes Federation (Sun et al., 2022) suggest that over 537 million people (10% of the global population) had diabetes in 2021. Further, the same report highlights that the worldwide prevalence of diabetes is expected to rise to 783 million people (12.2% of the global population) by 2045. This is an increase of 46% in the absolute number of people who are predicted to have diabetes by 2045 (Sun et al., 2022). Data specific to the UK exhibits the same trend. The prevalence of diabetes is suggested to have doubled in the past twenty years in the UK (Diabetes UK., 2019; González et al., 2009; Whicher, O'Neill, & Holt, 2020). Specifically in the UK, the prevalence of people living with type 1 diabetes is 37.6 thousand, and the prevalence of people living with type 2 diabetes is 4.2 million and is increasing in both types of diabetes. Indeed, more recently Diabetes UK. (2023b) has published statistics estimating that over five million people in the UK are now living with diabetes, including over 1 million people who are yet to be diagnosed.

1.2.4 Diagnosing diabetes

The initial diagnosis of diabetes in adults is made based on clinical grounds that hyperglycaemia is present. This is evidenced by four markers: glycated haemoglobin (HbA1c), a marker of average blood glucose concentrations over the previous 2-3 months, fasting plasma glucose (FPG), a 75g oral glucose tolerance test (OGTT) or a Random Plasma Glucose test (American Diabetes Association, 2014). The cut offs for diabetes diagnosis are presented in *Table 1* according to criteria stipulated by National Institute for Health and Care Excellence (NICE) (National Institute for Health and Care Excellence [NICE], 2023a, 2023b) and the World Health Organisation(World Health Organisation [WHO]. 2019).

Table 1. *Criteria for Diabetes Diagnosis.*

	Diabetes diagnosis cut offs
HbA1c	≥6.5% (48 mmol/mol)
FPG	≥126 mg/dL (7.0 mmol/L)
Random Plasma Glucose	≥200 mg/dL (11.1 mmol/L)*
OGTT	≥200 mg/dL (11.1 mmol/L)

*This criterion is sufficient in the presence of classic diabetes symptoms.

1.2.5 Treatment and lifestyle management of diabetes

Diabetes management aims to optimise the overall health and quality of life for people living with diabetes by focusing on several key health markers, including blood glucose levels, cholesterol, blood pressure, and foot and eye health. These areas are recommended by the UK Quality and Outcomes Framework (QoF) (National Institute of Health and Care Excellence [NICE]. 2024; NHS England., 2024). The QoF provides targets and incentives for GP surgeries to deliver quality clinical care. In diabetes, the recommended management activities include monitoring and managing blood pressure and cholesterol to reduce cardiovascular risk, conducting regular foot and eye exams to prevent complications like neuropathy and retinopathy, and promoting weight management and smoking cessation to enhance overall health outcomes and quality of life. Specific clinical targets for HbA1c in diabetes management exist (e.g., 48 mmol/mol or 6.5%, as recommended by the NHS), but each person is unique, and their individual circumstances will be considered when determining their target.

Additionally, for all people with diabetes (type 1 and type 2) diabetes self-management education is recommended (Chatterjee et al., 2018; National Institute for Health and Care Excellence [NICE], 2023a, 2023b) to support people with diabetes to have the knowledge and tools to manage their condition. The American Association of Diabetes Educators (Powers et al., 2017) has defined seven key self-management behaviours that should be addressed in self-management education. The relevance of these behaviours may differ by individual and diabetes type, but they are as follows: healthy eating, physical activity, monitoring glucose, medication use, risk reduction, problem solving, and healthy coping. Additionally, NICE recommends that self-management education should be offered to people with diabetes at the time of diagnosis, with ongoing maintenance sessions (National Institute for Health and Care Excellence [NICE], 2023a, 2023b).

1.2.6 Complications of diabetes

Chronic hyperglycaemia has been consistently linked to long-term damage of bodily organs. The injurious effects of diabetes have traditionally been divided into two distinct groups, microvascular (damage to the small blood vessels) and macrovascular (damage to the large blood vessels) complications (Fowler, 2008). Macrovascular complications include cardiovascular disease, stroke, and peripheral artery disease. Microvascular complications include diabetic nephropathy (damage to the kidneys), neuropathy (damage to the nerves), and retinopathy (damage to the eyes). The consequences of these complications are well-established and can lead to blindness, renal failure, neuropathic pain, foot ulcers and amputation (Gregg, Sattar, & Ali, 2016; Nickerson & Dutta, 2012). However, rates of traditional complications appear to be reducing (Gregg et al., 2014) potentially due to clinical advances in diabetes management. This is promising, however review evidence by Pearson-Stuttard et al. (2022) now suggests that other, non-traditional chronic complications of hyperglycaemia such as cancer, liver disease and affective disorders (e.g., depression and anxiety) hold significant disease burden in diabetes and should be considered.

1.2.7 Hypoglycaemia in diabetes

Hypoglycaemia (low blood glucose levels) is a challenging side effect of diabetes medication affecting people with both type 1 and type 2 diabetes who use insulin or other diabetes medications, such as sulfonylureas (Nakhleh & Shehadeh, 2021). Hypoglycaemia can cause acute symptoms such as blurred vision, tiredness, heart palpitations, sweating, and confusion. Hypoglycaemia can also lead to seizures and loss of consciousness (NHS UK, 2023).

1.3 The impact of diabetes on psychological and emotional wellbeing

At a basic level, the interaction of psychological, societal, and biological processes within long-term physical health conditions (LTCs) are well understood within biopsychosocial model (Bolton & Gillett, 2019; Engel, 1977) (summarised in **Figure 1.** The biopsychosocial model of health. page 22).

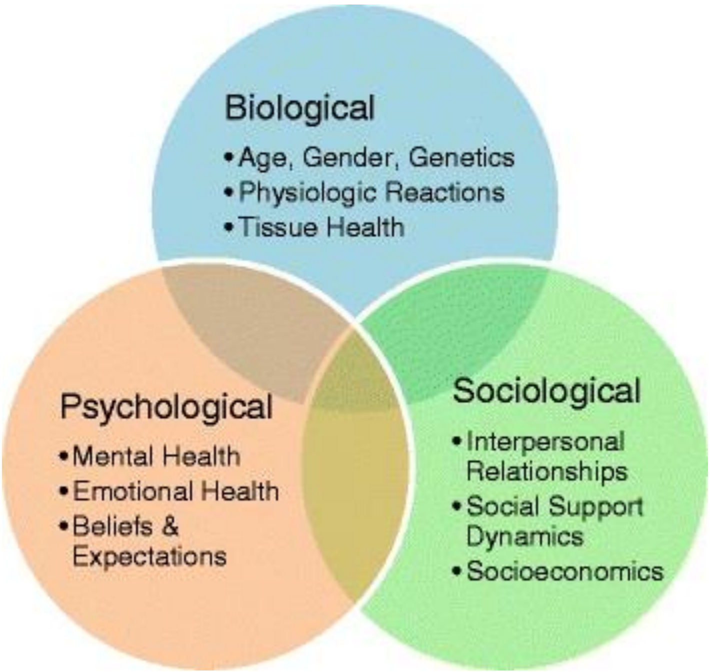

Figure 1. *The biopsychosocial model of health.*

An illustration of the biopsychosocial (biological, psychological and social) model taken from Gliedt et al. (2017).

Additionally, the burden of adjusting to and continually living with an LTC is recognised (Hoyt & Stanton, 2018; Moos & Schaefer, 1984; Moss-Morris, 2013). Diabetes is no exception to this; diabetes and its demands can be relentless with the potential to take a considerable emotional toll on the person living with diabetes. Indeed, living with diabetes is complex and poses numerous emotional, behavioural, and cognitive challenges. These challenges include (but are not limited to) the stress of the initial diagnosis, the ongoing adjustment to living with diabetes and the ongoing self-management of diabetes. Self-care behaviours highlighted above such as medication taking, healthy eating, physical activity, blood glucose monitoring and ongoing problem solving are behaviourally and cognitively burdensome (Snoek, 2022). Further, people living with diabetes often fear the possibility of acute hypoglycaemia and the long-term complications associated with hyperglycaemia (Snoek, Hajos, & Rondags, 2014). Moreover, those living with diabetes may experience distress surrounding interpersonal relationships with loved ones and healthcare professionals (Stuckey et al., 2014).

This thesis focuses on common mental health conditions such as depression and anxiety. Discussion of other mental health conditions such as major psychiatric disorders often termed severe mental illness (including schizophrenia, psychotic depression and bipolar disorder) and their impact on individuals with diabetes are beyond the remit of this thesis. For a review on this see Holt and Mitchell (2015).

1.3.1 Depression

Depression is formally defined using psychiatric diagnostic criteria from the International Classification of Diseases (ICD-11) (World Health Organization., 2021) and the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) (American Psychiatric Association., 2013). According to this criterion, depression (also known as major depressive disorder) is a mood disorder based on the presence or absence of affective and somatic symptoms. Core symptoms of major depression in the DSM-5 include: 1) a diminished/irritable mood 2) a decrease in pleasure or interest (anhedonia). Additional symptoms include: 3) feelings of guilt or worthlessness, 4) fatigue, 5) suicidal ideation, 6) difficulties concentrating, 7) weight loss or gain, 8) changes in psychomotor activity and 9) changes in sleep (American Psychiatric Association., 2013). In the DSM-5, for a diagnosis of major depressive disorder to be made, symptoms must last at least two weeks. Additionally, an individual must have five of the nine symptoms listed above including a minimum of one of the core symptoms. This criterion is similar in the ICD-11 (World Health Organization., 2021). The gold standard diagnostic measurement for depression is a clinical interview (e.g., the Structured Clinical Interview for DSM-5 (SCID-5). However, more commonly validated self-report measures of depression are used to assess levels of depressive symptoms (e.g., the Patient Heath Questionnaire-9; PHQ-9) (Kroenke, Spitzer, & Williams, 2001).

Estimates from epidemiological research suggest that the prevalence of depression is doubled in people living with diabetes when compared to the general population (Odds Ratio OR= 2.0, 95% Confidence Interval (CI) 1.8 to 2.2; Anderson 2001).

A recent systematic review with meta-analysis (k=44; Farooqi (2022) showed that people with type 1 diabetes and type 2 diabetes had greater odds of experiencing depression when compared to those without diabetes (type 1 diabetes = OR = 2.10, 95% CI: 1.23 to 3.52; type 2 diabetes = OR = 1.76, 95% CI: 1.55 to 2.01). Moreover, this effect did not appear to be moderated by methods of depression assessment (e.g. self-report vs clinical interview). However, the authors acknowledge this may be due to a lack of statistical power in this meta-analysis where only aggregate data is available.

When studies with no control group were meta-analysed (k=248 studies) the prevalence of depression in people with type 2 diabetes was reported as 28% (95% CI; 27%-29%). Sub-group analyses showed prevalence estimates were higher when self-report measures were used (30%, 95% CI 28% - 32%) compared with diagnostic clinical interviews (22%, 95% CI 19% - 24%). Further, a systematic review of the literature on type 1 diabetes by Barnard, Skinner and Peveler (2006) demonstrated that the prevalence rate of depression in type 1 diabetes (*k*=10) was 13.4% in studies with no control group.

Meta-analytic evidence suggests that depression in diabetes is associated with poorer self-management behaviours (adherence to diet, exercise, medication, foot care, blood glucose monitoring and appointment attendance) (*k*=47 studies; *r*= 0.21, 95% CI 0.17–0.25) (Gonzalez et al., 2008), a greater number or more severe diabetes complications (*k*=27 studies; *r*=0.25, 95% CI=0.22-0.28) (De Groot et al., 2001). Further, systematic review evidence has found that depression in diabetes is associated with reduced quality of life (Schram, Baan, & Pouwer, 2009) and increased healthcare usage (Egede, Zheng, & Simpson, 2002; Molosankwe et al., 2012). Additionally, there is some meta-analytic evidence suggesting that depression is associated with poorer glycaemic control in diabetes (*k*=24 studies; *r*= 0.17, 95% CI 0.13 to 0.21) (Lustman et al., 2000). Additionally, a study by Schmitt, McSharry, et al. (2021) found that baseline depression predicted higher HbA1c four years later in people with type 1 diabetes indirectly via less optimal self-care at follow-up ($\beta = 0.19$, $p = 0.011$).

Evidence also suggests that co-morbid depression in diabetes has been associated with an increased risk of developing macrovascular (Hazard Ratio (HR) = 1.38; 95% CI: 1.30–1.47) and microvascular (HR = 1.33; 95% CI: 1.25–1.41) complications prospectively (Nouwen et al., 2019). Further, baseline depression in people with diabetes has been associated with an increased risk of all-cause mortality (k=16; HR=1.46, 95% CI=1.29–1.66), and cardiovascular mortality (*k*=16; HR=1.39, 95% CI=1.11–1.73) compared to those with diabetes but without depression.

As highlighted above, the relationship between depression and diabetes is well established, and the impact of depression on clinical outcomes is significant. Furthermore, depression is an understandable consequence of diabetes due to the burden of living with the condition (Snoek, 2022). Therefore, one interpretation of the relationship between depression and diabetes is that the burden of diabetes increases rates of depression (Moulton, Pickup, & Ismail, 2015).

However, it is important to acknowledge that consistent research has also demonstrated a bi-directional relationship between depression and diabetes (Hackett & Steptoe, 2017; Moulton, Pickup, & Ismail, 2015). In type 2 diabetes specifically, previous studies have demonstrated that depression is a risk factor for the development of diabetes (Kan et al., 2013; Mezuk et al., 2008). Indeed, research has explored both direct and indirect pathways to understand how depression may be implicated in the onset of type 2 diabetes. For a full review on these potential mechanisms, see Hackett and Steptoe (2017).

In brief, both depression and type 2 diabetes are associated with the dysregulation of neuroendocrine pathways including the hypothalamic-pituitary-adrenocortical (HPA) axis such as increased cortisol output. This has implications as increased activation of the HPA axis and dysregulated cortisol output are associated with cardiovascular disease, insulin resistance and the regulation of blood glucose. Indeed, dysregulated cortisol has been shown to be predictive of new onset of type 2 diabetes (Hackett et al., 2016).

Another hypothesised mechanism is through inflammatory processes (Moulton, Pickup, & Ismail, 2015; Wang et al., 2013). Increased proinflammatory cytokines, and other inflammatory markers such as C-reactive protein, TNF-α have been implicated in both depression and type 2 diabetes. Furthermore, a heightened inflammatory response has been prospectively shown to be a risk factor for developing type 2 diabetes in initially healthy individuals (Wang et al., 2013).

Additionally, indirect mechanisms exist between depression and the later development of type 2 diabetes through shared environmental and lifestyle factors, such as diet, smoking, reduced physical activity and socioeconomic deprivation (Moulton, Pickup, & Ismail, 2015).

1.3.2 Anxiety

Anxiety disorders are a group of disorders characterised by excessive worry (American Psychiatric Association., 2013). Currently, there are numerous anxiety disorders listed in the DSM-5. These include generalised anxiety disorder (GAD), panic disorder, obsessive compulsive disorder, social anxiety disorder, specific phobias (e.g., spiders), post-traumatic stress disorder, acute stress disorder, separation anxiety disorder and selective mutism. However, evidence suggests GAD is the most prevalent clinical disorder in people with diabetes (Grigsby et al., 2002). The diagnosis of GAD is made by applying categorical thresholds to symptoms. In the DSM-5 these symptoms are excessive worry more days than not over a 6-month period, feeling irritable, tense or having problems concentrating or sleeping (American Psychiatric Association., 2013; National Institute for Health and Care Excellence [NICE]. 2011). As with major depression, GAD is typically assessed using a clinical interview. However, symptoms of anxiety are also commonly measured using validated self-report measures such as the Generalised Anxiety Disorder Scale (GAD-7) (Spitzer et al., 2006).

A meta-analysis by Grigsby et al. (2002) (*k*=18) explored the prevalence of anxiety for individuals with diabetes measured through diagnostic interview and self-reported measures. The review found that overall, 40% of people with diabetes had elevated anxiety symptoms (measured via self-report) and 14% of people with diabetes met the criteria for a diagnosis of GAD (measured via clinical interview). Further, findings from Smith et al. (2013) indicate that adults with type 1 diabetes or type 2 diabetes have a 1.25-fold increased odds of anxiety (measured via self-report or clinical interview) (*k*=12; OR=1.25, 95% CI 1.10 to 1.39) compared to adults without diabetes.

More recently, a meta-analysis by Amiri and Behnezhad (2019) demonstrated that diabetes is associated with an 1.48-fold increase in odds of anxiety (*k*=23; OR = 1.48; 95% CI = 1.27–1.74). This association did not appear to be significantly moderated by the study design, diabetes type or measurement of anxiety (clinical interview vs self-report).

The impact of anxiety on outcomes in diabetes is less clear as findings are equivocal. However, an early study by Lustman et al. (2000) meta-analysed results from 11 cross sectional studies and found that anxiety disorders when measured using clinical interview were associated with worsened glycaemic control (*r*=0.25; 95% CI 0.10-0.38) . However, when measured through self-report questionnaires there was no significant relationship between anxiety and HbA1c (*r*=0.07; 95% CI 0.01-0.13). In other cross-sectional work, elevated symptoms of anxiety have been shown to be related to poorer quality of life (Chyun et al., 2006) and poorer adherence to self-care behaviours for adults living with diabetes (Smith, Pedneault, & Schmitz, 2015).

1.3.3 Comorbid depression and anxiety

Symptoms of anxiety are commonly co-morbid with depressive symptoms in LTCs (DeJean et al., 2013). Specifically, cross-sectional estimates suggest that adults living with diabetes (*n*= 17, 623) have twice the odds (OR = 1.99, 95% CI 1.22-3.25) of experiencing co-morbid depression and anxiety than those without diabetes after controlling for key clinical and demographic confounding variables (Deschênes, Burns, & Schmitz, 2015).

In the same study (Deschênes, Burns, & Schmitz, 2015), comorbid depression and anxiety was associated with a greater likelihood of disability (OR = 1.93, 95% CI: 1.09–3.43) than if depression or anxiety occurred alone. However, in the study by Deschênes, Burns and Schmitz (2015) differences between type 1 diabetes and type 2 diabetes were not explored.

Additionally, a further cross-sectional study (*n*=6590) found that for adults with diabetes, comorbid depression and anxiety was associated with more severe depression and anxiety symptoms irrespective of diabetes type (Nefs et al., 2019) than having elevated symptoms of depression alone (type 1 diabetes; PHQ-9 total scores; co-morbid symptoms versus depression alone $d = 0.86$; $p < 0.001$; type 2 diabetes; co-morbid symptoms versus depression alone $d = 1.01$; $p < 0.001$) or anxiety alone (type 1 diabetes**;** GAD-7 total score; comorbid symptoms versus anxiety alone, $d = 0.48$; $\mathrm{p} < 0.001$; type 2 diabetes; comorbid symptoms versus anxiety alone, $d = 0.62$; $p < 0.001$).

In the same study (Nefs et al., 2019), comorbid depression and anxiety in diabetes was associated with sub-optimal diabetes self-care behaviours such as, not taking blood pressure lowering tablets as recommended, being a smoker and not meeting the recommended guidelines for healthy eating and exercise compared to no/minimal anxiety and depression symptoms in diabetes.

Alongside this, evidence suggests that sub-threshold symptoms of depression and/or anxiety (defined as symptoms that do not meet full diagnostic criteria for either condition alone) often occur in people living with LTCs (Geraghty et al., 2017) such as diabetes (Fisher, Skaff, et al., 2008; Hermanns et al., 2006). Despite not meeting diagnostic criteria, these symptoms may still be causing a high level of distress for people living with diabetes. Additionally, evidence suggests subthreshold symptoms of depression impact diabetes-self management behaviours (Pibernik-Okanović et al., 2011; van der Feltz-Cornelis et al., 2021) and glycaemic control (Fisher, Gonzalez, & Polonsky, 2014). This suggests that these subthreshold symptoms may hold clinical relevance in diabetes.

In light of this, it has been argued that using formal diagnostic labels of depression and anxiety in the context of an LTC such as diabetes pathologizes an understandable negative emotional response to an objectively challenging illness (Coventry et al., 2011; Hudson & Moss-Morris, 2019). Hence, terms distress, illness distress or illness-related distress are commonly used to describe negative emotional responses to illness and reflect a broader conceptualisation, because these terms include both symptoms of depression and anxiety (Esbitt, Tanenbaum, & Gonzalez, 2013; Leventhal et al., 2004). The concept of illness-related distress in diabetes first emerged from research on stress and coping (Lazarus & Folkman, 1984) and emotional regulation (Lazarus, 1991). Theoretically, this research poses that emotions arise in specific situations and contexts from both acute (e.g. diagnosis) and chronic stressors (e.g. adhering to a long-term treatment regimen).

1.3.4 Diabetes-related distress

Specific to diabetes, diabetes-related distress has long been cited as a key psychological concept in diabetes. The concept of diabetes-related distress was first proposed almost 30 years ago (Polonsky et al., 1995). Diabetes-related distress reflects the emotional response to the everyday experience of living with diabetes and considers the threat and burden of living with a chronic LTC such as diabetes (Skinner, Joensen, & Parkin, 2020). Diabetes distress is considered to include a core construct of "emotional distress" which is a continuous construct and consists of both: 1) content and 2) severity. The content of emotional distress in diabetes is linked to its clinical challenges and management (Esbitt, Tanenbaum, & Gonzalez, 2013). The severity element reflects how extreme a person's symptoms of distress are and, in some instances, may meet criteria for depression and/or anxiety according to formal diagnostic categories (Fisher, Gonzalez, & Polonsky, 2014). Therefore, diabetes distress is conceptually distinct from the psychiatric labels of depression and anxiety whereby diagnosis occurs based on the presence, severity and duration of specific symptoms without acknowledging its causal aetiology (Fisher, Gonzalez, & Polonsky, 2014).

To highlight this difference, research has shown that people who meet established cut-offs for diabetes-related distress on self-report measures may not always meet diagnostic cut-offs for depression (Fisher, Gonzalez, & Polonsky, 2014; Fisher et al., 2007). In one study Fisher, Skaff, et al. (2008) found that over three quarters (84.1%) of people with diabetes with moderate or high diabetes-related distress did not meet cut-offs for a diagnosis of major depressive disorder. Additionally, Fisher, Skaff, et al. (2008) found that over half (66.7%) of patients with major depressive disorder also displayed moderate or high levels of diabetes-related distress. This suggests that people living with diabetes and high levels of diabetes-related distress may not be depressed in the way we currently understand it, but rather experience depressive symptoms related to diabetes (Fisher, Gonzalez, & Polonsky, 2014; Tanenbaum & Gonzalez, 2012). Indeed, qualitative findings from young adults (aged >18) living with type 1 diabetes and mild-to-moderate depressive symptoms (measured through validated self-report measures) concurs with this (Clarke et al., 2018). The qualitative findings indicate that participants felt it more accurate to consider their emotional struggles in the context of their diabetes than as a discrete mental health condition.

Diabetes-related distress is measured via validated self-report questionnaires such as the 17-item Diabetes Distress Scale (DDS) (Polonsky et al., 2005) and the 20-item Problem Areas in Diabetes (PAID) scale (Polonsky et al., 1995). Moreover, shorter and more specific versions of these scales have been developed and validated such as the DDS-2, a 2 item scale (Fisher, Glasgow, et al., 2008), the Type 1-DDS scale (Fisher et al., 2015) the PAID-5 and PAID-1 scale (5 and 1 items, respectively) (McGuire et al., 2010). From this, psychometric testing has generated cut-off scores on these measures to determine the presence of clinically significant diabetes-related distress (Schmitt et al., 2016). The presence on diabetes-related distress is defined using the following cut offs; PAID ≥ 40 (Polonsky et al., 1995) and DDS-17 mean scores ≥ 2 (Fisher et al., 2012). Further, Fisher et al. (2012) suggested three potential sub-groups of distress cut offs: "little or no diabetes-related distress" (DDS<2.0), "moderate diabetes-related distress" (DDS = 2.0– 2.9), and "high diabetes-related distress" (DDS ≥3.0).

Despite depression and diabetes-related distress being distinct constructs, Snoek, Bremmer and Hermanns (2015) highlights that measures of diabetes-related distress do show strong positive correlations with both self-reported (*r*=0.48; Fisher 2015, Center for Epidemiologic Studies Depression CES-D Scale; PHQ-9 Reddy, 2013 *r*=0.50) and clinical interview (Fisher 2015; WHO Composite International Diagnostic Interview CIDI = *r*=0.15 MINI; MINI International Neuropsychiatric Interview, Carper, 2014 *r*=0·04) measures of depression suggesting conceptual overlap. However, data indicates that there is still variance in diabetes-related distress that remains unexplained (Snoek, Bremmer, & Hermanns, 2015) further reinforcing the argument that these concepts are not completely synonymous.

Whilst prevalence estimates of diabetes-related distress vary across samples, research indicates that it affects a substantial number of adults with diabetes. Specifically, pooled meta-analytic evidence suggest that ~36% (95% CI; 0.31 - 0.41) of adults with T2D experience significant diabetes-related distress (Perrin et al., 2017). Meta-analytic evidence surrounding the prevalence of diabetes-related distress in type 1 diabetes is unavailable, however individual study estimates suggests that 20-42% of adults with type 1 diabetes experience elevated diabetes-related distress (Fisher et al., 2016; Sturt, Dennick, Due-Christensen, & McCarthy, 2015).

Taken together, these findings may suggest that there are four prominent common emotional responses experienced by people living with diabetes 1) those experiencing depression but not diabetes-related distress 2) those experiencing diabetes-related distress but not meeting thresholds for depression 3) those experiencing diabetes-related distress and depression ("distressed-depressed") 4) those who are not experiencing depression or distress (Skinner, Joensen, & Parkin, 2020).

Similar to depression and anxiety, diabetes-related distress is cross-sectionally associated with poorer quality of life for people living with diabetes (Carper et al., 2014). Elevated diabetes-related distress has also been cross-sectionally and longitudinally associated with poorer self-reported self-management behaviours (such as diet, medication adherence, blood glucose monitoring and physical activity) (standardised b −0.16, $p = .007$) (Schmitt, Bendig, et al., 2021). Additionally, elevated diabetes-related distress is related to a greater number of diabetes-complications (Pintaudi et al., 2015) and higher blood glucose levels (Kasteleyn et al., 2015; Schmitt, Bendig, et al., 2021). Indeed, more recent evidence suggests that the relationship between depression and poorer glycaemic control that has been observed previously (Lustman et al., 2000) may be mediated by diabetes-related distress (Hessler et al., 2017; Schmitt et al., 2015; Snoek, Bremmer, & Hermanns, 2015). This suggests that depression has a unique impact on diabetes outcomes whilst also impacting outcomes indirectly via diabetes distress.

Taken together, depression, anxiety and diabetes-related distress affect a substantial number of adults living with diabetes. Additionally, meta-analytic literature (which is the most robust evidence base as numerous studies are pooled together to establish the overall effect) suggests that poorer psychological wellbeing has a negative impact on clinical outcomes. Specifically, this evidence suggests that depression and diabetes-related distress have the largest impact on clinical outcomes, with further research needed surrounding the impact of anxiety on diabetes outcomes.

1.4 The economic impact of diabetes and psychological distress

In the UK, it is estimated that comorbid psychological distress alongside an LTC increases healthcare costs by 45%–75% (Naylor et al., 2012) equating to an extra £1760–£2933 per patient, per year. LTCs with comorbid psychological conditions also generate wider economic costs, such as increased absence from work and disability leave (Naylor et al., 2016; Pooler & Beech, 2014). Specific to diabetes, consistent evidence has identified the association between psychological distress and increased healthcare costs (Das-Munshi et al., 2007; Hutter, Schnurr, & Baumeister, 2010; Molosankwe et al., 2012). Further, in the national strategy document the “Five Year Forward view for Mental Health” it was suggested that reducing psychological distress in diabetes may reduce overall costs to the English NHS by up to 15% (Mental Health Taskforce, 2016).

1.4.1 Psychological care in diabetes

Both pharmacology and psychotherapy can be used to improve psychological outcomes in diabetes (Gold et al., 2020). However, NICE recommends psychotherapy as the first line intervention due to potential contraindications and risk benefit-ratios in diabetes (Baumeister, Hutter, & Bengel, 2014; National Institute for Health and Care Excellence [NICE], 2023a, 2023b; National Institute for Health and Care Excellence [NICE]. 2009). Additionally, there is some evidence to suggest that psychotherapy treatment may benefit both psychological symptoms and glycaemic control in adults, whereas psychiatric medications may only reduce psychological symptoms (Robinson et al., 2018). Therefore, psychotherapy may be the preferred treatment.

Cognitive Behavioural Therapy (CBT) is a commonly used psychological therapy that posits that cognitions (thoughts), behaviours, emotions and physical sensations all interact and influence one and other within our individual and social context. CBT postulates that a change in one of these areas may instigate changes in another (Beck, 1979, 1991).

NICE recommends CBT treatment for the management of depression and anxiety across all levels of severity (National Institute for Health and Care Excellence [NICE]. 2011, 2022). Further, NICE recommend use of CBT as a treatment for depression in the context of LTCs such as diabetes (National Institute for Health and Care Excellence [NICE]. 2009).

It has been argued that CBT is the ‘gold standard’ psychological therapy for treating anxiety and depression. A meta-analytic review by David, Cristea and Hofmann (2018) suggests that this is due to the robust evidence base around the therapeutic modality, highlighting its superiority in terms of efficacy compared to other psychotherapy approaches. However, a recent review by Cuijpers et al (2023) titled “Five Decades of research on Psychological Treatments of Depression” acknowledged the efficacy of CBT but questioned the superiority of this approach. The authors argued that this narrative may be due to the high volume of evidence that exists for CBT compared to other psychological treatments rather than superior efficacy compared to other therapeutic approaches.

Nonetheless, CBT has the most empirical support as a psychological treatment for adults with LTCs (Fordham et al., 2021; National Collaborating Centre for Mental Health., 2018). Alongside traditional CBT described above, review evidence has indicated that third-wave CBT may hold potential for treating psychological outcomes in LTCs (Graham et al., 2016). Third-wave CBT approaches are an umbrella term for therapeutic modalities such as acceptance and commitment therapy (ACT), mindfulness and compassion focused therapy. It has been argued that third-wave approaches may hold utility in LTCs where illness-related distress and worry is understandable and often realistic. Indeed, third-wave CBT approaches place the focus on one’s response to their cognitions, emotions, behaviours, and physical sensations. Therefore, aiming to increase meaningful activity in the presence of distress. Traditional CBT places focus on the appraisal of cognitions, emotions, behaviours and physical sensations often with the primary aim of evaluating and reducing distress.

What is clear from the literature is that depression, anxiety and diabetes-related distress affect may adults living with diabetes, and this can substantially impact on clinical and economic outcomes. However, despite overlap, the literature highlights a conceptual distinction between depression and diabetes distress. Indeed, research indicates that diabetes-related distress may have distinct influence on clinical outcomes in diabetes separate to depression. Currently, the effects of CBT on psychological distress outcomes in LTCs are well established. Furthermore, meta-analytic evidence has demonstrated some potential of CBT and third wave CBT for improving psychological outcomes for adults with diabetes (Graham et al., 2016; Li et al., 2017; Uchendu & Blake, 2017; Yang, Li, & Sun, 2020). However, little is known about the effects of these interventions on diabetes-related distress. Given the evidence suggesting that diabetes-related distress may have distinct influence on clinical outcomes in diabetes separate to depression, understanding the effect of CBT on this outcome may be important.

1.4.2 Definition of terms used within this thesis.

So far, the distinction between terms depression, anxiety, and diabetes-related distress have been discussed. Throughout this thesis, the term psychological distress will be used as a general descriptor of low mood and anxiety. The terms depression and/or anxiety will be used specifically when discussing these concepts and the term illness-specific distress or diabetes-related distress will be used to refer to distress that is conceptually linked to having an LTC such as diabetes.

1.5 Chapter conclusion

This chapter presented an overview of literature highlighting the high prevalence of depression, anxiety and diabetes-related distress for adults living with diabetes and the impact of this on clinical and economic outcomes. Further, this chapter outlined existing literature asserting a conceptual distinction between depression and diabetes-related distress. Additionally, this chapter presented research evidence suggesting that diabetes-related distress may have distinct influence on clinical outcomes in diabetes, separate to depression. From research evidence it appears that CBT is effective for improving psychological outcomes such as depression and anxiety in LTCs. However, the evidence surrounding the efficacy of CBT for diabetes-related distress remains unclear.

Chapter 2. Systematic Review [published manuscript]

2.1 Chapter overview

The preceding chapter highlighted the need to provide psychological support for people living with diabetes. Additionally, gaps in the existing literature were highlighted surrounding the effects of CBT on diabetes-related distress. This chapter presents a published systematic review and meta-analysis: The effectiveness of cognitive behavioural therapy and third-wave cognitive behavioural interventions on diabetes-related distress (Jenkinson et al., 2022) that was conducted as part of this thesis.

Please note the Supplementary Tables for this published paper are presented in Appendix A rather than in the main body of the thesis. Due to journal requirements at diabetic medicine, the published article only includes 50 references in the manuscript reference list with the remaining in the supplementary document. Further, the referencing style follows journal requirements (American Medical Association; AMA). However, for the purpose of this thesis all in-text references have been included in the main body of this text and the referencing style had been amended to American Psychological Association (APA) referencing.

2.2 Published article

The effectiveness of Cognitive Behavioural Therapy and third wave Cognitive Behavioural interventions on diabetes-related distress: a systematic review and meta-analysis.

Running title: Investigating CBT treatment for diabetes-related distress: a review.

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Abstract word count: 245

Manuscript word count: 5593

Conflicts of interest: None to declare.

Novelty statement (max 100 words).

What is already known?

- CBT is effective at treating depression in diabetes but findings for diabetes-related distress are inconclusive.

What has this study found?

- CBT interventions significantly reduced distress and depression.
- Third-wave CBT significantly reduced anxiety.
- There were no significant effects for either therapy on glycated haemoglobin.
- Interventions delivered by a psychological practitioner including a digital component and behavioural activation appeared to bolster the effects of CBT on distress.

Implications of the study

- This review compared CBT and third-wave CBT for diabetes-related distress and provides clinical utility by identifying intervention components that may be most useful for treating diabetes-related distress.

Acknowledgements

This study was funded by King’s College London, Department of Psychology. We would like to extend of thanks to all the study authors who responded to our request for intervention manuals and additional data.

Abstract (max 250 words)

Aim: Diabetes-related distress is common in diabetes and has implications for wellbeing. Cognitive Behavioural Therapy (CBT) and third-wave CBT hold promise as treatments for diabetes-related distress, although previous findings are inconclusive. We aimed to conduct a systematic review with meta-analysis to understand the efficacy of these interventions in treating diabetes-related distress, whilst also assessing the associative benefits of these interventions on depression, anxiety, and glycaemic control. We also aimed to conduct a narrative synthesis, and sub-group analyses to identify intervention components most useful in treating diabetes-related distress**.**

Method: We searched seven electronic databases from inception to April 2021. Data extraction was independently performed by two reviewers. Methodological quality was assessed. The protocol was registered with the Prospective Register Of Systematic Reviews (PROSPERO): CRD42021240628.

Results: We included 22 randomised controlled trials investigating the efficacy of CBT and third-wave CBT interventions on diabetes-related distress. CBT for diabetes-related distress significantly reduced distress (SMD =-0.278, p=0.010) and depression (SMD = -0.604, p=0.016). Third-wave CBT for diabetes-related distress significantly reduced anxiety (SMD = -0.451, p=0.034). No significant effect of either intervention on glycated haemoglobin was observed. CBT interventions that included a digital component, were delivered by a psychological practitioner, and included behavioural activation bolstered the effects on diabetes-related distress.

Conclusions: CBT aiming to target diabetes-related distress is beneficial for distress and depression. Third-wave CBT for diabetes-related distress is beneficial for anxiety. More work is needed to optimise interventions to improve both mental and physical health outcomes in people with diabetes.

Keywords Diabetes Mellitus, Type 2; Diabetes Mellitus, Type 1; Cognitive Behavioural Therapy; Mindfulness; Acceptance and Commitment Therapy; Psychological Distress

Introduction

Psychological distress is common in diabetes. People with diabetes are two times more likely to experience depression compared to those without diabetes (Khaledi et al., 2019; Sartorius, 2018), and have a 25% higher prevalence of anxiety (Smith et al., 2013). Furthermore, diabetes-related distress is estimated to occur among 40% of people with diabetes(Perrin et al., 2017; Skinner, Joensen, & Parkin, 2020). Diabetes-related distress is an illness-specific psychological distress that reflects a person's emotional response to the demands and challenges of living with diabetes (Snoek, Bremmer, & Hermanns, 2015). It considers psychosocial adjustment and challenges faced by individuals with diabetes (Skinner, Joensen, & Parkin, 2020). Although related (Snoek, Bremmer, & Hermanns, 2015), diabetes-related distress is distinct from depression and anxiety (Snoek, 2020; Snoek, Bremmer, & Hermanns, 2015), as these disorders are assessed using thresholds of somatic and affective symptomology (Hudson & Moss-Morris, 2019) irrespective of context or cause (Sturt, Dennick, Due-Christensen, & McCarthy, 2015). Unlike depression or anxiety, diabetes-related distress is said to be closely attached to the day-to-day experience of living with diabetes whereas depression and/or anxiety is generally unrelated to a specific condition.

A lot of research to date has focused on depression and anxiety in diabetes. This may be explained by evidence associating depression with poorer glycaemic control (Lustman et al., 2000), increased risk of diabetes complications (Nouwen et al., 2019) and reduced quality of life (Gómez-Pimienta et al., 2019; Schram, Baan, & Pouwer, 2009). However, researchers have been investigating diabetes-related distress as a key psychological outcome in diabetes for over twenty-five years (Bawa et al., 2020; Polonsky et al., 1995; Skinner, Joensen, & Parkin, 2020). Psychological distress seen within diabetes is often conceptually different to that in those living with general depression and anxiety (e.g. emotional burden of diabetes management, the burden of potential future complications and the social impact of diabetes (Hendrieckx et al., 2019; Polonsky et al., 2005). Indeed, evidence now suggests that diabetes-related distress may be more closely linked to glycaemic control than depression (Fisher et al., 2010; Hessler et al., 2017; Schmitt, Bendig, et al., 2021). Furthermore, it has shown associative relationships with quality of life (Carper et al., 2014) and self-management behaviours (Dennick, Sturt, & Speight, 2017; Fisher et al., 2010) that may have implications for metabolic outcomes. Therefore, understanding treatment for diabetes-related distress, may potentially be imperative to improve emotional-wellbeing and physical outcomes in diabetes. Psychological therapies offer one treatment strategy in this regard.

In the United Kingdom, Cognitive Behavioural Therapy (CBT) is the recommended psychological treatment for managing anxiety and/or depression in the context of long-term conditions such as diabetes (National Collaborating Centre for Mental Health, 2018; National Institute for Health and Care Excellence [NICE]. 2009). CBT posits that cognitions are central to behavioural, emotional, and physical responses (Beck, 1979; Greenberger & Padesky, 2015; Padesky, 2020) with each of these elements constantly interacting and influencing each other (Greenberg & Padesky, 1995). Most previous review studies have explored the effectiveness of CBT for depression, anxiety, and glycaemic control, with diabetes-related distress as an additive component. A 2017 meta-analysis (Uchendu & Blake, 2017) investigated the effect of CBT interventions on glycated haemoglobin (HbA1c) as a primary outcome, along with depression, anxiety, and diabetes-related distress as secondary outcomes. CBT significantly reduced depression and anxiety in the short and medium term with moderate effect. CBT also significantly reduced depression in the long term with small effect. For HbA1c, CBT had a small statistically significant effect in the short and medium term but not the long term. Too few studies were identified to meta-analyse diabetes-related distress outcomes.

A second 2017 review (Li et al., 2017) investigated the effects of CBT for people with diabetes and a co-morbid depression. The review found that CBT produced a significant moderate reduction in depression. CBT did not have a significant effect on anxiety or HbA1c. Further, only two studies in this review looked at diabetes-related distress and meta-analysis showed that CBT did not have a statistically significant effect on this outcome. A third review in 2020 (Yang, Li, & Sun, 2020), explored the effects of CBT on studies reporting either depression or anxiety, or HbA1c as primary outcomes. Across all follow-up time-points CBT had a large significant effect on depression. However, no statistically significant effect on anxiety was observed. For HbA1c, CBT showed a significant moderate effect. Diabetes-related distress was not included in the review.

Overall, the meta-analytic evidence to date suggests that CBT may be effective at reducing depression. However, findings regarding anxiety and HbA1c are mixed. Furthermore, given the high prevalence of diabetes-related distress and its implications on clinical outcomes, more research is needed on the effectiveness of CBT for diabetes-related distress. No previous reviews exploring CBT in diabetes have placed diabetes-related distress as the primary outcome, meaning that relevant studies are missed. Considering such studies will help to disentangle the effectiveness of CBT interventions on diabetes-related distress specifically. Measuring depression, anxiety and HbA1c as secondary outcomes, may enable a greater understanding of the added benefits for these outcomes when targeting diabetes-related distress.

Alongside consideration of traditional CBT, the potential of third-wave CBT (Hofmann & Asmundson, 2008) approaches such as acceptance and commitment therapy (ACT; an approach encouraging acceptance of unwanted thoughts and feelings) (Hayes et al., 2004) and mindfulness-based therapy (aiming to increase present moment awareness) (Baer, 2003) may help define what psychological interventions are most effective in treating diabetes-related distress. Third-wave interventions differ from traditional CBT interventions in their content. Third-wave techniques are primarily focused on how individuals respond to their emotions, behaviours, and cognitions. Whereas traditional CBT commonly focuses on the appraisal or modification of antecedent emotions, behaviours and cognitions (Hofmann & Asmundson, 2008). A review on the use of third-wave interventions to reduce diabetes-related distress in type 2 diabetes alone (Ngan, Chong, & Chien, 2021), failed to find that mindfulness and acceptance-based interventions significantly reduced diabetes-related distress up to 1-month post-intervention. However, the included interventions in this review showed benefits for improving depression, anxiety, and glycaemic control. Another review (Bogusch & O'Brien, 2019) investigated the use of mindfulness-based interventions alone in type 1 and type 2 diabetes. The authors concluded that the treatment-control comparison effect estimates were small and unreliable, so no meta-analysis was conducted. This suggests that further investigation is needed into the efficacy of third-wave interventions on diabetes-related distress for individuals with type 1 and type 2 diabetes.

Additionally, a more in-depth analysis of the type of interventions offered (i.e., their active ingredients) and their mode of delivery will further the development of diabetes-related distress interventions, as similar, earlier reviews (Yang, Li, & Sun, 2020) did not include diabetes-related distress as an outcome. Further, the inclusion, and separate analysis of traditional CBT and third-wave interventions may limit treatment heterogeneity, informing conclusions about the efficacy of each intervention type as a tool for treating diabetes-related distress and may inform future intervention development. Therefore, this review has six objectives:

1) To examine the effectiveness of all traditional CBT interventions on diabetes-related distress alone.
2) To examine the effectiveness of CBT interventions that target diabetes-related distress primarily on diabetes-related distress, depression, anxiety, and HbA1c.
3) To examine the effectiveness of all third-CBT interventions on diabetes-related distress alone.
4) To examine the effectiveness of third-wave CBT interventions that target diabetes-related distress primarily on diabetes-related distress, depression, anxiety and HbA1c.
5) To describe the content of CBT interventions and data permitting perform sub-group analyses to examine how the content and mode of delivery influences treatment effects on diabetes-related distress alone.
6) To describe the content of third-wave CBT interventions and data permitting perform sub-group analyses to examine how the content and mode of delivery influences treatment effects on diabetes-related distress alone.

Methods

The review protocol was pre-registered on PROSPERO (CRD42021240628). The research objectives were slightly refined to home in on diabetes-related distress as a primary intervention target. Our findings are reported in line with the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidance (Page et al., 2021).

Eligibility criteria

Two reviewers (EJ, IK) screened studies against the inclusion and exclusion criteria outlined in Table *1*. Restrictions were placed on the language of publication (English only).

Table 1. PICOS inclusion/exclusion criteria**.**

Variable	Inclusion	Exclusion
Population	• Participants with Type 1 diabetes and Type 2 diabetes. This includes both doctor-diagnosed and self-reported diabetes. • Adults aged ≥18. • Female and male. • All nationalities.	• Participants without Type 1 diabetes or Type 2 diabetes. • Participants with pre-diabetes (e.g., impaired glucose tolerance) and gestational diabetes. • Family members/ carers of those with Type 1 and Type 2 diabetes. • Age <18.
Intervention	• CBT interventions including both a cognitive and behavioural element. • Third wave CBT interventions (ACT/mindfulness-based interventions). • Delivered by psychologists, mental health workers, diabetes nurses, any professional trained to give the intervention or self-guided. • Delivered remotely or face to face in either an individual or group format.	• Non-CBT interventions. • Non-third wave CBT interventions (ACT/mindfulness-based interventions). • Lifestyle interventions. • Interventions which were not targeting diabetes-related distress

Variable	Inclusion	Exclusion
Comparator	• Usual care. Education is recommended as part of routine care for diabetes management by the NICE guidelines, hence education may form part of usual care. • Waitlist control, defined as a control condition where individuals can access the active treatment after a waiting period. • Placebo control, defined as a control condition that is similar to the intervention in components and structure without the therapeutic content. • Active control, where individuals in the comparator group receive an alternative active treatment. Education was not defined as an active control in this review.	• No comparator.
Outcome	• All studies included in this review had to measure diabetes-related distress as either a primary or secondary outcome.	• Psychosocial stress other than measures of distress/depression, such as measures of work stress or perceived stress.

Variable	Inclusion	Exclusion
	• The primary outcome of this review: Diabetes related distress as measured by validated scales such as the PAID or DDS. • Secondary outcomes of this review: i) psychological outcomes; Depression and anxiety measured through validated scales. ii) physical outcomes; Glycaemic control objectively assessed by glycated haemoglobin (HbA_{1c}) levels.	• Depression measured through diagnostic clinical interview. • Anxiety measured through diagnostic clinical interview. • Glycaemic control objectively assessed through fasting plasma glucose.
Study design	• RCT's or quasi-RCT's; where 'random' is used to describe the method for assigning subjects to groups.	• nRCT's.

Information sources

The following electronic databases were searched in April 2021: OVID MEDLINE, psycINFO, EMBASE, Cumulative Index to Nursing and Allied Health literature (CINAHL), Web of Science, PubMed and Cochrane Central Register of Controlled Trials (CENTRAL). No restrictions were placed on publication date. Reference lists of relevant articles were screened to identify articles not retrieved by the electronic search. Where protocols, or conference abstracts were identified, authors were contacted to retrieve the full text.

Search strategy

The search strategy included MeSH terms with appropriate Boolean operators (see Table S1).

Data extraction

Two reviewers (EJ, IK) independently extracted the data onto a purpose designed data extraction table. Data were extracted on: publication characteristics (e.g., place of origin), participant characteristics, baseline characteristics (e.g., baseline mood and HbA1c) and outcomes of interest, specifically continuous measures of diabetes-related distress, depression, anxiety and HbA1c. We extracted data on the timing of the post-intervention measurement. The post-intervention time point was defined as the earliest post-intervention data collection time point. Where studies used more than one measure to assess an outcome of interest, we prioritised extraction of the author identified primary outcome. Where the author did not differentiate between the primary and secondary outcome, we extracted data on the outcome that was most common across the included studies to enable data pooling. Where data was missing or unclear, authors were contacted. Details of intervention content were extracted by one reviewer (EJ) based on the Template of Intervention Description and Replication (TIDieR) guidance (Hoffmann et al., 2014). These details were extracted from published articles, supplementary materials, study protocols and where possible, manuals from authors.

Quality and Risk of Bias (RoB) assessment

Within-study bias

Methodological RoB was assessed independently (EJ, IK) following Cochrane Handbook (Higgins & Green, 2011) guidance. Each study was classified as having high, low or unclear RoB on the following domains: random sequence generation; allocation sequence concealment; blinding of participants, blinding of outcome assessment, completeness of outcome data and selective outcome reporting. RoB ratings are presented using RevMan5 (Cochrane Collaboration, 2014).

Between-study bias

Publication bias was a criterion selected to evaluate to if studies reporting statistically significant results were more likely to be published, potentially leading to an overestimation of the real effect size (Rothstein, Sutton, & Borenstein, 2006). This was tested using funnel plots and Egger's test (Egger et al., 1997).

Data synthesis and analysis

Analyses were conducted using STATA v16.0. For each included study individual effect sizes were calculated based on extracted data. Treatment effect estimates were pooled using random-effects meta-analysis with 95% confidence intervals (CIs) using the *metan* command. Results were pooled based on intervention type (CBT vs third-wave CBT) for each outcome i) diabetes-related distress ii) depression iii) anxiety and iv) HbA1c. The treatment effect on each outcome was expressed as standardised mean difference (SMD) between the intervention and control group at the post-intervention time point. In the case of multiple intervention or control groups we followed Cochrane Handbook guidance (Higgins & Green, 2011; Higgins, Thomas, & Chandler, 2022). For those trials where groups were similar, we combined data into a single intervention and control group so that the counting of participant data was not repeated. For those groups that were heterogeneous, we accounted for this by splitting the sample size of the shared group by the number of control or intervention groups to ensure that the study was not overpowered. Statistical heterogeneity was estimated using I^2, which describes variability in effect sizes due to treatment heterogeneity compared to variability due to chance (Higgins, Thomas, & Chandler, 2022). Following Cochrane guidance, $I^2 > 50\%$ represents moderate heterogeneity (Higgins, Thomas, & Chandler, 2022; Higgins et al., 2003). Where cluster trials were included an Intra-Cluster Coefficient (ICC) 0.002 was used (Higgins, Thomas, & Chandler, 2022). Where data was available for different outcome follow-up timepoints, pooled effect size estimates were generated for each time point, if the number of studies was > 10 and the distribution of studies across the sub-groups was relatively even, in line with Cochrane guidance (Higgins, Thomas, & Chandler, 2022).

Intervention content was descriptively reported in accordance with the TIDieR checklist (Hoffmann et al., 2014). Statistical sub-group analyses were then performed based on a priori defined intervention criteria to examine their impact on diabetes-related distress for CBT and third-wave CBT interventions 1) whether the intervention was diabetes specific, 2) whether the intervention included a digital component, 3) whether the intervention was delivered by a psychological practitioner, 4) the delivery format 5) whether between session homework was given, and whether the intervention included 6) goal setting, 7) cognitive restructuring, 8) psychoeducation, 9) behavioural activation, 10) the cultivation of acceptance (assessed among third-wave interventions only). As above, sub-group analyses were only conducted if there were >10 studies and the distribution of studies across sub-groups was approximately even (Higgins, Thomas, & Chandler, 2022).

Results

Study selection

The combined online and manual searches retrieved 1037 citations. After removing duplicates, 671 unique citations remained (Figure 1). Two independent reviewers (EJ, IK) reviewed citation titles and abstracts and identified 80 studies that were potentially relevant. Following full text screening, 22 studies were identified as meeting the inclusion criteria.

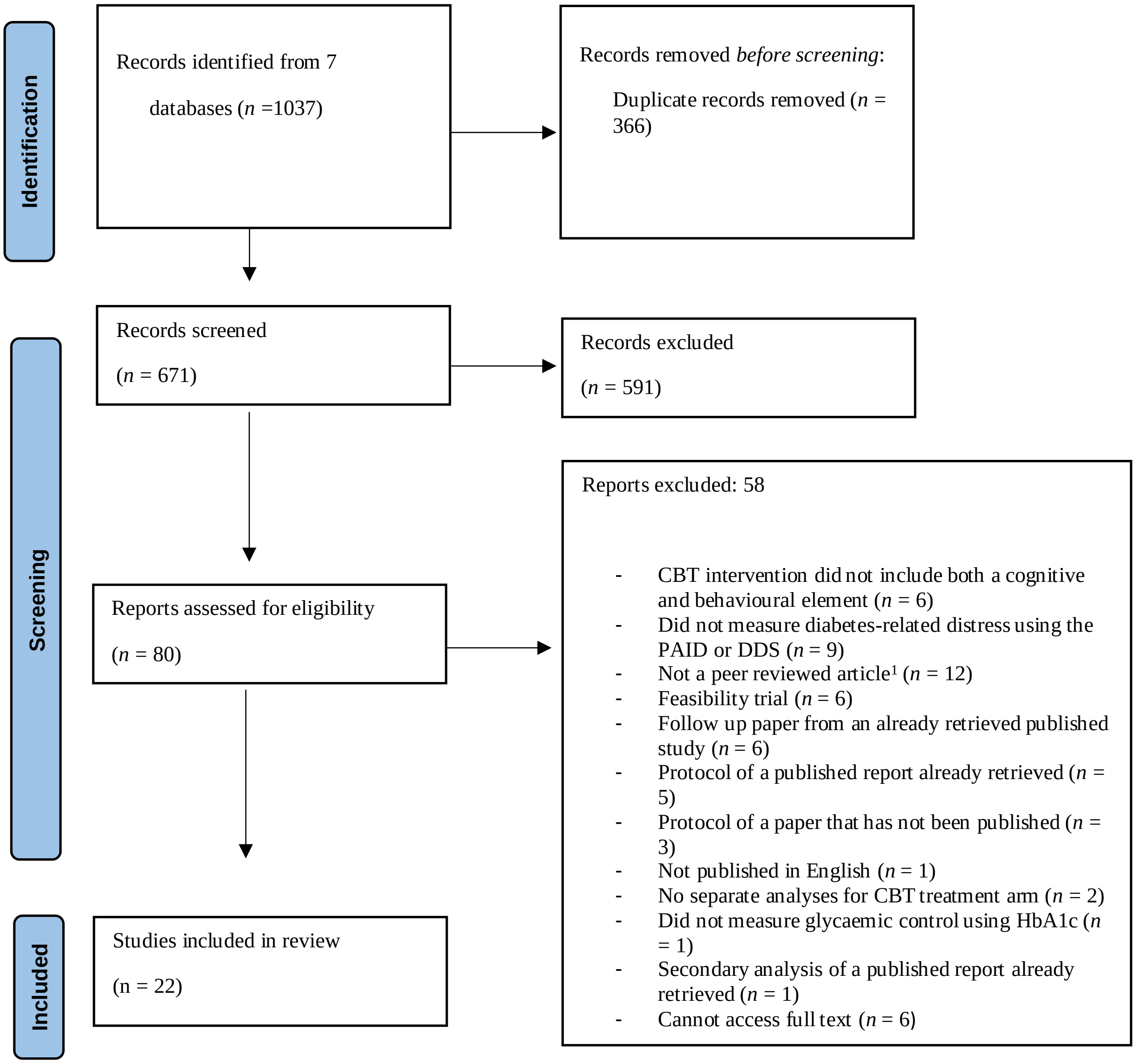
Study characteristics

The 22 identified RCTs comprised of 4123 participants (Table S2). A total of 20 studies randomised participants at an individual level and two studies randomised by clusters of health clinics (Chew et al., 2018; Ismail et al., 2018). The trials were published from 2004(Karlsen et al., 2004)-2021(Vaughan, Cully, & Petersen, 2021) and were conducted across 12 countries. The mean age of participants ranged from 37.8 (Van Der Ven et al., 2005) -70.7 (Lamers et al., 2011) years. The sample was predominantly female (54.9%).

A total of ten trials included participants with Type 2 diabetes (Chew et al., 2018; Clarke et al., 2019; De Groot et al., 2019; Fisher et al., 2013; Ismail et al., 2018; Lamers et al., 2011; Maghsoudi et al., 2019; Pearson et al., 2018; Pibernik-Okanović et al., 2015; Tunsuchart et al., 2020). The remainder included participants with Type 1 diabetes (Amsberg et al., 2009; Van Der Ven et al., 2005) or participants with both Type 1 and 2 diabetes (Friis et al., 2016; Hermanns et al., 2015; Karlsen et al., 2004; Newby et al., 2017; Nobis et al., 2015; Tovote et al., 2014; K. Van Bastelaar et al., 2011; van Son et al., 2013; Vaughan, Cully, & Petersen, 2021; Weinger et al., 2011). Of the included trials, 14 screened for elevated diabetes-related distress or depression, using clinical interviews (De Groot et al., 2019; Lamers et al., 2011; Newby et al., 2017) or specified cut offs within validated scales (Chew et al., 2018; Clarke et al., 2019; Fisher et al., 2013; Hermanns et al., 2015; Nobis et al., 2015; Pibernik-Okanović et al., 2015; Tovote et al., 2014; Tunsuchart et al., 2020; K. Van Bastelaar et al., 2011; van Son et al., 2013; Vaughan, Cully, & Petersen, 2021). Similarly, eight trials had a screening cut-off for HbA1c (Amsberg et al., 2009; Chew et al., 2018; Ismail et al., 2018; Pearson et al., 2018; Tunsuchart et al., 2020; Van Der Ven et al., 2005; Vaughan, Cully, & Petersen, 2021; Weinger et al., 2011).

Diabetes-related distress was the primary outcome in just over half of the studies (*k*=12; 54.5%). In 13 trials the Problem Areas In Diabetes (PAID) scale was used to measure diabetes-related distress (Amsberg et al., 2009; Karlsen et al., 2004; Lamers et al., 2011; Newby et al., 2017; Nobis et al., 2015; Pearson et al., 2018; Pibernik-Okanović et al., 2015; Tovote et al., 2014; K. Van Bastelaar et al., 2011; Van Der Ven et al., 2005; van Son et al., 2013; Vaughan, Cully, & Petersen, 2021; Weinger et al., 2011) and in eight trials the Diabetes Distress Scale (DDS) was used (Chew et al., 2018; Clarke et al., 2019; De Groot et al., 2019; Fisher et al., 2013; Friis et al., 2016; Ismail et al., 2018; Maghsoudi et al., 2019; Tunsuchart et al., 2020). One study included both measures (Hermanns et al., 2015). All studies measured diabetes-related distress post-intervention, but the timing of the measurement varied from less than 6 weeks (Chew et al., 2018; Clarke et al., 2019; De Groot et al., 2019; Friis et al., 2016; Hermanns et al., 2015; Karlsen et al., 2004; Lamers et al., 2011; Maghsoudi et al., 2019; Newby et al., 2017; Nobis et al., 2015; Pearson et al., 2018; Pibernik-Okanović et al., 2015; Tovote et al., 2014; Tunsuchart et al., 2020; K. Van Bastelaar et al., 2011; van Son et al., 2013; Vaughan, Cully, & Petersen, 2021) to more than 6 weeks post-intervention (Amsberg et al., 2009; Fisher et al., 2013; Ismail et al., 2018; Van Der Ven et al., 2005; Weinger et al., 2011). Traditional CBT interventions accounted for 18 and third-wave CBT interventions accounted for 5 of the included studies, respectively. One study (Tovote et al., 2014) had a CBT intervention arm and a third-wave CBT arm.

Figure 1. PRISMA flow diagram.



- CBT intervention did not include both a cognitive and behavioural element (*n* = 6)
- Did not measure diabetes-related distress using the PAID or DDS (*n* = 9)
- Not a peer reviewed article[1] (*n* = 12)
- Feasibility trial (*n* = 6)
- Follow up paper from an already retrieved published study (*n* = 6)
- Protocol of a published report already retrieved (*n* = 5)
- Protocol of a paper that has not been published (*n* = 3)
- Not published in English (*n* = 1)
- No separate analyses for CBT treatment arm (*n* = 2)
- Did not measure glycaemic control using HbA1c (*n* = 1)
- Secondary analysis of a published report already retrieved (*n* = 1)
- Cannot access full text (*n* = 6)

Figure 1: PRISMA flowchart diagram [1]The citations received were supplementary material (*n*=9), poster presentations (*n*=2) and conference abstracts (*n*=1). Abbreviations: CBT: Cognitive Behavioural Therapy; DDS: Diabetes Distress Scale; HbA1c: Glycated Haemoglobin; PAID: Problem Areas in Diabetes Scale.

Objective 1: Meta-analysis of all traditional CBT interventions on diabetes-related distress

Only 17 studies with 18 comparisons provided sufficient data for meta-analysis, as one study had multiple control arms (Weinger et al., 2011). There was a small statistically significant effect of CBT on diabetes-related distress (SMD=-0.149, p=0.021; 95% CI -0.276 to -0.023, I^2= 54.8%, p=0.003; Figure 2). Another study that did not provide sufficient data to be pooled (De Groot et al., 2019), reported that CBT alongside CBT and exercise led to a significant reduction in distress (p=0.003 and p=0.008 respectively). Sub-group analyses showed that the effectiveness of CBT on diabetes-related distress dissipated with a post-intervention outcome collection timepoint greater than six weeks (Appendix A). There was no significant impact on efficacy estimate when diabetes-related distress questionnaires (PAID and DDS) were analysed separately (data not shown).

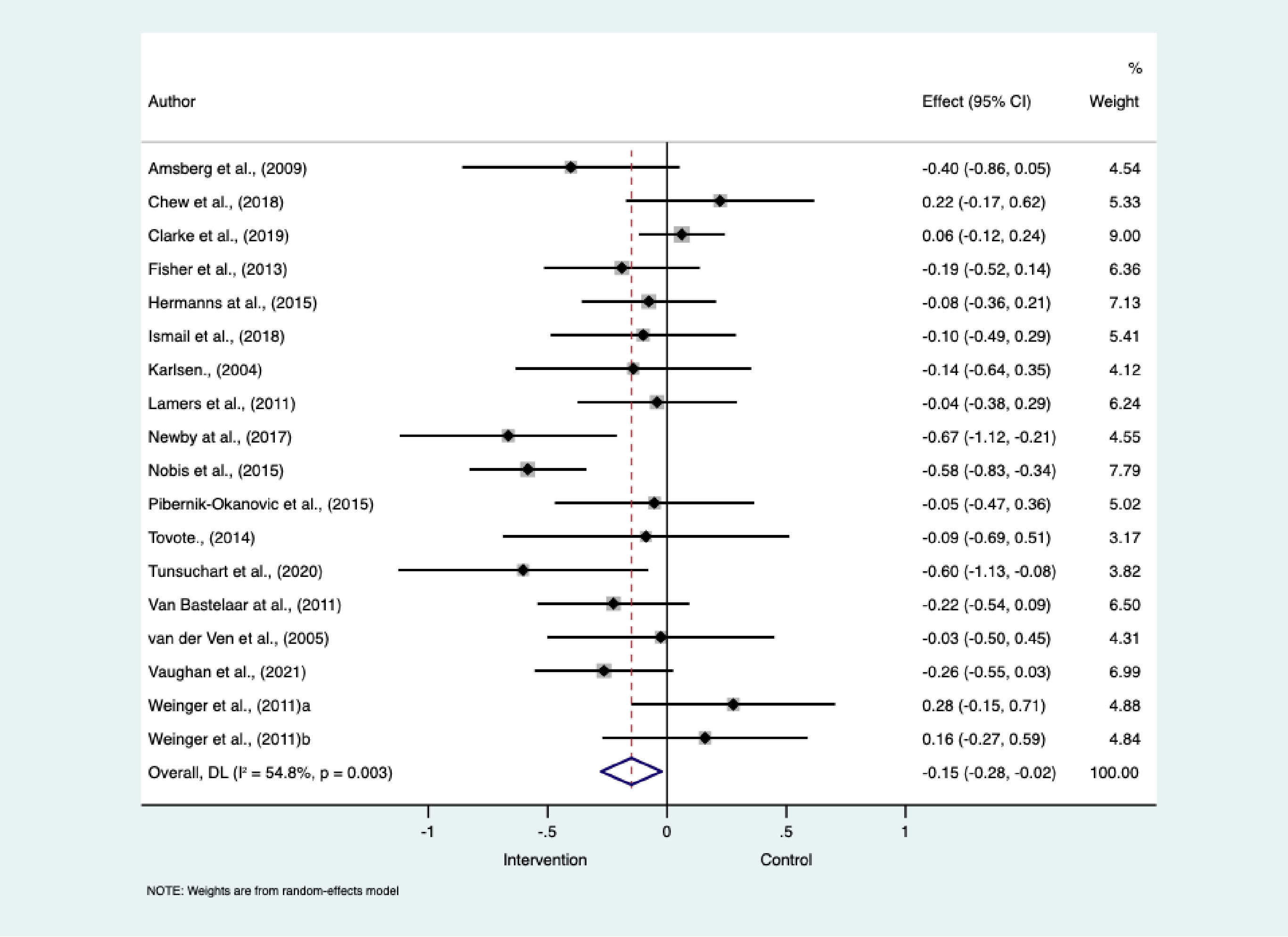


Figure 2. Forest plot of the effect Cognitive Behavioural Therapy interventions on diabetes-related distress using first time-point data. This diagram is a graphical representation of the meta-analytic findings, showing the earliest time-point effect sizes and errors of each included study. There was a significant effect of Cognitive Behavioural Therapy interventions on diabetes distress, in favour of the intervention. Note, when looking at data from Weinger et al,. (2011), ^{a} represents study data using a placebo control condition, ^{b} represents study data using treatment as usual control condition.

Objective 2: Meta-analysis of traditional CBT interventions targeting diabetes-related distress primarily on outcomes.

Diabetes-related distress

Only 8 studies cited diabetes-related distress as the primary outcome and provided sufficient data for meta-analysis. There was a small statistically significant effect of CBT on diabetes-related distress, when it was the primary intervention outcome (SMD =-0.278, *p*=0.010; 95% CI-0.488 to -0.068, I^2 = 62.8%, *p* =0.009; Figure 3).

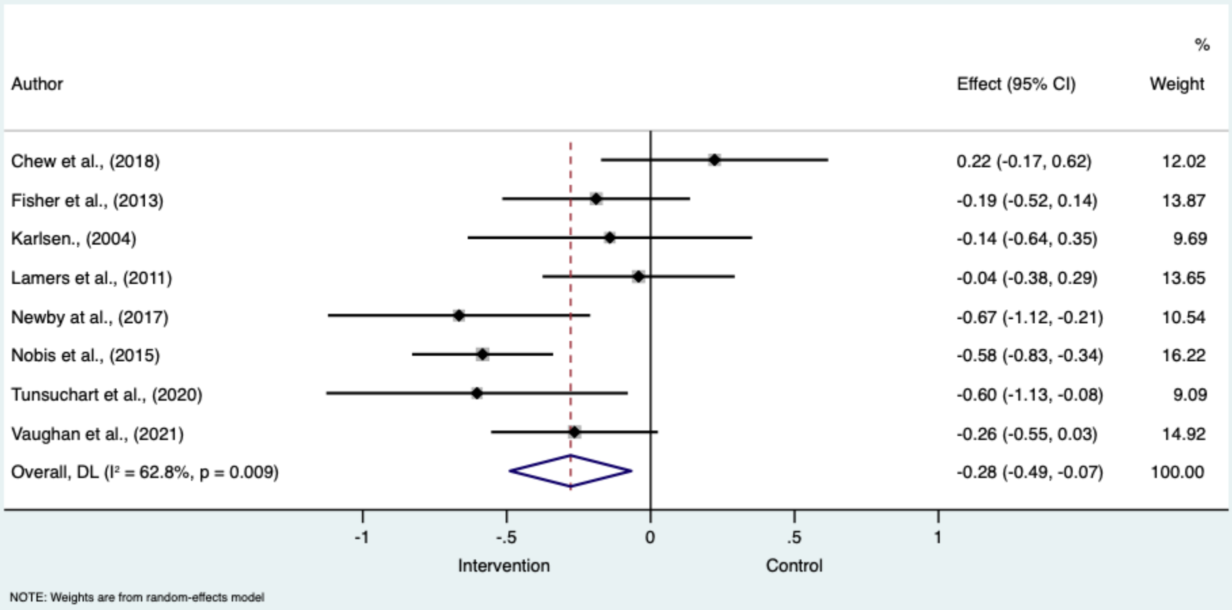


Figure 3. Forest plot of the effect of Cognitive Behavioural Therapy interventions that aim to target diabetes-related distress primarily on diabetes-related distress using first time-point data. This diagram is a graphical representation of the meta-analytic findings, showing the earliest time-point effect sizes and errors of each included study. There was a significant effect of Cognitive Behavioural Therapy interventions to treat diabetes related distress on diabetes related distress.

Depression

Pooling data from 3 studies, there was a moderate significant effect of CBT for diabetes-related distress on depression (SMD = -0.604, p=0.016; 95% CI= -0.198 to -0.111; I^2 82.3%, p<0.003; Figure 4A).

Anxiety

Pooled analyses could not be conducted as only one study (Newby et al., 2017) measured anxiety. The individual study estimate evidenced a large statistically significant effect of CBT for diabetes-related distress on anxiety (g=0.72, p=0.002).

HbA1c

HbA1c was measured in 6 trials. Pooled analyses revealed a small statistically non-significant effect of CBT for diabetes-related distress on HbA1c levels (SMD = -0.045, p=0.812; 95% CI = - 0.417 to 0.326; I^2 =74.7% p=0.001; Figure 4B).

For all outcomes within this objective, there were too few studies to explore the impact of data collection timepoint on reported effect sizes.

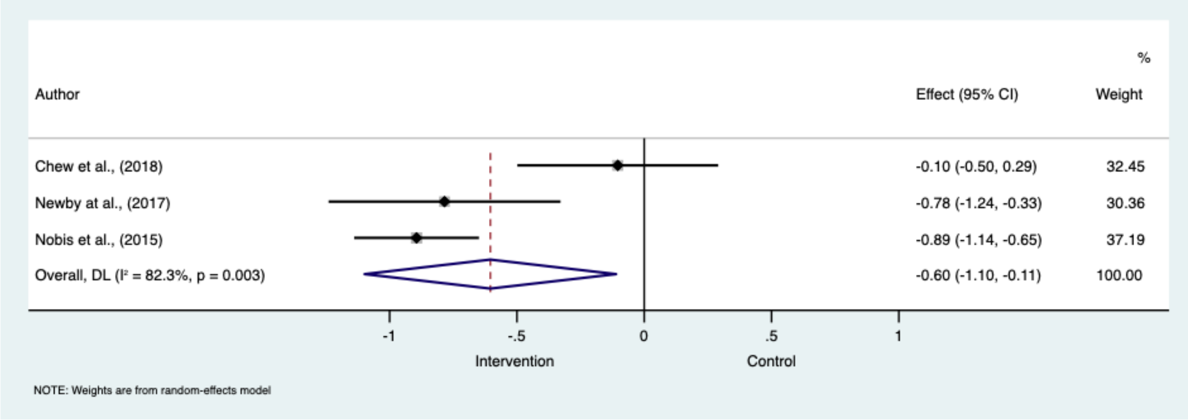


Figure 4A. Forest plot of the effect of Cognitive Behavioural Therapy interventions that aim to target diabetes-related distress primarily on depression using first time-point data. This diagram is a graphical representation of the meta-analytic findings, showing the earliest time-point effect sizes and errors of each included study. There was a significant effect of Cognitive Behavioural Therapy interventions for diabetes-related distress on depression.

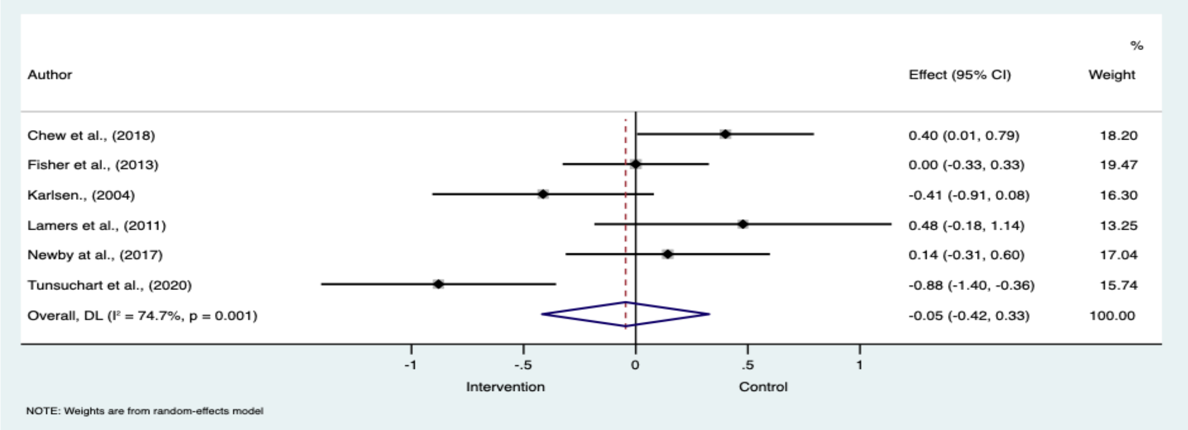


Figure 4B. Forest plot of the effect of Cognitive Behavioural Therapy interventions that aim to target diabetes-related distress primarily on HbA1c using first time-point data. This diagram is a graphical representation of the meta-analytic findings, showing the earliest time-point effect sizes and errors of each included study. There was a non-significant effect of Cognitive Behavioural Therapy interventions for diabetes-related distress on HbA1c, in favour of the intervention.

Objective 3: Meta-analysis of all third-wave CBT on diabetes-related distress

There was a small but non-significant effect of third-wave CBT interventions on diabetes-related distress across 5 studies (SMD= -0.135, *p*=0.504; 95% CI = -0.532 to 0.262, I^2= 73.1%, *p*=0.005; Figure 5).

There were too few studies to explore the impact of data collection timepoint on reported effect sizes. There was no significant impact on efficacy estimate when diabetes-related distress questionnaires were analysed separately (data not shown).

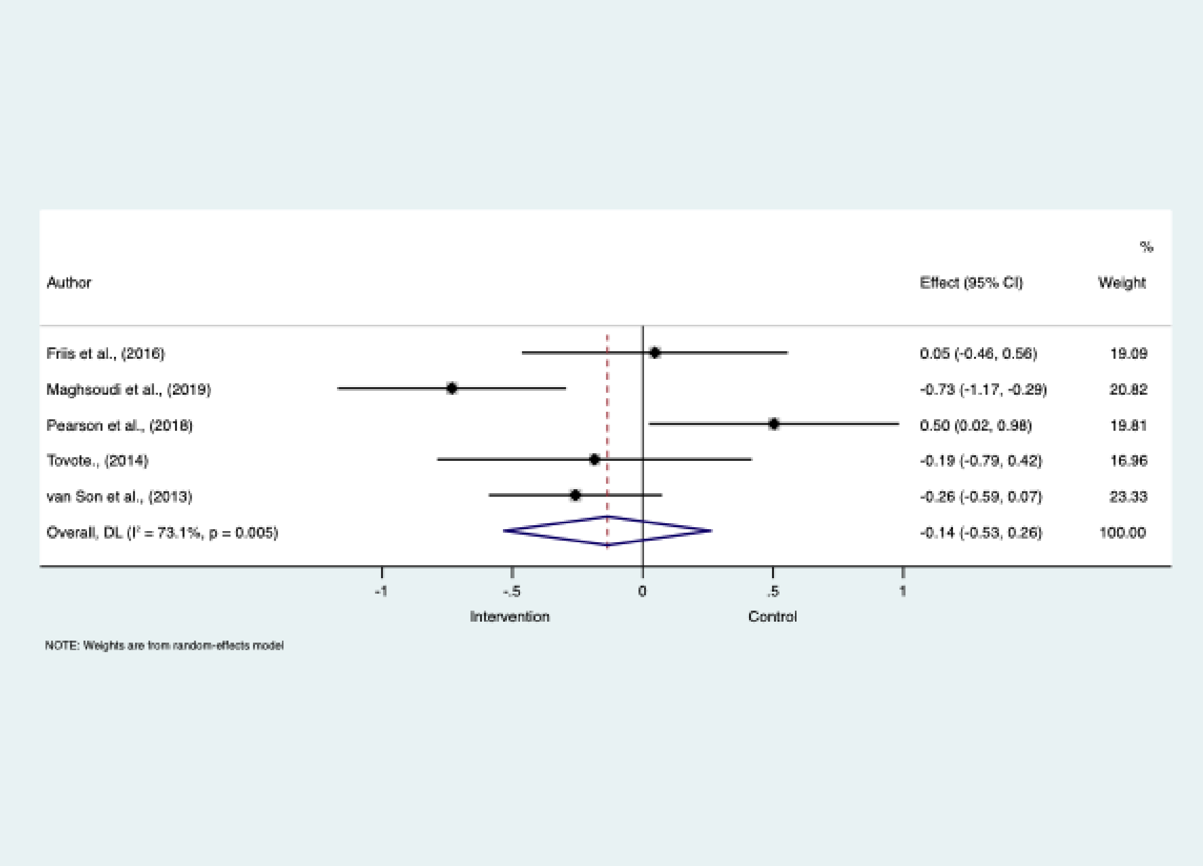


Figure 5. Forest plot of the effect third-wave Cognitive Behavioural Therapy interventions on diabetes-related distress using first time-point data. This diagram is a graphical representation of the meta-analytic findings, showing the earliest time-point effect sizes and errors of each included study. There was a non-significant effect of third-wave Cognitive Behavioural Therapy interventions on diabetes distress, in favour of the intervention.

Objective 4: Meta-analysis of third-wave CBT interventions targeting diabetes-related distress primarily on outcomes.

Diabetes-related distress

In 4 included studies diabetes-related distress was the primary outcome and these provided sufficient data for meta-analysis. There was a small but non-significant effect of third-wave CBT interventions on diabetes-related distress across 4 studies (SMD= -0.122, *p*=0.619; 95% CI= -0.605 to 0.360, I^2=79.8%%, *p*=0.002; Figure 6).

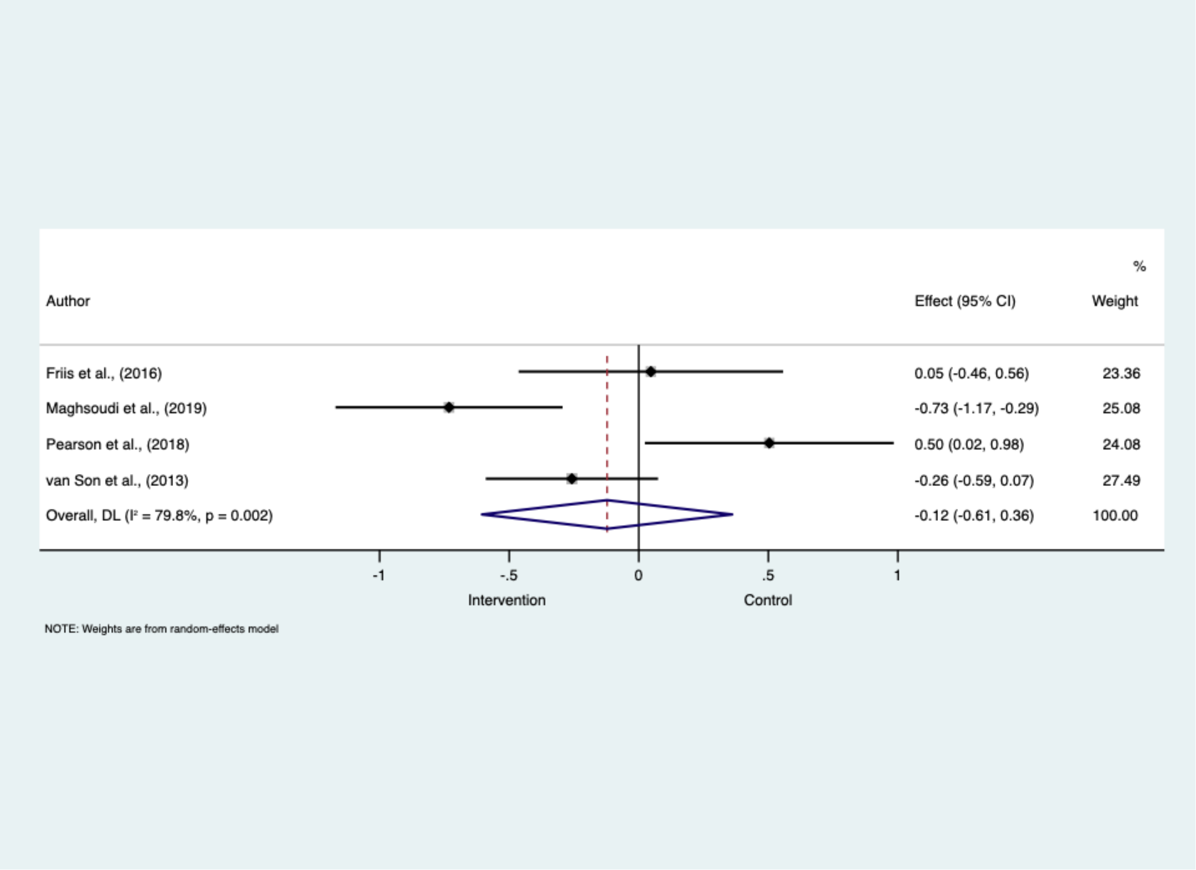


Figure 6. Forest plot of the effect of third-wave Cognitive Behavioural Therapy interventions that aim to target diabetes-related distress primarily on diabetes-related distress using first time-point data. This diagram is a graphical representation of the meta-analytic findings, showing the earliest time-point effect sizes and errors of each included study. There was a non-significant effect of third-wave Cognitive Behavioural Therapy interventions to treat diabetes-related distress on diabetes-related distress, in favour of the intervention.

Depression

A small statistically non-significant effect of third-wave CBT for diabetes-related distress on depression was observed in pooled analyses of 3 studies (SMD =-0.205, *p*=0.509; CI = -0.811 to 0.402; I^2=82.7%, *p* =0.003; Figure 7A).

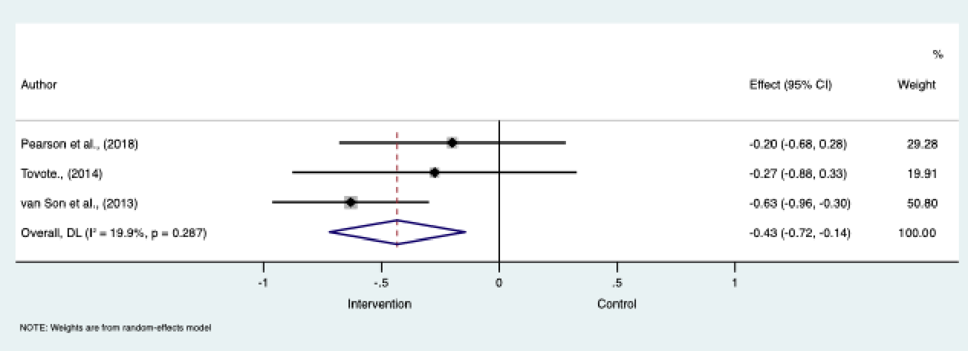


Figure 7A. Forest plot of the effect third-wave Cognitive Behavioural Therapy interventions on depression using first time-point data. This diagram is a graphical representation of the meta-analytic findings, showing the earliest time-point effect sizes and errors of each included study. There was a non-significant effect of third-wave Cognitive Behavioural Therapy interventions on depression, in favour of the intervention.

Anxiety

Only two studies measured the effect of third-wave interventions for diabetes-related distress on anxiety. There was a moderate statistically significant effect detected in pooled analyses (SMD = -0.451, p=0.034; 95% CI =- -0.867 to -0.035; I^2=52.2%. p=0.148; Figure 7B).

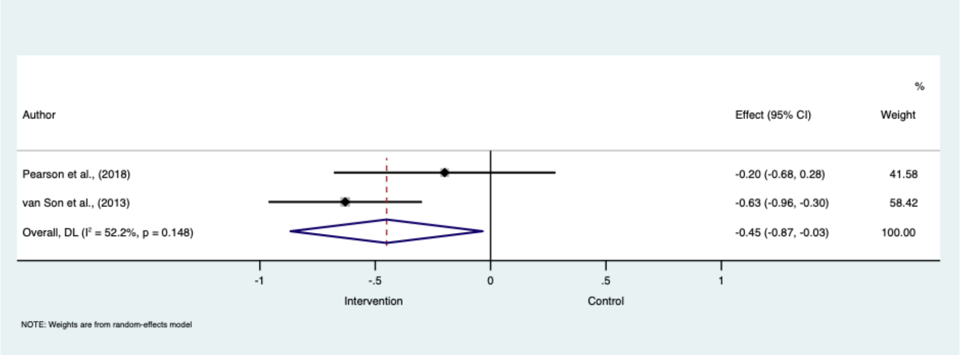


Figure 7B. Forest plot of the effect of third-wave Cognitive Behavioural Therapy interventions that aim to target diabetes-related distress primarily on anxiety using first time-point data. This diagram is a graphical representation of the meta-analytic findings, showing the earliest time-point effect sizes and errors of each included study. There was a significant effect of third-wave Cognitive Behavioural Therapy interventions for diabetes-related distress on anxiety.

HbA1c

There was no statistically significant effect of third-wave CBT for diabetes-related distress on HBA1c in pooled analyses of 3 RCTs (SMD = 0.016, p=0.910; 95% CI= -0.265 to 0.297; I^2 =22.6%, p=0.275; Figure 7C).

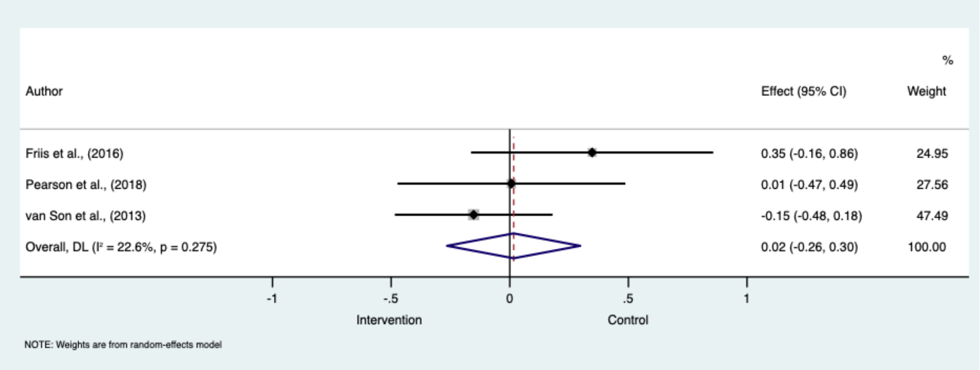


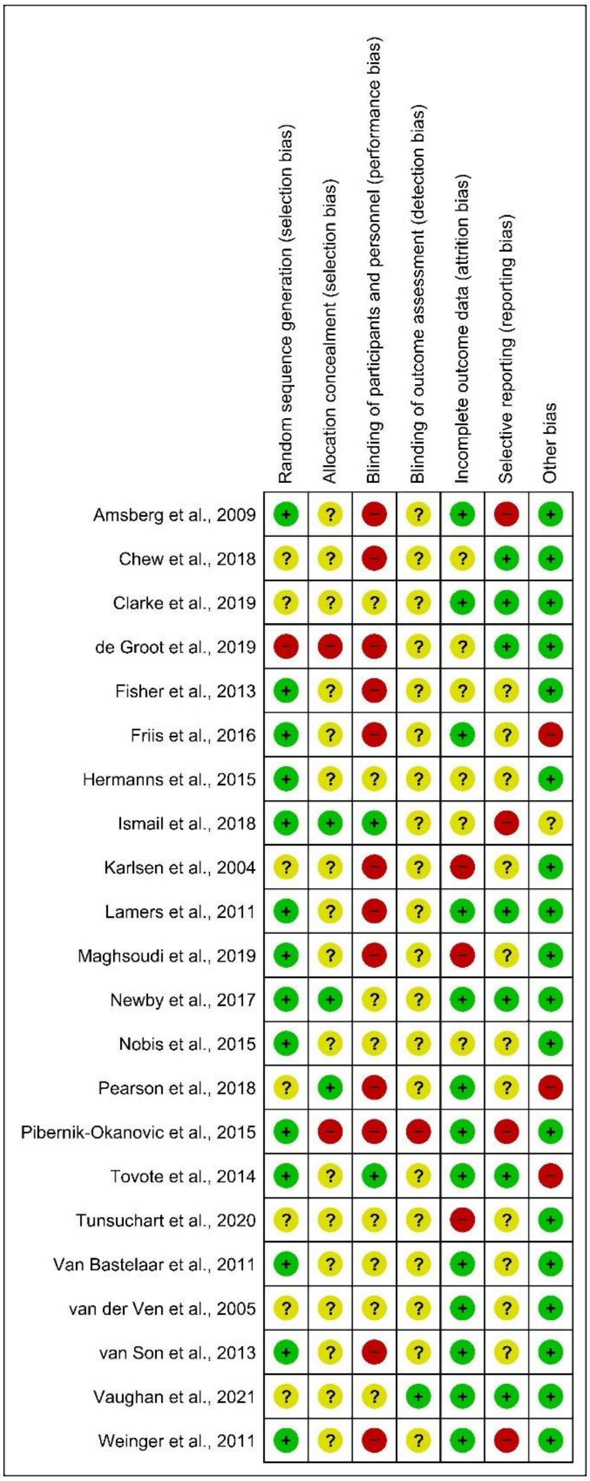
Figure 7C. Forest plot of the effect of third-wave Cognitive Behavioural Therapy interventions that aim to target diabetes-related distress primarily on HbA1c using first time-point data. This diagram is a graphical representation of the meta-analytic findings, showing the earliest time-point effect sizes and errors of each included study. There was a non-significant effect of third-wave Cognitive Behavioural Therapy interventions for diabetes-related distress on HbA1c, in favour of the control condition.

For all outcomes within this objective, there were too few studies to explore the impact of data collection timepoint on reported effect sizes.

Objectives 1-4: *RoB analysis:*

Within study RoB

There was a high prevalence of unclear or high RoB across the included studies (Figures 8 and 9). The categories of allocation concealment, blinding of outcome assessment and selective reporting were often not adequately reported. Due to the therapeutic nature of the interventions, it was often not possible to blind participants and personnel to treatment and downgrading evidence because of this alone may not be reasonable (Button & Munafò, 2015). Therefore, we considered other areas that could impact bias (e.g., treatment adherence, fidelity).



	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Binding of participants and personnel (performance bias)	Binding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Amsberg et al., 2009	+	?	−	?	+	−	+
Chew et al., 2018	?	?	−	?	?	+	+
Clarke et al., 2019	?	?	?	?	+	+	+
de Groot et al., 2019	−	−	−	?	?	+	+
Fisher et al., 2013	+	?	−	?	?	?	+
Friis et al., 2016	+	?	−	?	+	?	−
Hermanns et al., 2015	+	?	?	?	?	?	+
Ismail et al., 2018	+	+	+	?	?	−	?
Karlsen et al., 2004	?	?	−	?	−	?	+
Lamers et al., 2011	+	?	−	?	+	+	+
Maghsoudi et al., 2019	+	?	−	?	−	?	+
Newby et al., 2017	+	+	?	?	+	+	+
Nobis et al., 2015	+	?	?	?	?	?	+
Pearson et al., 2018	?	+	−	?	+	?	−
Pibernik-Okanovic et al., 2015	+	−	−	−	+	−	+
Tovote et al., 2014	+	?	+	?	+	+	−
Tunsuchart et al., 2020	?	?	?	?	−	?	+
Van Bastelaar et al., 2011	+	?	?	?	+	?	+
van der Ven et al., 2005	?	?	?	?	+	?	+
van Son et al., 2013	+	?	−	?	+	?	+
Vaughan et al., 2021	?	?	?	+	+	+	+
Weinger et al., 2011	+	?	−	?	+	−	+

Figure 8. Risk of Bias summary: review authors’ judgement about each risk of bias item for each included study.

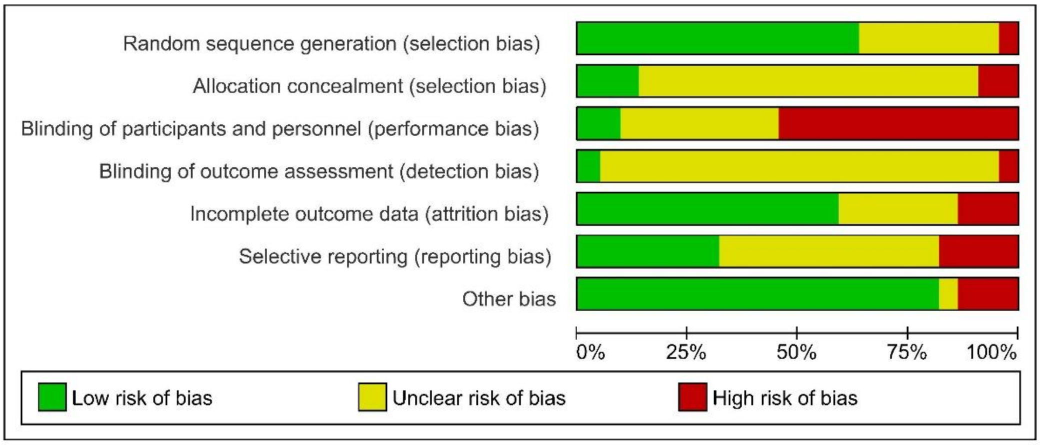


Figure 9. Risk of Bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Between study bias

There was no evidence of publication bias. Results from the Egger's test ranged from p=0.17 to p=0.72 (for funnel plot representation see Supplementary figures S7-S15).

Objective 5: Content of CBT interventions

CBT interventions ranged from 5 days (Hermanns et al., 2015) to 12 months (Ismail et al., 2018) in length (see Table S3 and S4). Of the included interventions four (23%) were web-based self-guided interventions with minimal (Newby et al., 2017; Nobis et al., 2015; K. Van Bastelaar et al., 2011) or no clinician support (Clarke et al., 2019). Another study (Fisher et al., 2013) was predominantly web-based with an additional face-to-face problem-solving therapy session delivered by university graduates. One intervention (Vaughan, Cully, & Petersen, 2021) was telephone based. The remaining interventions were delivered by a range of health care professionals in either a face-to-face group format, or on an individual basis. The face-to-face interventions were predominantly delivered within the community. Most CBT interventions (k=11; 61%) were diabetes specific (defined as including diabetes specific content or following diabetes specific protocols). CBT interventions commonly included the identification and management of unhelpful thoughts relating to low mood, beliefs about diabetes and diabetes self-management. A key therapeutic technique used was cognitive restructuring (k=11; 61.1%). Over half of the CBT interventions (k=12; 66%) used psychoeducation. Predominantly psychoeducation focused on the link between mood difficulties and diabetes (Amsberg et al., 2009; Chew et al., 2018; De Groot et al., 2019; Hermanns et al., 2015; Nobis et al., 2015; K. Van Bastelaar et al., 2011) or education regarding diabetes treatment and management (Karlsen et al., 2004; Vaughan, Cully, &

Petersen, 2021; Weinger et al., 2011). When psychoeducation was not diabetes specific, it focused on the link between mental and physical wellbeing (Newby et al., 2017; Pibernik-Okanović et al., 2015; Tovote et al., 2014). Behavioural activation was utilised in eight CBT interventions (Fisher et al., 2013; Ismail et al., 2018; Newby et al., 2017; Nobis et al., 2015; Pibernik-Okanović et al., 2015; Tovote et al., 2014; K. Van Bastelaar et al., 2011; Vaughan, Cully, & Petersen, 2021). This involved pleasant activity scheduling to increase mood, self-efficacy and physical activity.

Sub-group analyses

Of the eight a priori defined potential moderators of CBT treatment effects on diabetes-related distress the following variables bolstered the effects of CBT: having a digital component (SMD=-0.30, *p*=0.05) versus not having a digital component (SMD=-0.08, *p*=0.19); delivered via a psychological practitioner (SMD=-0.26, *p*=<0.001) versus not delivered by a psychological practitioner (SMD=-0.06, *p*=0.54); individual (SMD=-0.23, *p*=0.01) versus group delivery formats (SMD=-0.15, *p*=0.60); and including a behavioural activation component (SMD=-0.29, *p*=<0.001) versus interventions without behavioural activation (SMD=-0.02, *p*=0.76) (for full analyses see Table 2).

Table 2: Results from subgroup analyses for Cognitive Behavioural Therapy interventions.

Intervention type	**Potential moderator**	**Subgroups**	**Number of studies**	**SMD**	***p*-value**	**Lower 95% CI**	**Upper 95% CI**	**I^2**	***p*-value**
CBT *(total n=17)*									
	Diabetes specific intervention	Yes	12[1]	-0.137	0.078	-0.290	0.015	53.4%	0.014
		No	6	-0.186	0.140	-0.434	0.061	60.4%	0.027
	Included a digital component	Yes	5	-0.299	0.047*	-0.594	-0.004	81.4%	*p*<.001
		No	13[1]	-0.080	0.185	-0.198	0.038	11.9%	0.325
	Delivered by a psychological practitioner	Yes	8	-0.262	*p*=<0.001**	-0.409	-0.115	12.5%	0.333
		No	10[1]	-0.057	0.537	-0.236	0.123	64.4%	0.003
	Delivery format	Individual	9	-0.226	0.013*	-0.405	-0.047	65.2%	0.003
		Group	9[1]	-0.147	0.602	-0.274	-0.020	34.0%	0.146
	Between session homework	Yes	12[1]	-0.163	0.057	-0.330	0.005	64.3%	0.001
		No	1	-0.141	0.575	-0.635	0.352	NR	
		Not reported	5	-0.104	0.356	-0.326	0.117	43.5%	0.132
	Included: goal setting	Yes	13[1]	-0.145	0.065	-0.299	0.009	55.1%	0.008
		No	5	-0.162	0.201	-0.409	0.086	58.1	0.049
	Cognitive restructuring	Yes	11[1]	-0.124	0.103	-0.274	0.025	31.5%	0.147
		No	7	-0.176	0.126	-0.401	0.049	73.7%	0.001
	Behavioural activation	Yes	8	-0.294	*p*<0.001**	-0.453	-0.136	37.1%	0.133
		No	10[1]	-0.022	0.758	-0.159	0.115	28.4%	0.183
	Psychoeducation	Yes	12[1]	-0.167	0.059	-0.340	0.006	60.2%	0.004
		No	6	-0.080	0.315	-0.235	0.076	23.5%	0.257

[1] this estimate includes two data points from the same study with two separate control groups.

[2] "included a digital component" is defined as any study where the intervention that had a digital element/delivery format. This may have been in conjunction with face-to-face treatment or a standalone digital intervention (for more information on the intervention content of each study, see supplementary table S3).

*Significant to 0.05 **Significant to 0.001

Objective 6: Content of third-wave CBT interventions

Interventions used approaches such as psychological flexibility which underpins ACT(Maghsoudi et al., 2019) and mindfulness (Tables S5 and S6). The mindfulness-based interventions included mindful self-compassion (MSC) (Friis et al., 2016), mindfulness-based cognitive therapy (MBCT) (Tovote et al., 2014; van Son et al., 2013) and self-guided mindfulness practice (Pearson et al., 2018). These interventions were all eight weeks in length. Session frequency ranged from daily (Pearson et al., 2018) to weekly (Friis et al., 2016; Maghsoudi et al., 2019; Tovote et al., 2014; van Son et al., 2013). Psychological practitioners provided 4 of the interventions (Friis et al., 2016; Maghsoudi et al., 2019; Tovote et al., 2014; van Son et al., 2013). These were delivered face-to-face in a group format within the community. The remaining intervention was self-guided to be completed at home (Pearson et al., 2018). None of the third-wave CBT interventions were diabetes-specific. Techniques within the interventions were heterogeneous due to differing therapeutic approaches, however some commonalities existed. Over half of the interventions (*k*=3; 60%) involved psychoeducation (Friis et al., 2016; Maghsoudi et al., 2019; Tovote et al., 2014) which focussed on providing an understanding around how the intervention may influence emotional wellbeing.

The mindfulness-based interventions encouraged the cultivation of mindfulness and encompassed guided meditation to increase present moment awareness. Some interventions (*k* = 2) included meditations focused on enhancing self-compassion, with the aim of providing participants with tools to develop a compassionate inner voice (Friis et al., 2016; van Son et al., 2013). Within the MBCT interventions (Tovote et al., 2014; van Son et al., 2013) the management of distress centred around the identification of unhelpful cognitions and included behavioural activation. The ACT intervention (Maghsoudi et al., 2019) involved techniques such as cognitive defusion in which individuals aim to step back from their distress to reduce its impact and influence. The identification of values and utilising committed action (taking actions to live in line with your values) were also techniques used to manage distress within this intervention.

A priori defined sub-group analyses

As only five third-wave CBT studies were identified these were not performed.

Discussion

This review of 22 RCT studies indicates that traditional CBT interventions successfully improve symptoms of diabetes-related distress. More specifically, where diabetes-related distress was the primary outcome of the CBT studies the overall effect on diabetes-related distress was significantly larger than when it was not. Findings were similar for third-wave CBT interventions, albeit non-significant. Furthermore, we found that CBT aiming to treat diabetes-related distress also significantly reduced depression. Moreover, third-wave CBT aimed at treating diabetes-related distress significantly reduced anxiety. Our narrative synthesis explored the effects of all CBT interventions and findings suggest that while CBT in diabetes is mainly delivered face-to-face, internet and telephone formats are also used. Furthermore, these CBT interventions tended to be tailored for diabetes. In contrast, all third-wave interventions were delivered face-to-face and were not adapted for diabetes. Based on data availability, we could only explore moderators of CBT treatment effects. Our results suggest that CBT interventions that are delivered one-to-one by a psychologically trained professional, include a digital delivery format, and a behavioural activation component are likely to improve the effectiveness of CBT on diabetes-related distress.

Diabetes-related distress

This is the first review to meta-analyse diabetes-related distress outcomes for CBT interventions and show that CBT can improve it. This is in contrast with previous reviews that were unable to meta-analyse diabetes-related distress outcomes (Uchendu & Blake, 2017) or found no effect of CBT on diabetes-related distress based on two studies (Li et al., 2017). In these reviews, diabetes-related distress was not the primary outcome, and therefore they likely did not capture all relevant studies. This may account for the diverging findings.

In our review we conducted separate analyses for all studies including diabetes-related distress (as a primary or secondary outcome) and studies where diabetes-related distress was the primary outcome. We assume that where diabetes-related distress was the primary outcome, the intervention was aiming to target this specifically. We found that interventions targeting distress primarily were more effective. This has implications for treatment delivery and outcomes and enables a clearer understanding of the efficacy of targeted interventions. This also has implications for future study planning when selecting the primary endpoint and conducting power calculations.

Another novel aspect of this review is the identification of intervention components that are likely to enhance the effects of CBT interventions. We were unable to limit sub-group analyses to studies where diabetes-related distress was the primary outcome, due to the small number of studies where this was the case (k=8). This increases uncertainty around how these components may bolster the effects on diabetes-related distress specifically. CBT including a digital component and delivered by a psychological practitioner produced a significantly larger effect on diabetes-related distress than interventions not including these components. Although, a previous review (Sturt, Dennick, Hessler, et al., 2015) found that interventions delivered by general clinicians reduced distress the most, this review was not specific to CBT interventions which may account for the contrasting findings. Our work suggests that CBT interventions in particular may be more beneficial when delivered by a trained psychological practitioner (Baumeister et al., 2014). Digital interventions provide advantages such as increased treatment accessibility, reduced costs and increased scalability when compared with traditional face-to-face delivery (Fairburn & Patel, 2017; Thew, 2020). These are important factors to consider in diabetes, as the existing treatment burden can be high (De Groot, Golden, & Wagner, 2016; Spencer-Bonilla et al., 2021).

Further, CBT interventions that included behavioural activation (a technique in which people are encouraged to adopt experiences that they find rewarding) reduced distress at a significantly greater rate than interventions that did not. This finding is in keeping with earlier work linking this technique with reduced distress in cancer survivors (Fernández-Rodríguez et al., 2021). Living with diabetes is complex and can be challenging. Therefore, behavioural activation may enable individuals with diabetes to engage in things they enjoy thus reducing distress. For example, our narrative synthesis suggests this technique can increase self-efficacy and physical activity (Nobis et al., 2015). As diabetes-related distress is associated with poor self-efficacy and poor self-management behaviour(Lin et al., 2017; Sturt, Dennick, Due-Christensen, & McCarthy, 2015) by targeting these factors using behavioural activation people with diabetes may feel an increased sense of mastery around diabetes management which may improve distress.

Studies that were tailored to diabetes appeared to hold promising treatment potential, although the effect estimate was non-significant. When comparing this to studies that were not tailored to diabetes the pooled effect size was smaller. One explanation for this may be that within the non-diabetes-specific subgroup, there were two large individual study estimates. These studies may have acted as outliers, skewing the overall magnitude of the findings. Caution is therefore, needed in interpreting this particular result. Taken as a whole, our findings offer the possibility that tailoring CBT interventions to diabetes may bolster the effects of CBT on reducing diabetes-related distress.

Third-wave CBT interventions produced a comparable (though non-significant) effect estimate to that of traditional CBT for diabetes-related distress. The results were also comparable in analyses where diabetes-related distress was the primary outcome. However, this result was also small and non-significant. Due to the low number of studies in the analyses (*k*=5 and *k*=4 respectively) we were likely underpowered to detect a significant effect (Cohen, 2013). The small difference in these effect estimates may also be due to the small number of included studies. Therefore, more research is needed to understand the efficacy of third-wave interventions on diabetes-related distress.

Analyses exploring potential moderators of treatment effects were not possible for third-wave interventions due to the small number of studies available. However, our narrative synthesis suggests that mindfulness meditation, cognitive restructuring, behavioural activation, cultivation of acceptance, cognitive defusion and utilising committed action were key techniques utilised to try and reduce diabetes-related distress within these interventions.

Secondary outcomes

CBT to treat diabetes-related distress was effective at significantly reducing depression. This is promising as it suggests that CBT to treat diabetes-related distress may have associative benefits for depression outcomes for people with diabetes. However, it is important to note that the pooled effect estimate was small, contrasting with the moderate(Li et al., 2017; Uchendu & Blake, 2017) to large(Yang, Li, & Sun, 2020) effect estimates seen in previous reviews. In two of these previous reviews depression[30, 31] was the primary outcome. Consistent with Medical Research Council guidance (Skivington et al., 2021) our analyses found that interventions targeting distress specifically, bolstered the effect of CBT on this outcome. This may also be the case for depression thus leading to larger effect estimates in previous reviews.

A pooled estimate investigating CBT to treat diabetes-related distress for anxiety could not be calculated as only one study included diabetes-related distress as the primary outcome and measured anxiety. This is surprising as one element of diabetes-related distress surrounds anxieties linked to the condition[14]. The one study (Newby et al., 2017) in our review evidenced CBT for diabetes-related distress significantly reduced anxiety. Although, this conclusion cannot be generalised. In contrast with our review, previous reviews have included three[29, 30] to eight(Yang, Li, & Sun, 2020) studies that measure anxiety. However, these studies did not consider diabetes-related distress primarily. These previous reviews considered anxiety alongside general depression as the primary outcome(Li et al., 2017; Yang, Li, & Sun, 2020) which may account for these mixed findings. As highlighted above, it could be that where diabetes-related distress is the primary outcome (as measured by a diabetes-specific assessment tool) the target of these interventions may be focused on diabetes-specific anxieties (such as fear of hyper (Polonsky et al., 2021)/hypoglycaemia (Fidler, Elmelund Christensen, & Gillard, 2011) and fear of future complications (Hendricks & Hendricks, 1998; Kuniss et al., 2019) rather than general anxieties which appear conceptually different and may require different therapeutic techniques. Therefore, this may explain why many of our studies did not assess anxiety as an outcome. Hence, questions remain about the associative benefits of CBT for diabetes-related distress on anxiety. This suggests that more RCTs are needed to explore this.

CBT for diabetes-related distress was not associated with a significant reduction in HbA1c. Our findings diverge from evidence showing that CBT improves glycaemic control with moderate effect(Yang, Li, & Sun, 2020) and in the short- and medium-term(Uchendu & Blake, 2017). Like depression, one explanation for this may be that HbA1c was the primary outcome of interest in these two reviews not diabetes-related distress. A previous review (Schmidt et al., 2018) of psychological interventions (not just CBT) found that HbA1c was only significantly reduced in response to diabetes-specific, not generic interventions. This is further supported elsewhere (Berry et al., 2015) which suggests that diabetes-specific CBT interventions may hold potential to improve glycaemic control alongside diabetes-related distress.

There was a small non-significant reduction in depression following third-wave interventions that aimed to treat diabetes-related distress. However, only three studies assessed the effect of CBT for diabetes-related distress on depression, so we may have been underpowered to detect a statistically significant effect. However, our finding diverges from a recent review(Ngan, Chong, & Chien, 2021) which found mindfulness and acceptance-based interventions efficacious at significantly reducing depression with moderate effect in type 2 diabetes. The main outcome of interest within this review(Ngan, Chong, & Chien, 2021) was diabetes-related distress and glycaemic control. The inclusion criteria for this review were studies that included diabetes-related distress or glycaemic control as a study outcome. This is promising; however, it is unclear how many of the intervention studies had diabetes-related distress as the primary outcome. Therefore, this may account for the diverging findings.

We found third-wave CBT interventions significantly reduced anxiety, with a moderate effect. Our findings are in line with recent review evidence(Ngan, Chong, & Chien, 2021). Although, it is important to consider that only two studies were included in the pooled estimate. Despite this, our findings suggest that third-wave CBT treatment aimed at reducing diabetes-related distress can also significantly reduce anxiety for individuals with diabetes. This is promising as it implies that third-wave interventions for diabetes-related distress can benefit anxiety in parallel. It is also needs to be considered that although the two studies had a diabetes-specific primary outcome, none of the third-wave interventions were tailored to the condition of diabetes. This poses the potential that unlike CBT interventions, third-wave CBT interventions may not need to include diabetes specific content to improve anxiety outcomes. However, more work is needed to investigate this.

Our findings highlighted a small, non-significant effect of third-wave CBT for diabetes-related distress on HbA1c favouring the control rather than the intervention condition. Similar to depression, this diverges from earlier review evidence (Ngan, Chong, & Chien, 2021). However, only three of the included third-wave CBT interventions measured HbA1c. This is surprising as glycaemic control is an integral part of diabetes-management. Therefore, more RCT's examining third-wave CBT interventions that consider emotional, and physical health outcomes are needed. Moreover, as highlighted above none of the third-wave interventions in our review were diabetes-specific. Previous trial evidence (Gregg et al., 2007) found that a diabetes-specific ACT intervention significantly improved HbA1c compared to diabetes education alone. Therefore, tailoring third-wave interventions to include diabetes-specific components may result in parallel improvements in emotional and physical outcomes in diabetes. It is also important to note that assessing improvement in glycaemic control is not unidirectional. Unlike emotional health outcomes, some individuals may benefit from a lowering HbA1c, whereas others may benefit from increasing HbA1c, depending on specific self-management behaviours, physical health status and the underpinnings of their diabetes-related distress. Therefore, caution should be taken when interpreting our mixed results for glycaemic control.

Our review provides a novel contribution to the literature as it enables the comparison between CBT and third-wave CBT interventions on diabetes-related distress. Moreover, the review enables a greater understanding of the associative benefits of CBT and third-wave CBT for diabetes-related distress on other emotional and physical health outcomes. Further, the narrative synthesis and exploratory subgroup analyses highlights intervention techniques that may have the greatest influence when treating distress. However, this review is not without limitations. Despite the focus of the review being on the benefit of interventions to treat diabetes-related distress specifically, our sub-group analyses did not reflect this. We included studies where diabetes-related distress was the primary and secondary outcome measure to increase statistical power and to keep in line with recommendations(Higgins, Thomas, & Chandler, 2022). We only included studies published in English which may have influenced the generalisability of our findings. There was moderate statistical heterogeneity present within the analyses. There was also evidence of high or unclear RoB on numerous domains. Further, due to the small number of included studies, particularly for the third-wave intervention type, we may have been underpowered to detect a statistically significant effect for some outcomes. Therefore, our meta-analytic findings should be interpreted with caution.

Conclusions

This review suggests CBT is effective at reducing diabetes-related distress overall and this effect is increased when diabetes-related distress is the primary outcome. CBT targeted to treat diabetes-related distress also significantly reduced depression but not anxiety and HbA1c. Third-wave CBT interventions for diabetes-related distress were effective at reducing anxiety. Given methodological limitations, our findings should be interpreted with caution. Moving forward, more robust interventional studies aimed at treating diabetes-related distress primarily, are required. There is also a need to consider both mental and physical health outcomes in future CBT and third-wave CBT interventions in diabetes, as evidence in this area is currently lacking.

2.3 Chapter conclusion

This chapter presented a published systematic review with meta-analysis conducted as part of this thesis. The review findings demonstrate the efficacy of CBT for reducing diabetes-related distress. Additionally, the review findings show that CBT for diabetes-related distress has benefits for depression in adults with diabetes. Third-wave CBT interventions aiming to treat diabetes-related distress were effective at reducing anxiety, however more work is needed to confirm this. The review also highlighted that CBT including a digital component, behavioural activation and delivered by a psychological clinician enhance treatment effects for adults with diabetes and co-morbid psychological distress. Additionally, the potential of tailoring CBT protocols to consider the challenges of living with diabetes as a way to bolster treatment effects was discussed in this chapter.

Chapter 3. Introduction to empirical studies in this thesis

3.1 Chapter overview

The preceding chapter demonstrated that CBT aiming to target diabetes-related distress is beneficial for diabetes-related distress and depression. Third-wave CBT for diabetes-related distress was shown to have a beneficial effect on anxiety in adults with diabetes. CBT interventions that included a digital component, behavioural activation and were delivered by a psychological clinician, appeared to bolster the effects of CBT on diabetes-related distress.

Additionally, the preceding chapter highlighted the potential of tailored CBT to improve treatment effects. Therefore, this chapter will review the literature surrounding tailored CBT to improve depression, anxiety, and illness-specific distress in context of diabetes. Additionally, this chapter will provide an overview of the literature surrounding internet-enabled CBT as a treatment for mood outcomes. The chapter will conclude with a summary of the research gaps, outlining the rationale for the empirical research studies in the remaining chapters of this thesis.

3.2 An argument for tailored CBT in diabetes.

The meta-analytic review findings presented in Chapter 2 were the first to show that CBT significantly improves diabetes-related distress (k=18; SMD = −0.149, p = 0.021; 95% CI −0.276 to −0.023, I^2 =54.8%, p = 0.003) however, treatment effects were small. Interventions targeting diabetes-related distress primarily were shown to be more effective (n=8; SMD=-0.28, p= 0.010, 95% CI −0.488 to −0.068, I^2 = 62.8%, p = 0.009) albeit the effect size remained small. However, despite diabetes-related distress being the primary outcome of the included studies and thus we assume a key target for change, the effect sizes of these intervention on depression (k= 3 studies; SMD = −0.604, $p = 0.016$) and anxiety (n=1; g=0.72, 95% CI 0.25-1.19) were medium.

Additionally, chapter 2 presented a meta-analysis of the effects of third-wave CBT interventions aiming to treat diabetes-related distress across all three outcomes. Anxiety was the only outcome to significantly improve in response to third-wave CBT intervention across two meta-analysed studies (SMD = −0.451, $p = 0.034$; 95% CI = −0.867 to −0.035; $I^2 = 52.2\%$. $p = 0.148$).

Taken together, these findings suggest that CBT and third-wave CBT interventions for diabetes-related distress may be beneficial for improving diabetes-related distress, depression, and anxiety in the context of diabetes. However, the treatment effects for diabetes-related distress remain small with wide confidence intervals, albeit significant. Therefore, more research is needed to confirm this. Additionally, work is needed to bolster these treatment effects.

One way to do this may be to tailor interventions. Existing research shows that psychological interventions that target mechanisms of action which trigger and perpetuate psychological distress in the context of living with a LTC (Carroll et al., 2022) such as diabetes bolster effectiveness, improving treatment outcomes (De Lusignan et al., 2016; Fischer et al., 2015; Schmidt et al., 2018). Further, qualitative work with adults living with diabetes has indicated that tailored psychological treatment that considers the challenges of living with diabetes is more acceptable than treatment that does not (Clarke et al., 2018).

However, in Chapter 2 (Jenkinson et al., 2022), sub-group analyses for diabetes-tailored interventions (k=12) did not produce statistically significant improvements in diabetes-related distress despite the trend in findings indicating that tailored interventions produce lower diabetes-related distress scores (SMD = −0.137, $p = 0.078$; 95% CI = −0.290 to 0.015).

Further, the wide confidence intervals surrounding this estimate highlight the potential of tailoring but indicate uncertainty around the effects of tailoring on diabetes-related distress. Therefore, more interventional studies of tailored CBT to treat diabetes-related are needed to explore this. However, adapting CBT protocols increases costs, resources, and requires specialised training for therapists (Mental Health Taskforce, 2016; National Collaborating Centre for Mental Health., 2018). Group therapy unique to illness groups is one solution for tailoring treatment in diabetes. However, studies on the efficacy of group CBT therapy to treat diabetes-related distress are lacking and where they do exist, findings are mixed (Schmidt et al., 2018; van der Feltz-Cornelis et al., 2021). Additionally, running diabetes-specific groups is resource intensive and is likely unfeasible for healthcare services long-term as the demand for accessible mental health treatment is constantly increasing (Askew & Solomons, 2019). Therefore, health services need psychological treatments that are effective and acceptable yet can be provided at scale. One potential solution may be internet-enabled CBT.

3.3 Internet-enabled CBT

Internet-enabled CBT is one way to up-scale the delivery of psychological therapies (Andrews & Williams, 2015). Traditionally, psychological therapies such as CBT have been delivered through face-to-face, or telephone sessions. However, over the last twenty years, much research has explored online delivery of psychological therapies (Andersson, 2016). Psychological therapies that would have previously been delivered face-to-face treatment can now be delivered over the internet. Internet-enabled CBT (sometimes called internet-delivered CBT; iCBT, or computerised CBT; cCBT, or digital CBT) is defined by the English NHS as “the delivery of therapy through an internet-based programme, which is accessed by the patient in their own time” (NHS Data Model and Dictionary., 2023).

Since the COVID-19 pandemic, the need for more accessible psychological treatment options has increased generally (Mahoney et al., 2021). Thus, alongside internet-enabled CBT, remote therapy delivery is now commonplace. Remote therapy is different to internet-enabled CBT. With remote therapy, face-to-face CBT is delivered via online videoconferencing (such as Microsoft Teams, Zoom or Skype). The evidence surrounding internet-enabled CBT predominantly refers to CBT accessed through a treatment platform via the internet with or without the support of a therapist. The term digital CBT is also commonly used to describe these interventions. Therefore, the terms "digital" and "internet-enabled" CBT will be used interchangeably to refer to these types of interventions in this thesis.

Internet-enabled CBT programmes can differ in their features and format. Although, typically, internet-enabled CBT programmes deliver the same therapeutic content as face-to-face CBT (e.g., psychoeducation, cognitive restructuring, behavioural skills, relapse prevention) through text and/or audio and/or video. Responsive page layouts mean that internet-enabled CBT can be accessed anywhere with an internet connection at any time, through a desktop computer, a mobile phone or a tablet (Vlaescu et al., 2016). Internet-enabled treatment often includes structured modules or assignments for users to complete, alongside supplementary resources that can be printed for patients to refer back to. Additionally, like traditional CBT many internet-enabled CBT programmes comprise of a course of sessions to be completed over time (weekly or bi-weekly) and include homework tasks. Internet-enabled CBT can be self-guided or guided. In self-guided treatment patients navigate the materials on their own. Guided treatment means that patients have regular contact with a clinician, usually on the telephone or through asynchronous messaging within the treatment platform (Andersson, 2016).

3.3.1 Advantages of internet-enabled CBT

Delivering CBT via the internet overcomes barriers to traditional CBT and improves the availability and accessibility of evidence based psychological treatment (Andersson & Titov, 2014). For example, internet-enabled CBT removes the need for therapists and patients to be located together. For patients this may reduce physical barriers such as geography, time, finance, and mobility constraints (Webb, Rosso, & Rauch, 2017). Additionally, internet-enabled CBT may reduce psychological barriers such as the stigma that is associated with receiving psychological therapy which may be particularly relevant for patients with diabetes who experience ill-health, who may feel stigmatised and may have numerous and/or clashing healthcare appointments (Clarke et al., 2018; Webb, Rosso, & Rauch, 2017).

For healthcare services, internet-enabled CBT can increase the availability of treatment. On average therapists spend 15-20 minutes , per patient per week, providing support through a course of internet-enabled CBT (Andersson et al., 2013). In contrast, in traditional CBT patients are typically seen for 30-50 minutes once per week over the treatment course (NHS Digital., 2023b) thus meaning that more patients can be seen than in a traditional format. Additionally, overall available resource is likely to increase if more patients access treatment with the same number of clinicians (Andersson, 2016). Further, as the content and resources are present within the online platform, therapist preparation time will likely reduce. Finally, preliminary evidence suggests that internet-enabled CBT may be cost-effective for adults with diabetes (Nobis et al., 2018).

3.3.2 Efficacy of internet-enabled CBT: General Population

Since the 1990’s over 200 RCTs have been published exploring the effectiveness of internet-enabled CBT (Andersson, 2016). Many RCTs have shown efficacy of internet-enabled CBT to treat psychological distress within the general population. An early meta-analysis of 12

RCTs by Andersson and Cuijpers (2009) demonstrated that internet-enabled CBT significantly improved depression when compared to a waiting list control with small to moderate effect (*k*=15 RCTs; *d*=0.41 95% CI 0.29–0.54).

More recently, Andrews et al. (2018) updated their previous meta-analysis (Andrews et al., 2010) pooling together RCT's of internet-enabled CBT to treat both depression and anxiety compared with wait-list control, treatment as usual, or an attentional control condition (e.g., pseudo-active treatments such as psychoeducation). This meta-analysis found that across all the included studies, internet-enabled CBT improved depression and anxiety with a large treatment effect) (*k*=64 RCTs, *g* = 0.80, 95% CI 0.68–0.92). These findings therefore indicate that internet-enabled CBT produces superior improvements in depression and anxiety in the general population compared to control conditions.

Additionally, early meta-analytic evidence indicates that guided interventions produce larger improvements in anxiety and depression outcomes than unguided interventions in the general population (*k*=8 RCTs, pooled SMD = −0.27, 95%-CI: −0.45 to −0.10) (Baumeister et al., 2014). In agreement with this, a recent network meta-analysis using individual patient data by Karyotaki et al. (2021) found that guided interventions produce greater improvements in depression symptoms (measured via the PHQ-9) than unguided interventions following treatment (*k*=39 RCTs, guided vs unguided mean difference (MD) −0.8; 95% CI, −1.4 to −0.2). This is promising, however, it should be noted that on the PHQ-9 a clinically meaningful change is considered to be 5 points of more (Kroenke, Spitzer, & Williams, 2001), hence a change of -0.8 reported in the study by Karyotaki et al. (2021) is small.

As highlighted above, many RCTs have compared Internet-enabled guided CBT to a waitlist control, treatment as usual or an attentional control (another intervention without active CBT ingredients). Findings suggest that when these comparators are used, internet-enabled CBT appears to produce superior treatment effects for the general population (Andrews et al., 2018). This is promising, but comparing to non-active control conditions can often inflate effect estimates (Gold et al., 2017; Mohr et al., 2009). Thus, meta-analyses have also compared internet-enabled CBT to face-to-face CBT (Carlbring et al., 2018; Cuijpers et al., 2010). When compared to face-to-face CBT, guided internet-enabled CBT appears to hold equivalent effectiveness for treating psychological outcomes in the general population (k=20; g = .05; 95% CI, −0.09 to 0.20) (Carlbring et al., 2018) underlining the potential of these interventions to support traditional delivery.

In sum, internet-enabled CBT with the support of a therapist across the general population holds promise for providing a scalable model to deliver psychological therapy. Its value in the context of LTCs is summarised below.

3.3.3 Efficacy of internet-enabled CBT: LTCs

Amongst those living with LTC(s), three meta-analytic reviews have reported statistically significant small effects of digital therapies on depression and anxiety outcomes (Johnson et al., 2024; Mehta, Peynenburg, & Hadjistavropoulos, 2019; White et al., 2022).

The study by (Mehta, Peynenburg, & Hadjistavropoulos, 2019) specifically explored CBT and found that internet-enabled CBT significantly reduced anxiety (SDM = 0.45 ± 0.09, $p < .001$) and depression (SDM = 0.31 ± 0.04, $p < .001$) with small effect. The meta-analysis by White et al. (2022) was not restricted to CBT interventions and found that overall online psychological interventions significantly reduced depression, and general psychological distress symptoms with moderate effect (depression: k=59; g = 0.30; 95% CI 0.22–0.39; psychological distress k=28; g = 0.36 95% CI 0.23–0.49) and anxiety with small effect (k=43; g = 0.19; 95% CI 0.12–0.27). However, sub-group analyses indicated that overall CBT-based interventions (*k*=39) vs those that were not CBT based (*k*=20) produced significantly larger reductions in outcomes for those with LTCs.

Similarly, the study by Johnson et al. (2024) was not restricted to CBT interventions and included internet and mobile interventions. However, this review differed to the two above as it only considered RCTs where the intervention considered the mind-body interaction. Overall, the findings from this review demonstrated that internet and mobile mind-body interventions significantly reduced depression scores (*k*=53; SMD = -0.33; 95% CI -0.40 to -0.26, *p*<0.001) and anxiety scores (*k*=50; SMD = -0.26; 95% CI -0.36 to -0.17, *p*<0.001). Sub-group analyses did not reveal significant differences between CBT-based interventions (*k*=28%), compared to those that were not CBT-based interventions (*k*=10) and those that had a combination of CBT and non-CBT techniques (*k*=18) on depression (*p*=0.35) or anxiety (*p*=0.09).

In two reviews' therapist-supported digital interventions showed larger treatment effects than unsupported interventions (Mehta, Peynenburg, & Hadjistavropoulos, 2019; White et al., 2022) and in the remaining review (Johnson et al., 2024) no significant differences were observed.

However, it should be noted that in the three reviews (Johnson et al., 2024; Mehta, Peynenburg, & Hadjistavropoulos, 2019; White et al., 2022) there was heterogeneity amongst the LTC populations studied. Additionally, the review's by White et al. (2022) and Johnson et al. (2024) were not restricted to CBT interventions and the study by Johnson et al. (2024) was not restricted to web-based interventions.

These reviews focused on LTCs rather than diabetes specifically. Of the studies in these reviews only 2 included individuals with diabetes and used a web-based and CBT modality (Newby et al., 2017; K. Van Bastelaar et al., 2011). Both of these studies were included in the systematic review in Chapter 2 of this thesis (Jenkinson et al., 2022). These studies demonstrated statistically significant improvements in diabetes-related distress (Van Bastelaar 2011; $p<0.001$; Newby 2017; $g=0.80$, $p=0.01$) and depression (Van Bastelaar 2011; $d = 0.29$; $p<.001$; Newby 2017; $g=0.78$, p<0.001). Additionally, Newby et al. (2017) found that internet-enabled CBT significantly reduced anxiety ($g=0.72$, 95% CI 0.25-1.19, $p<0.001$) for adults with diabetes.

Since the publication of the review presented in chapter 2 of this thesis (Jenkinson et al., 2022), only one additional RCT study has evaluated an internet-enabled CBT intervention to treat depression, diabetes-related distress and anxiety in diabetes (Carreira et al., 2022). This study comprised of Spanish adults with Type 1 diabetes and the intervention was therapist-guided and included diabetes-specific content. Participants were randomised to the intervention ($n=35$) or the waiting-list control group ($n=30$). Between group results indicate that the intervention produced significant improvements in self-reported depression ($p= 0.001$; measured by the Spanish version of the Beck Depression Inventory-Fast Screen; BDI-FS (Beck et al., 2011), diabetes-related distress ($p= 0.015$; measured by the DDS-17; Polonsky et al. (2005), trait anxiety ($p= 0.004$) and state anxiety ($p=0.039$) measured by the Spanish version of the State Trait Anxiety Inventory (Seisdedos, 1982; Spielberger, 1970).

Taken together, these findings demonstrate that internet-enabled CBT is effective at improving psychological outcomes for adults with diabetes (Jenkinson et al., 2022). Additionally, as discussed above, internet-CBT may overcome barriers to access for people living with diabetes (Clarke et al., 2018) and provide a more scalable solution to the provision of psychological support. Therefore, NICE clinical guidelines recommend internet-enabled CBT to treat depression in the context of LTCs (National Collaborating Centre for Mental Health, 2010; National Institute for Health and Care Excellence, 2018).

3.4 The development of COMPASS: a transdiagnostic CBT program to treat depression and anxiety in context of LTCS.

In response to this, the research team at Kings College London developed "COMPASS – Navigating your Long-Term Condition" prior to the conception of this thesis. COMPASS integrates physical and mental health by focusing on illness self-management alongside mood management. COMPASS is a transdiagnostic therapist guided internet-enabled CBT intervention to treat psychological distress. Transdiagnostic means that the treatment protocol can be applied in the context of any or many LTC(s).

Two of the named PhD supervisors on this thesis were involved in the development of COMPASS (JLH and RMM). The development of COMPASS was guided by the UK Medical Research Council (MRC) Guidance (Craig et al., 2008; Skivington et al., 2021) and the person-based approach (Yardley et al., 2015) gathering iterative feedback from patients living with LTCs. Below the theoretical underpinnings of the COMPASS intervention development and the intervention components are outlined.

3.4.1 Theoretical underpinning of COMPASS and its treatment manual

Prior to the development of COMPASS, the research Team at King's College London developed the Transdiagnostic Model of Adjustment to LTCs to explain processes of psychological adjustment that occur in the context of LTCs (for more information see Carroll et al. (2022). This theory informed the development of COMPASS.

In brief the Transdiagnostic Model of Adjustment to LTCs postulates that living with LTC(s) such as diabetes includes acute critical events and ongoing illness stressors such as diagnosis, ongoing uncertainty and/or symptom management. The theory proposes that these unique stressors can disrupt a person’s equilibrium. To regain this equilibrium an ongoing process of adjustment is needed which includes:

a) developing accurate interpretations of illness and symptoms.

b) establishing cognitive, behavioural, and emotional responses to illness and symptoms that are appropriate to one’s situation.

c) being able to evaluate and adapt one’s coping mechanisms depending on how well they work for the individual.

Within this process cognitive, behavioural, and contextual factors occur that act as facilitators or barriers to adjustment. Drawing on this theory, the identification of key mechanisms of action that trigger and sustain anxiety and/or depression in the context of an LTC(s) were identified, thus highlighting potential treatment mechanisms. See *Figure 2* for a graphical depiction of the Transdiagnostic Model of Adjustment to an LTC taken from Carroll et al. (2022).

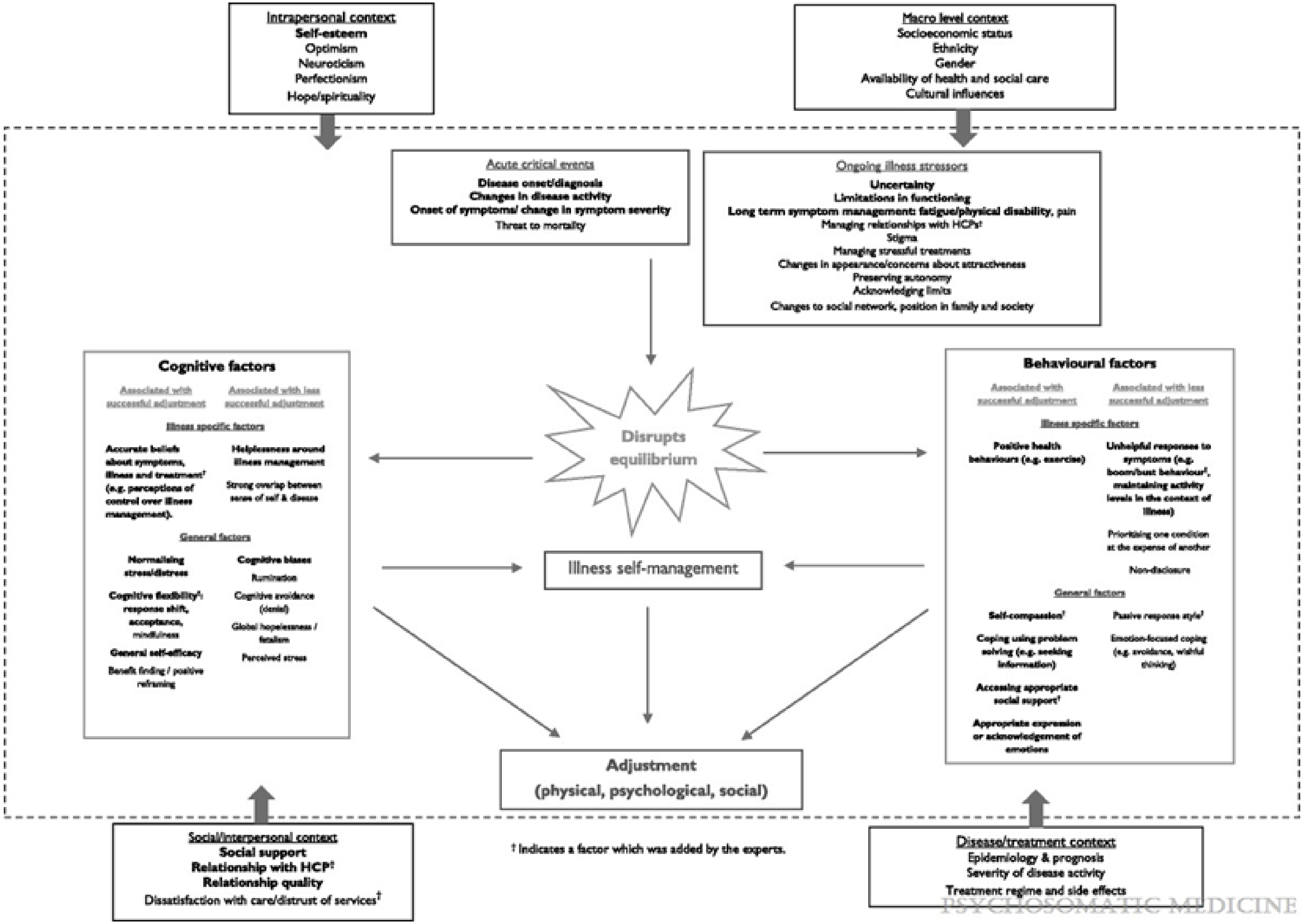


Figure 2. *Transdiagnostic Model of Adjustment to an LTC.*

3.4.2 COMPASS intervention: Format and procedures

COMPASS consists of 11 online modules whereby the CBT "active ingredients" target processes linked to the onset and maintenance of distress across a range of LTCs identified within the Transdiagnostic Model of Adjustment to LTCs (Carroll et al., 2022) described above. The name of each module, CBT techniques that are taught and the evidence-based mechanisms of action that is targeted in each COMPASS session are shown in *Table 2,* taken from Hulme et al. (2021).

The intervention is self-led with patients working through the online modules at their own pace. COMPASS is guided by therapist trained to deliver COMPASS CBT. The recommendation is that patients receive 6x 30-minute therapist support sessions via the telephone, videoconferencing or via the COMPASS platform messaging system. This is in line with NICE guidance for treating depression in the context of LTCs (National Collaborating Centre for Mental Health, 2010).

Table 2. *COMPASS module names, CBT techniques used and mechanisms of action.*

COMPASS module name	**CBT techniques used (description lists evidence-based CBT competency domain(s) title(s) followed by the specific CBT skills)**	**Evidence-based cognitive-behavioural mechanisms assessed/targeted**
Core session that patients complete before continuing with the rest of COMPASS		
Navigating COMPASS 1) Mapping my LTC	*Domain: Assessment, formulation, engagement and planning* - Assessment - Guided discovery	- Cognitive-behavioural processes associated with depression and anxiety in LTCs
2) Key Skills	*Domain: Specific Interventions* - Goal setting - Problem solving	- Feelings of helplessness and hopelessness because of LTC self-management demands.
COMPASS quadrant: North – Navigating change and uncertainty		
1) Managing uncertainty	*Domain: Applying psychological principles to support self-management AND Specific interventions* - Worry tree and balancing illness self-management skills with emotion focussed coping	- Uncertainty linked to LTC symptoms and longer-term health and social outcomes - Low perceptions of control
2) Power of thoughts	*Domain: Applying psychological principles to support self-management AND Specific interventions* - Cognitive reappraisal	- Unhelpful/inaccurate beliefs about living with a LTC
COMPASS quadrant: East – Even keel		
1) Achieving routine	*Domain: Specific Interventions* - Planning patterns of activity and rest - Self-Monitoring - Identifying and managing sleep problems	- Inconsistent “boom-bust” patterns of activity whereby a person “booms” and overdoes things which results in them becoming “bust”.
2) Managing symptoms	*Domain: Specific Interventions and Psychologically informed cross-condition interventions* - Attentional techniques - Symptom and Activity records - Cognitive reappraisal - Relaxation	- Focussing on symptoms and coping in an unhelpful way, for example, self-focussing on symptoms, reassurance seeking, resting which in turn leads to physical deconditioning and an stops ability to learn more adaptive self-management coping behaviours
3) Emotions	*Domain: Specific Interventions* - Normalising - Behavioural activation - Acceptance* - Emotional expression*	- Withdrawal from positive and reinforcing events.

COMPASS module name	**CBT techniques used (description lists evidence-based CBT competency domain(s) title(s) followed by the specific CBT skills)**	**Evidence-based cognitive-behavioural mechanisms assessed/targeted**
COMPASS quadrant: South – Support		
1) Strengthening personal relationships	*Domain: Assessment, formulation, engagement* - Assertive communication - Emotional expression*	- Social support from others (helpful and unhelpful)
2) Making use of professional support and information	*Domain: Assessment, formulation, engagement (drawing on wider CBT competency frameworks e.g. systemic therapy) AND Psychologically informed cross-condition interventions* - Sign posting and care co-ordination - Assertive communication	- Helpless and overwhelmed by complex symptoms, self-management routines, and healthcare professionals.
COMPASS Quadrant: West – Living well		
1) Healthy lifestyle	*Domain: Psychologically informed cross-condition interventions* - Nutrition - Exercise - Sleep - Medications	- Helplessness and overwhelmed by complex self-management routines
2) I'm me, not my LTC	*Domain: Psychologically informed cross-condition interventions AND Specific Interventions* - Compassion focussed interventions* - Motivational interviewing - Cognitive restructuring	- Loss of identity and sense of self because of LTC(s)
3) Managing stress	*Domain: Psychologically informed cross-condition interventions AND Specific Interventions* - Priority setting/proactive self-management skills - Relaxation	- Helpless and overwhelmed by LTC and its wider consequences

3.5 Real World Evaluations (Effectiveness Studies)

All the evidence reviewed above focused on robust efficacy studies which have aimed to evaluate an intervention's ability to alter the main outcome measure in the context of a research study (Curran et al., 2012) . Efficacy trials are concerned with internal validity and often follow rigorous procedures to recruit and retain participants which may reduce the generalisability of findings to the real world. For example, individuals who consent to and participate in research are often more motivated to engage with therapy and internet-enabled CBT. Additionally, the application of strict inclusion and exclusion criteria may remove certain demographic and clinical characteristics (e.g. co-morbidities) that may be present in real-world practice for people with diabetes. Moreover, in an RCT conducted in a controlled research environment, adherence is often supported and monitored by a team of researchers potentially enhancing the observed treatment effects (Bauer & Kirchner, 2020; Cohen et al., 2008). Effectiveness studies differ from efficacy studies. Effectiveness studies are most concerned with external validity and exist to evaluate the effectiveness of an intervention in the context of a heterogeneous real-world sample (Curran et al., 2012).

However, despite the distinction between research study types (Curran et al., 2012) this does not mean that effectiveness studies are a panacea for the limitations of efficacy studies. More recently researchers have highlighted that effectiveness alone does not always translate into *adoption* in real-world clinical settings (Lipschitz et al., 2019). Indeed, classic studies have demonstrated that it takes approximately 17 years for research to translate into real world practice that benefits patients (Balas & Boren, 2000; Bauer & Kirchner, 2020; Morris, Wooding, & Grant, 2011; Mosteller, 1981). Furthermore, it has been estimated that approximately 50% of clinical research interventions never make into routine usage (Bauer & Kirchner, 2020). This gap has been seen previously in internet-enabled therapies (Folker et al., 2018), as well as other psychological interventional and bio-medical research (Colditz &

Emmons, 2012). Therefore, the non-uptake of effective interventions is persistent and not unique to internet-CBT interventions in and of themselves.

Considering these statistics many clinicians and academics have argued that we must move away from efficacy and effectiveness trials alone, and towards ***implementation*** research to transcend the gap between research and practice. Indeed, the MRC (Skivington et al., 2021) added 'implementation' to their framework for Developing and Evaluating Complex Interventions in the latest guidance update. The update highlighted that "*To deliver solutions for real world practice, complex intervention research requires strong and early engagement with patients, practitioners, and policy makers, shifting the focus from the binary question of effectiveness to whether and how the intervention will be acceptable, implementable, cost effective, scalable, and transferable across contexts*".

3.6 Diabetes Psychology Services in England: the role of COMPASS

COMPASS has been evaluated via a RCT (Picariello et al., 2024b) and an effectiveness study within routine NHS care (Seaton et al., 2023) and has demonstrated efficacy and real-world effectiveness for improving outcomes. The findings of these studies will be discussed in more detail in chapter 4 of this thesis. Nonetheless, COMPASS offers a potential model for implementing tailored CBT for treating psychological outcomes for people with diabetes in routine care. However, despite the high prevalence of common mental health conditions in diabetes, psychological support in routine care within the UK is limited. This was highlighted by Diabetes UK in their "Too Often Missing" report (Diabetes UK, 2019). As part of the report, 2667 people living with diabetes and their carers were surveyed about mental health in diabetes. Of those living with diabetes, 75% said they do not feel they are able access the mental health support they need highlighting a clear gap between demand and supply.

Traditionally, the provision of psychological support in the context of diabetes has been restricted to secondary care. These services may be separate mental health services, psychological medicine services within general hospitals, or clinical health psychology services embedded within specialist multidisciplinary diabetes teams. However, the availability of support often depends on local funding (Diabetes UK, 2019). Thus, experiences of accessing support vary widely. Where support is available, many health care professionals working in diabetes have highlighted their concerns surrounding the physical accessibility of this support (Primary Care Diabetes Society, 2018) indicating that long waitlists, travel, and opening times of current services are a problem.

However, in 2008, Talking therapies services (formerly known as Improving Access to Psychological Therapy (IAPT) services) were created by NHS England to provide evidence-based psychological therapies for depression and anxiety within primary care, following the guidelines of NICE. In 2016, the Five Year Forward View for Mental Health policy document (Mental Health Taskforce, 2016) outlined the prioritisation of integrated mental and physical healthcare for people living with LTCs. Thus, Talking Therapies services expanded to provide psychological treatment for patients with LTCs and common mental health conditions. It was demonstrated that these integrated services would improve outcomes for patients. Additionally, integrated care would reduce annual expenditure by the English National Health Service (NHS) by £1,760 per person (National Collaborating Centre for Mental Health., 2018). In line with this, new guidelines were published (named “IAPT-LTC”) to support the creation, implementation, and expansion of these pathways in primary care (National Collaborating Centre for Mental Health., 2018). Within these guidelines, internet-enabled CBT were recommended as a treatment option and is now a core part of the delivery of psychological therapy for people living with LTCs.

The delivery of psychological treatment for people living with LTCs within primary care in England was transformed through the introduction of LTC pathways within Talking Therapies. Indeed, Talking Therapies-LTC provided referral and treatment pathways outside of secondary care services, thus increasing access to evidenced based treatments. Internet-enabled CBT supports this. However, evidence from Talking Therapies services consistently shows that outcomes are poorer for those with LTCs (including diabetes) compared to those without (Seaton et al., 2023). Therefore, this highlights the remaining potential to increase the effectiveness of psychological interventions for people with diabetes and supports the clinical values of implementing a targeted interventions to improve mental healthcare in this patient group. However, as highlighted above, there is a need to move towards implementation research to explore the reality of intervention delivery in routine care.

3.7 Theoretical Approaches used to inform implementation science in this thesis

Implementation science has been defined as *"the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services"* (Eccles, 2006).

Across the world, numerous theoretical frameworks, models and theories are used to guide implementation. In general, frameworks, models and theories within implementation science are tools that can assist with planning, guiding, or evaluating the process of implementing evidence into practice (Lynch et al., 2018). The terms "theory", "framework" and "model" are often used interchangeably. However, many researchers argue that there is a distinction, therefore the following definitions have been taken from Lynch et al. (2018); "A framework lists the basic structure and components underlying a system or concept" whereas "a theory may be explanatory or predictive, and underpins hypotheses and assumptions about how implementation activities should occur.” Additionally, a model can be defined as “a simplified representation of a system or concept with specified assumptions”.

Many implementation frameworks, theories and models exist. In fact, one publication by Birken et al. (2017) surveyed implementation scientists and found that over 100 different theories have been employed, spanning various disciplines including health and psychology. Additionally, another publication by Skolarus et al. (2017) (developed from the review by Tabak et al. (2012) identified 61 commonly used implementation theoretical frameworks. Given the large number of theoretical frameworks available, selecting the appropriate one can be a challenging process. A comprehensive review of all available frameworks is beyond the scope of this thesis. However, for a detailed review please see Birken et al. (2017).

For the purpose of this thesis, the focus of this section will be on reviewing the RE-AIM framework (Reach, Effectiveness, Adoption, implementation, and Maintenance) (Glasgow et al., 2019; Glasgow, Vogt, & Boles, 1999) as this framework has been as used to define outcomes throughout this body of work. The RE-AIM framework was selected by considering the guidance from Lynch et al. (2018), who in their publication ‘A Guide for Selecting Theoretical Approaches in Implementation Projects’ present five key questions to consider when choosing an implementation approach: 1) ***Who:*** Are you looking at individuals, groups or wider settings? 2) ***When:*** Are you planning, conducting or evaluating? 3) ***Why:*** What is your aim and what do you need to understand? 4) ***How:*** What data will be available to use? 5) ***What:*** what resources do you have to support you?

The RE-AIM framework has been selected because the focus of this thesis is to evaluate and explore the process of implementing COMPASS. RE-AIM (Glasgow, Vogt, & Boles, 1999) provides a structured and consistent approach for defining and evaluating implementation outcomes at an individual, and service / system level across healthcare contexts and services. Further, RE-AIM has been used to support the collection and evaluation of both qualitative and quantitative data (Holtrop et al., 2021; Holtrop et al., 2018). Additionally, RE-AIM has been used to define outcomes when evaluating the success of implementation in real-world observational studies as evidenced by 450 publications (Tabak et al., 2012), enabling comparisons with existing literature (Holtrop et al., 2021). Notably, the RE-AIM framework has been applied to implementation research in diabetes healthcare in England (Knowles et al., 2019) and other locations (Glasgow et al., 2006), allowing this work to build on existing implementation research in this area.

The RE-AIM framework shaped the research questions of this thesis (presented in section 3.8 below) by providing a comprehensive structure for addressing both quantitative and qualitative aspects of the implementation process. Considering the dimensions of RE-AIM guided the formulation of research objectives that could be explored using a mixed-methods approach. Quantitative data was used to assess outcomes such as reach and effectiveness, while qualitative methods were employed to explore more nuanced aspects like the adoption.

3.8 Chapter summary and flow of remaining thesis chapters

Based on evidence reviewed in chapter 1, it appears that there is a need for psychological support within adult diabetes care. Currently, CBT is the most evidence-based psychological treatment for diabetes. However, as discussed in chapter 1 and the introduction of chapter 2, the effectiveness of CBT for treating diabetes-related distress is not well-established. Additionally, which intervention components have the most impact on diabetes-related distress outcomes was unclear. Therefore, the published systematic review (Jenkinson et al., 2022) presented in chapter 2 aimed to investigate this. The published findings presented in chapter 2 suggest that CBT appears to be effective for treating diabetes-related distress. Further, evidence points towards the benefit of using a tailored intervention.

However, as outlined in chapter 3 implementing a tailored intervention at scale across the NHS remains a challenge. Evidence suggests that digitally delivered CBT can assist with upscaling treatment and has benefits for engagement. Furthermore, digital CBT guided by a therapist appears to produce equivalent treatment effects to face-to-face treatment of psychological outcomes in the general population (Carlbring et al., 2018) and bolsters efficacy when treating diabetes-related distress specifically (Jenkinson et al., 2022). COMPASS, is an existing therapist-guided digital CBT intervention that has been shown to be effective in treating distress across a range of LTCs (Picariello et al., 2024a). However, the effectiveness and the implementation of COMPASS in routine diabetes care remains uncertain. Therefore, this PhD aims to evaluate the implementation of COMPASS for adults with diabetes and co-morbid psychological distress in routine NHS care.

Thus, this thesis will present 3 more studies alongside the meta-analysis in chapter 2 to address the overall following research questions:

3.8.1 Chapter 4 Research Questions

Is it feasible to implement COMPASS into routine NHS care for people with diabetes and co-morbid psychological distress?

What are the barriers and facilitators to implementing COMPASS into routine care people with diabetes from the perspective of patients?

3.8.2 Chapter 5 Research Questions

Following this, chapter 5 will present a quantitative cross-sectional study to investigate the following question: Does having an LTC impact on assessment attendance, treatment engagement, and receipt of a digitally delivered intervention compared to people without an LTC when offered as part of routine care offered by NHS Talking Therapies?

The aim of this chapter is to gain a wider insight into patient engagement outcomes. This will enable us to explore if any of the barriers or facilitators to engagement identified in chapter 4 are specific to 1) COMPASS 2) digital interventions 3) the diabetes population.

3.8.3 Chapter 6 Research Questions

Finally, chapter 6 will qualitatively explore: what are the barriers and facilitators to implementing COMPASS into routine care for people with diabetes from the perspective of those who are implementing COMPASS and wider stakeholders?

This will enable this thesis to triangulate both qualitative and quantitative data sources from multiple perspectives to explore the implementation of COMPASS into routine NHS care for adults with diabetes and comorbid psychological distress and ultimately address the overall aim of this body of work.

Chapter 4. Mixed methods implementation study

4.1 Chapter overview

The preceding chapter provided a comprehensive overview of the evidence base for CBT for adults with diabetes. Additionally, chapter 3 introduced COMPASS, an existing internet-enabled CBT intervention and outlined the rationale for moving away from effectiveness studies and towards implementation research. Alongside this, uncertainties surrounding the use of COMPASS in routine NHS care were highlighted. Therefore, this chapter presents a mixed-methods study exploring implementation of COMPASS into routine NHS care for adults with diabetes. This chapter is to be submitted for publication hence the researcher will use the pronoun “we” to refer to the research team included in this study.

4.2 Introduction

Diabetes is a chronic metabolic disorder characterised by high blood glucose levels (American Diabetes Association, 2020). Current estimates suggest that irrespective of type, diabetes affects approximately 7% of the UK population and this is increasing (Whicher, O’Neill, & Holt, 2020). Diabetes requires constant self-management. Therefore, it is unsurprising that in a UK-based survey, 70% of people living with diabetes said they felt overwhelmed by the demands of their condition (Askew & Solomons, 2019). Robust evidence shows that living with diabetes is associated with increased depression (Khaledi et al., 2019), anxiety (Smith et al., 2013) and distress specific to living with diabetes (named diabetes-related diabetes) (Polonsky et al., 2005; Skinner, Joensen, & Parkin, 2020). Associations between such distress and poorer outcomes in adults with diabetes are well-established. Specifically, high levels of distress have been associated with reduced quality of life (Gómez-Pimienta et al., 2019), poorer glycaemic control (Lustman et al., 2000; Schmitt et al., 2015) and increased risk of complications (Nouwen et al., 2019). Additionally, review evidence by Molosankwe et al. (2012) suggests that co-morbid depression in adults with diabetes has adverse effects on healthcare services through increased healthcare utilisation and costs. In light of this, national and international guidelines recognise the need for psychological support in diabetes as part of routine care (Speight et al., 2020).

In the UK, the National Institute of Health and Care Excellence (NICE) recommends Cognitive Behavioural Therapy (CBT) as a psychological treatment for the management of anxiety and/or depression in the context of long-term conditions (LTCs) (National Collaborating Centre for Mental Health, 2010). Meta-analytic findings highlight the efficacy of CBT as a treatment to improve depression, anxiety, and diabetes-related distress for adults with diabetes (Jenkinson et al., 2022). Furthermore, CBT that includes a digital component and is delivered by a psychological practitioner may bolster the effects of these interventions on diabetes-related distress specifically (Jenkinson et al., 2022). Additionally, CBT may hold potential as a treatment for improving blood glucose levels (Uchendu & Blake, 2017; Yang, Li, & Sun, 2020). CBT protocols that integrate LTC-specific concerns demonstrate better clinical outcomes, acceptability, and engagement for people with diabetes (Nobis et al., 2015; Wroe et al., 2018) and other LTCs (Fischer et al., 2015). However, often in routine National Health Service (NHS) care, CBT protocols fail to consider LTC-specific concerns (Seaton et al., 2023). Tailoring CBT protocols is cost and resource intensive which pose challenges for NHS services as the demand for psychological support and thus therapists' time is increasing (Pierce et al., 2020; Verbist et al., 2023) .

To address this gap, our team developed a therapist-guided digital CBT intervention called "COMPASS – navigating your long-term condition" using the Medical Research Council (MRC) framework (Skivington et al., 2021). COMPASS is transdiagnostic meaning its content can be applied to treat depression and anxiety across LTCs. Its development was informed by the transdiagnostic model of adjustment (Carroll et al., 2022; Moss-Morris, 2013), which proposes that distress in LTCs (including diabetes) is in part, triggered and maintained, by mechanisms specific to having an LTC that psychiatric models of depression and anxiety are unable to account for.

The efficacy of COMPASS has been robustly evaluated through a Randomised Controlled Trial (RCT) (*n*=194) (Hulme et al., 2021; Picariello et al., 2024b). The findings suggested it is an effective treatment for improving general psychological distress measured by the PHQ-ADS (Standardised Mean Difference, SMD = 0.71; 95% Confidence Interval, CI = 0.48-0.95), anxiety measured by the GAD-7 (SMD = 0.70, 95% CI = 0.43-0.97), and depression measured by the PHQ-9 (SMD = 0.62; 95% CI = 0.40-0.84) with moderate to large treatment effects when compared with standard charity support for four common LTCs. However, adults with diabetes were not included in this trial, so the efficacy of COMPASS for this group is unclear.

The real-world effectiveness and acceptability of COMPASS was evaluated when used as part of routine NHS care with mixed methods (Seaton et al., 2023). The study explored the effectiveness of COMPASS within one Talking Therapy service and six physical health secondary care services for people with LTCs (including diabetes). Talking Therapy services (formerly Improving Access to Psychological Therapies) are NHS primary care services that provide psychological therapy for common mental health conditions (i.e. depression and anxiety) within the general population, including those with LTCs. Conversely, in secondary care psychological support is typically provided by embedded psychology services within physical care settings. Quantitative findings by Seaton et al. (2023) indicated that patients using COMPASS demonstrated statistically significant improvements in distress (d= -0.42, 95% CI =-0.7 to -2.7; $p \leq 0.001$), depression (d= -0.37, 95% CI =-3.7 to -1.7; $p \leq 0.001$), and anxiety (d= -0.42, 95% CI =-3.6 to -1.2; $p \leq 0.001$). Moreover, qualitative findings suggested that COMPASS is an acceptable treatment. Specifically, patients valued the LTC-tailored content. However, some patients interviewed reflected on how a digital delivery method was a barrier to treatment engagement and indicated a preference for face-to-face therapy. In sum, both the RCT and real-world evaluation of COMPASS show it is an effective intervention. However, Seaton et al. (2023) qualitative analyses highlight that internet-enabled treatments such as COMPASS may not be an acceptable treatment modality for some people in routine care.

The Five Year forward View for Mental Health Policy Document (Mental Health Taskforce, 2016) identified internet-enabled therapies as one way to improve access to mental health support and placed a specific focus on providing integrated mental and physical healthcare across England (National Collaborating Centre for Mental Health., 2018). However, despite the established effectiveness of COMPASS, currently the extent to which COMPASS meets the needs of the intended population and how it is used in routine practice is unknown. Thus, there is a clear need to move away from effectiveness research alone and further explore the feasibility and acceptability of implementing interventions into routine care. Specific to diabetes, there is a push for better mental health service provision (Askew & Solomons, 2019). Indeed, a recent paper by Sachar, Breslin and Ng (2023) co-created by people living with diabetes and healthcare professionals set out theoretical recommendations for how this could happen, arguing that appropriate and effective resources exist, but more work is needed to support local implementation of these resources in diabetes.

Therefore, this study aims to explore the implementation of COMPASS for adults with diabetes. Additionally, we aim to explore the contextual barriers and facilitators to implementing COMPASS in NHS care using mixed-methods. The specific research objectives for this study are defined following the RE-AIM dimensions (Reach, Effectiveness, Adoption, implementation, and Maintenance) (Glasgow et al., 2019; Glasgow, Vogt, & Boles, 1999) and are presented in *Table 3*. Note, maintenance is not assessed because this was not feasible within the timeframe of this thesis. The rationale for the selection of the RE-AIM framework (Glasgow, Vogt, & Boles, 1999) has been outlined in chapter 3 (section 3.7; page 106).

Table 3. *RE-AIM dimensions and corresponding research questions.*

RE-AIM Dimension	RE-AIM definition	Study research question
Reach	The participation rate from the eligible population frame.	1. What proportion of PwD[1] referred **for psychological support are eligible to use COMPASS**? 2. What proportion of **eligible PwD are willing to use COMPASS**?
Effectiveness	The impact of an intervention on intended outcomes.	1. What is the **effectiveness** of COMPASS on self-reported outcomes.[1]
Adoption	The participation of staff and the system to implement the intervention[2].	1. What are the barriers and facilitators to the **adoption** of COMPASS from the perspective of PwD and how does this effect the potential reach, effectiveness and implementation of COMPASS?
Implementation	To what extent was and can the intervention be implemented as intended in the real world and what (if any) local adaption occurred?	1. How many online sessions did participants complete on COMPASS? 2. How many therapist support sessions were attended by participants on COMPASS? 3. What amount of time did the therapist spend supporting the participant? 4. What mode of delivery was the therapist support provided?

PwD; people with diabetes. [1] Depression, patient health questionnaire – 9 item (PHQ-9) (Kroenke, Spitzer, & Williams, 2001); Anxiety, Generalised anxiety disorder scale – 7 item (GAD-7)(Spitzer et al., 2006); Diabetes-related distress, The Diabetes Distress Scale-17 (DDS-17) (Polonsky et al., 2005); Functioning, Work and Social Adjustment Scale (WSAS) (Mundt et al., 2002); Quality of life The European Quality of Life Scale three level version (EQ-5D-3L) (EuroQol group, 1990).[2](Holtrop, Rabin, & Glasgow, 2018).

4.3 Methods

4.3.1 Study design and setting

The study was observational mixed methods study, utilising a single arm pre-post quantitative design with nested qualitative interviews. The study received NHS ethical approval (REC: 22/WA/0017).

This study was conducted across three inner London NHS Foundation Trusts: South London and Maudsley (SLaM), Homerton Healthcare, and Guys and St Thomas' (GSTT). Within these Trusts participants were recruited from two Talking Therapies providers (primary care mental health service), and a Diabetes and Endocrinology service (secondary care physical health service) where patients accessed COMPASS through the embedded psychology team. Data collection timeframes were not consistent across all the study sites; Talking therapies, February 2022-July 2023; and Diabetes and Endocrinology service June 2022-September-2022).

4.3.2 Participant eligibility

Service-specific eligibility criteria

As per routine care, in Talking Therapies individuals self-refer or are referred in by a healthcare professional. Under NHS guidance (NHS Digital., 2023b), patients must have clinically relevant depression (scores ≥10 on the Patient Health Questionnaire; PHQ-9 (Kroenke, Spitzer, & Williams, 2001) or anxiety (scores ≥8 on the Generalised Anxiety Disorder-7; GAD-7 (Spitzer et al., 2006). However, some patients who did not meet these cut offs could have been included based on clinician judgement made during an assessment. Talking Therapy services conduct a routine triage procedure to determine service and treatment eligibility (not specific to COMPASS). Following triage, patients are offered a choice of suitable treatments (e.g., guided self-help, internet-enabled CBT, face-to-face CBT).

In the diabetes service, patients are typically referred to the psychology team by medical clinicians. Prior to referral to the psychology service, psychological distress is identified through 1) informal conversations with patients where emotional wellbeing concerns are raised 2) through routine mental health screening in clinic. In the diabetes psychology service patients are offered COMPASS, a wait list place for face-to-face therapy with a psychologist, or a referral to Talking Therapies.

Study-specific eligibility criteria

Inclusion criteria were provided to the services to determine patients' eligibility for COMPASS: ≥18 years; medically or self-reported type 1 or type 2 diabetes; sufficient English language skills to interact with COMPASS; internet access and an email address to register on COMPASS and an indication that their depression/anxiety/distress is related to their diabetes. Therapists conducting the assessment were trained to assess this with specific prompts asking about whether patients' mood was related to their diabetes. Patients were excluded if they had evidence of substance dependency, cognitive impairment, a severe mental health conditions (e.g., psychosis, personality disorder) or had active suicidal plans.

4.3.3 Participant recruitment

In all services, following a referral, patients received a telephone assessment or face-to-face assessment with a therapist. Those who met the eligibility criteria were informed about COMPASS and the current study. They were asked if they consented to be contacted about study participation. If consent for contact was given, the research team got in touch to obtain informed consent. As COMPASS is routinely offered, where individuals declined to participate in the study, they were reassured their use of COMPASS would not be affected. In both services, patients who chose to uptake COMPASS were eligible to take part in the quantitative and qualitative elements of the study. Those who met the inclusion criteria for COMPASS but declined it were eligible to be interviewed for the current study only. Written informed consent was obtained from all participants.

4.3.4 COMPASS intervention

Patients who agreed to use COMPASS received an automated email with a link to COMPASS and their log-in details. Then therapists sent an in-site message to patients, explaining the process, scheduling their first call and encouraging them to complete the COMPASS introductory module. If someone did not login within two weeks of receiving the COMPASS email, they received a telephone call to support with digital onboarding.

In brief COMPASS is a web-based CBT treatment comprised of 11 sessions targeting mechanisms of action that trigger and sustain distress in LTCs (Carroll et al., 2022). The first COMPASS session is mandatory as self-assessment tasks generate a personalised CBT formulation of key problem areas. Following session one, patients are supported to choose their journey through COMPASS. Each quadrant of COMPASS explores different challenges associated with LTCs and mood management (e.g., managing uncertainty, optimising self-management, and utilising support). For more details on the content of COMPASS see Hulme et al. (2021) and Chapter 3 of this thesis.

4.3.5 COMPASS support and training

Patients using COMPASS were therapist-supported via in-site messaging or teleconferencing. Therapists aimed to assist participants to identify and apply the skills outlined in COMPASS. In the current study, COMPASS therapists were trained to deliver CBT and received technical and clinical CBT training from the COMPASS team. COMPASS therapists received fortnightly clinical supervision from a qualified clinical psychologist. In line with NICE guidelines for therapist-guided digital CBT (National Collaborating Centre for Mental Health, 2010), six 30-minute therapist support sessions over 10-12 weeks were recommended (equating to ~180 minutes). However, due to the implementation aim of the study, the delivery was guided by service capacity and participants' needs.

4.3.6 Outcomes

Below we list the outcomes collected to answer the specific RE-AIM research objectives.

Reach

The below information was extracted from routine service level databases where available: i) number of people with diabetes **referred** to the service ii) the number of people **eligible** to use COMPASS relative to the total number of referrals and reasons for ineligibility and iii) the number of people **willing** and reasons for unwillingness to use COMPASS.

Effectiveness

Baseline demographic and clinical measures

At baseline participants who were eligible, willing to use COMPASS and consented to take part in the current study provided self-reported demographic information on age, gender, ethnicity, education level, home environment, and postcode. Social deprivation decile was calculated based on postcode data using a publicly available government tool (English indices of deprivation 2019: Postcode Lookup (opendatacommunities.org) that gives a deprivation rank based on the Lower Super Output Area (LSOA) that each postcode falls under (McLennan. et al., 2019). The index of multiple deprivation decile is calculated by dividing the LSOAs into 10 equal groups, with a lower decile indicating greater social deprivation. Data on psychological and illness-specific medication uses and number/type of diagnosed conditions was also collected.

Self-reported outcome data (Baseline and 12-weeks)

Participants who chose to use COMPASS and consented to the current study also completed self-report outcomes measures at baseline and 12 weeks post-baseline. We aimed for the outcome measures to be completed prior to COMPASS login or therapist call, however as this was an observational study, the research team did not interfere with routine care.

Psychological outcomes

General psychological distress was measured using the *Patient Health Questionnaire Anxiety-Depression Scale (PHQ-ADS)* (Kroenke et al., 2016). This distress scale has a total of 16 items. Specifically, it includes the 9 items from the Patient Health Questionnaire (Kroenke, Spitzer, & Williams, 2001) and the 7 items from the Generalised Anxiety Disorder Scale (Spitzer et al., 2006). Each item is responded to on a 4-point Likert Scale (0-3). This composite depression and anxiety measure was used as depression and anxiety often cooccur in LTCs (Chilcot et al., 2018). Scores ≥10 were used to define the presence of psychological distress.

Depression was measured using the Patient Health Questionnaire – 9 item(PHQ-9) (Kroenke, Spitzer, & Williams, 2001). Each item is responded to on a 4-point Likert Scale (0-3). Scores range from 0-27 with higher scores indicating increased depressive symptoms. Scores ≥ 10 were used to define the presence of depression.

Anxiety was measured using the Generalised Anxiety Disorder Scale – 7 item (GAD-7) (Spitzer et al., 2006). Each item is responded to on a 4-point Likert Scale (0-3). Scores range from of 0-21; higher scores indicate increased anxiety symptoms. Scores ≥ 8 were used to define the presence of anxiety.

Diabetes Distress was measured using the *Diabetes Distress Scale-17* (DDS-17) (Polonsky et al., 2005). Scores ranges from 1-6; higher scores indicate increased distress. In the current study, mean item score of ≥2 was used to define the presence of diabetes-related distress. This was based on data from Fisher et al. (2012) stating the following cut offs: DDS ≥ 2.0 little Diabetes Distress; DDS = 2.0–2.9 Moderate Diabetes Distress; DDS ≥3.0 High Diabetes Distress.

Psychosocial outcomes

Functioning was measured using the 5-item *Work and Social Adjustment Scale (WSAS) (Mundt et al., 2002)*. The measure is responded to on a nine-point Likert scale (0-8). Items explore functioning across five dimensions: work, social life, home life, private life, and close relationships. Scores ranged from 0-40 with higher scores indicating greater functional impairment.

Quality of life was measured using *The European Quality of Life Scale three level version (EQ-5D-3L) (EuroQol group, 1990)* includes five items (range: 1-3) to assess a person's perception of their mobility, self-care, usual activities, pain/discomfort, anxiety and depression. Higher scores indicate poorer quality of life. The EQ-5D-3L also includes a visual analogue global health rating (range, 0-100).

Physical health outcomes

Glycaemic control was measured through self-reported glycated haemoglobin (HbA1c) levels. Date of HbA1c collection and source of result (memory or medical records) was also recorded. Data was presented as mmols/mol values using IFCC (International Federation of Clinical Chemistry) units as per current UK recommendations (Manley et al., 2023; National Glycohemoglobin Standardization Program). To provide context to our findings, as rule of thumb, an ideal HbA1c for an adult with diabetes is 48 mmol/mol (World Health Organisation [WHO]. 2019).

Adoption

The concept of adoption was investigated qualitatively (Holtrop, Rabin, & Glasgow, 2018). Specifically, qualitative (semi-structured interview) data was collected from patients in all three sites. Interviews took place following the 12-week quantitative data collection time-point. The interview schedule was semi-structured including open ended questions. To assess the feasibility of implementing COMPASS, we explored COMPASS users experience of the intervention. We also included prompts around barriers and facilitators to using COMPASS to capture patient perceptions of these. Additionally, to understand the wider implementation context we explored patients experience of their referral and assessment to psychological treatment (see appendix B for interview schedule).

Implementation

We collected data via the COMPASS platform on the number of online sessions completed, and the number of therapist support sessions attended by the participant who agreed to use COMPASS and registered on the platform. Additionally, therapist time (minutes) spent supporting the participant and the mode of support (e.g., teleconference vs in-site messaging) was collected. This data was downloaded from the COMPASS online platform at the end of the study.

4.3.7 Statistical Analysis

Data was analysed using STATA-17. Descriptive statistics were presented as frequencies (percentages), means (standard deviations; SD) and medians (range and interquartile range; IQR) and were used to quantify the outcomes related to Reach and Implementation. For implementation outcomes we conservatively included all participants in the analysis who had consented to the research study irrespective of their usage of COMPASS (e.g. number of logins). We also performed a sub-group per-protocol analysis evaluating implementation for those who engaged with COMAPSS (e.g. logged into ≥1 COMPASS online sessions).

Descriptive statistics were also used to outline the socio-demographic and clinical characteristics of those who completed the baseline questionnaire. Due to the small sample size we report both means (standard deviation) and medians (inter-quartile range) for the self-reported outcomes. Effectiveness analysis used both intention-to-treat (ITT) and per-protocol (PP) analyses. For ITT analyses if a participant was missing outcome data at follow-up their baseline scores were imputed as their outcome scores. PP analyses included all participants who had complete data at baseline and 12-week follow-up. For each outcome, repeated measures t-tests were used to assess mean differences between pre-post intervention scores. For each outcome measure we report effect sizes only and their precision (e.g., standard error (SE) and 95% confidence intervals (95% CIs), in line with CONSORT guidelines (Eldridge et al., 2016).

Sample size

In line with feasibility implementation study guidelines (Pearson et al., 2020), a priori power calculation was not conducted. However, based on established recommendations (Billingham, Whitehead, & Julious, 2013; Teare et al., 2014) a target sample of 90 was set with the aim to recruit 30 people with diabetes per setting. Furthermore, 30 per setting is higher than the recommended minimum of 12 per group recommended to estimate means and variances for continuous variables (Julious, 2005).

4.3.8 Qualitative data collection and analysis

Interviews were conducted and analysed by EJ. During the interviews only EJ and the participants were present. All interviews followed a semi-structured interview guide and were recorded on MS teams. The interviews were transcribed using a secure transcription service approved by the university. The interviews were checked for accuracy following transcription by E.J. Interviews ranged from 32 mins 51 seconds – 1hr, 36 minutes and 5 seconds in length. Data collection and analysis happened in parallel. Data collection stopped pragmatically when all consenting participants had been interviewed. For more discussion on sample size in thematic analysis, see Braun and Clarke (2021b).

Data was analysed using inductive thematic analysis following guidelines from Braun and Clarke (2006, 2019). This was to encourage reflexivity, and the identification of themes grounded in patient experience. Recordings were listened to, and transcripts read repeatedly so that the authors could familiarise themselves with the data. Transcripts were iteratively coded line by line. Using these codes the first author (EJ) began to identify and develop themes and sub-themes by examining the codes for patterns of shared meaning. These codes were then grouped into sub-themes and overarching themes. The themes were then discussed, refined and agreed on in relation to the entire dataset, ensuring that they accurately represented the data as a whole and addressed the research question.

4.3.9 Qualitative data: Reflexivity

In line with Braun and Clarke’s (2019) approach to thematic analysis, it is acknowledged that a researcher’s personal experiences, beliefs, and values inevitably influence data interpretation. For example, EJ conducted and analysed all the interview data. With an MSc in Health Psychology and considerable experience in qualitative interviewing, EJ’s background and expertise shaped her interaction with and interpretation of the data, particularly as these interviews form part of her PhD research. Over her four years with the COMPASS project, EJ has been involved in relationship building, training, and working with NHS services to implement COMPASS for adults with diabetes, which likely affected how she interpreted the experiences and narratives of adults living with diabetes who were using COMPASS.

Additionally, RMM and JLH have been responsible for the initial and ongoing development of COMPASS: Navigating Your Long-Term Condition. All authors also have experience in research and clinical practice with individuals managing LTCs (such as diabetes) across various settings. These experiences may have led to certain assumptions about the implementation of COMPASS within routine NHS care, which likely are reflected in the analysis. To acknowledge and consider the impact of this, EJ maintained reflexive field notes throughout the analysis process, and the codes, subthemes, and themes were discussed with the research team and peers at each stage. By embracing subjectivity as a resource (Braun & Clarke, 2021a) rather than a limitation, the analysis was enhanced, providing a richer understanding of the nuanced barriers and facilitators to implementing COMPASS in routine NHS care, while acknowledging the impact of the researchers' experiences and perspectives on the themes presented.

4.4 Quantitative Results

Reach

What proportion of people with diabetes are referred are eligible to use COMPASS?

Diabetes service

Forty-one (*n*=41) people with diabetes were referred for psychological support across four months. Of all healthcare professionals, medical consultants referred the most (*n*=17; 41.50%, 95% CI =12% to 40%), followed by nurses (*n*=8; 19.50%, 95% CI =9% to 35%), dieticians (*n*=1; 2.40%, 95% CI =0.06% to 13%), pharmacists (*n*=1; 2.40%, 95% CI =0.06% to 13%) and other (*n*=7; 17.10%, 95% CI =7%to 32%). No referrals were made in response to proactive screening for psychological distress. Seven participants had missing data on referral route (*n*=7; 17.10%, 95% CI =7% to 32%). Ten out of the 41 referrals (24%; 95% CI = 12% to 40%) were considered eligible to use COMPASS. There was a substantial amount of missing data on reasons for ineligibility (*n*=29; 71%, 95% CI 54% to 84%). When data was available reasons included no access to internet (*n*=1; 2%, 95% CI 0.06% to 13%) and already receiving treatment (*n*=1; 2%, 95% CI 0.06% to 13%). Eight out of ten people considered eligible to use COMPASS were willing to start the program (80%; 95% CI 44% to 97%). The two patients who declined COMPASS were wanted face-to-face therapy.

Overall, twenty percent of all referrals to the diabetes psychology service started on COMPASS (e.g. 8/41 = 20%; 95% CI = 8% to 35%).

Talking therapies services

Across the two *Talking Therapies* services *n*=777 people with diabetes were referred for psychological support across a 17-month timeframe. Self-referral was the most popular referral route into Talking Therapies (*n*=483; 62.20%, 95% CI =59% to 66%), followed by GP referral (*n*=172; 22.10% 95% CI = 19% to 25%), and other (*n*=116; 14.90%; 95% CI =12% to 18%). Referral source data was missing on six people with diabetes in Talking Therapies (*n*=6; 0.80% 95% CI = 0.30% to 2%). It was not possible to extract data on the number of people assessed for COMPASS eligibility; neither was it possible to extract data on the number of people willing to use COMPASS once eligibility was assessed.

Overall, 0.7% of all referrals to talking therapy services started on COMPASS (e.g. 6/777 = 0.7%; 95% CI 0.2% to 1.6%)

Effectiveness

What is the effectiveness of COMPASS on self-reported outcomes?

Self-reported pre-post outcomes.

Across all sites, a total of 14 patients chose COMPASS as a treatment option, a further twelve consented into the research study, of which nine (n=9; 75%; 95% CI = 42% to 95%) completed the baseline questionnaire and eight completed the follow-up questionnaire. Reasons for non-consent included no response to the research team (n=2). Reasons for non-completion of baseline questionnaire were low mood (n=1), learning difficulties impacting ability to complete questionnaires (n=1) and already receiving psychological support which was not identified at the eligibility assessment (n=1). In some instances, baseline questionnaires were completed following COMPASS access (n=4; 44%; 95% CI = 14% to 79%). In these cases, two (n= 2; 50%; 95% CI = 7% to 93%) participants had accessed one session prior to completion of the baseline questionnaire and two (n=2; 50%; 95% CI = 7% to 93%) participants had completed three sessions prior to the completion of the baseline questionnaire.

Table 4 and *Table 5* show the sociodemographic and clinical characteristics of the sample at baseline (*n*=9).

Participants who completed the baseline questionnaire were recruited from Talking Therapies (n=5; 55.56%) and the Diabetes Service (n=4; 44.44%). On average, participants were 38 years old (Standard Deviation; SD 14.14; range = 19-62), predominantly female (n=7; 77.78%) and from a minoritised ethnic background (n=5; 55.56%). The average deprivation decile was 4.38 (SD: 2.62; range = 2-9) suggesting the average participant lived in the 30%-40% most socially deprived areas in England.

The majority of people with diabetes in this study had a diagnosis of type 1 diabetes (n=5; 55.56%) and were using insulin (n=6; 66.67%). All people with diabetes self-reported that they were prescribed and were taking their medication. Participants had an average HbA1c level of 63.97 mmol/mol (SD= 16.06; range = 43.3 – 88.0) which is above the recommended range of 48 mmol/mol (National Institute for Health and Care Excellence [NICE], 2023a, 2023b). The majority of people with diabetes reported that the source of their HbA1c result was their memory (n=5; 55.56%) and two people with diabetes (n=2; 22.22%) reported that the result came from their medical records. There was missing data on source of HbA1c result for two participants at baseline (n=2; 22.22%) (see Table *4*).

Table 6 summarises preliminary ITT analyses exploring pre/post treatment effect of COMPASS (see appendix B for PP). As we were not powered to detect statistical differences, we did not perform significance testing. Therefore, these effect estimates are only descriptive to inform the design of a future hybrid-implementation study.

Pre-post analysis across all participants (*n*=9) indicated trends towards improvements in depression, anxiety, psychological distress. However, the confidence intervals around pre-post differences were large indicating uncertainty around the estimates. Mean change analysis from pre-treatment to post-treatment demonstrated mean depression scores reduced by -1.00 (standard error; se=0.70; scale range 0-27; 95% CI = -2.54 to 0.54) with a medium treatment effect (*d=-0.50).* Anxiety scores reduced by -0.80 (se=1.40; scale range 0-21; 95% CI =-3.92 to 2.40) indicating a small treatment effect (*d=-0.20).* General psychological distress reduced by -1.8 (se=1.93 scale range;0-48; 95% CI =-6.22 to 2.66; *d*=-0.31) and diabetes-distress reduced by -0.11 (se=0.30; scale range =17-102; 95% CI =-0.73 to 0.50; *d*=-0.14) Quality of life scores increased from pre-post treatment (mean change = 0.33 se=0.33; 95% CI -0.44 to 1.10) suggesting that health-related quality of life was poorer following COMPASS with small effect (*d*=0.33). Similarly social functioning scores increased suggesting poorer social functioning by 1.44 (se=2.50; scale range; 0-40; 95% CI =-4.30 to 7.20; *d* =0.20). Trends appear to show that overall HbA1c levels reduced following COMPASS with small effect (mean change = -*4.42,* se=*4.13*; 95% CI = -15.05 to 6.21; *d*=-0.22).

Diabetes service vs *Talking Therapies*.

Overall, effect sizes were larger in the diabetes service (see table *Table 6).*

Table 4. *Baseline sociodemographic & clinical characteristics of participants who completed the baseline questionnaire across two settings.*

Variable	**Total (*n*=9; 100%)**	**Diabetes Service (*n*=4; 45%)**	**Talking Therapies (*n*=5; 55%)**
	Mean (SD; range) **Number (%)**	**Mean (SD; range)** **Number (%)**	**Mean (SD; range)** **Number (%)**
Age (years)	38 (14.14; 19-62)	24.75 (4.35;19-29)	48.6 (8.35; 42-62)
Gender (% female)	7 (77.78%)	3 (75%)	4 (80%)
Minoritised ethnic group (% yes)	5 (55.56%)	1 (25%)	4 (80%)
Social deprivation (*n*=8)	4.38 (2.62; 2-9)	5.75 (3.20; 3-9)	3.00 (2.62; 2-4)
Living with partner (% yes)	4 (44.44)	1 (25%)	3 (60%)
Undergraduate/bachelor’s degree (% yes)	5 (55.56%)	2 (50%)	3 (60%)
Employed (% yes)	8 (88.89%)	3 (75%)	5 (100%)
Psychological medication; (% prescribed and taking)	2 (22.22%)	1 (25%)	1 (20%)
Type 1 diabetes (% yes)	5 (55.56%)	4 (100%)	1 (20%)
Diabetes medication; (% prescribed and taking)	9 (100%)	4 (100%)	5 (100%)
Using insulin (% yes)	6 (66.67%)	4 (100%)	2 (40%)
Self-reported % HbA1c (*n*=7)	8.01 (1.45; 6.2-10.2)	7.78 (1.91; 6.2-10.2)	8.33 (0.76; 7.5-9)
Self-reported mmol/mol HbA1c (*n*=7)	63.97 (16.06; 43.3-88)	61.25 (21.12; 43.3-88)	67.6 (8.34; 58.5-74.9)
HbA1c from medical record (% yes) (*n*=7)	2 (28.57%)	1 (25%)	1 (25%)

Key: HbA1c; glycated haemoglobin. *n*; number of patients.; SD= Standard Deviations.

Table 5. *Baseline and follow up scores on self-report psychological and psychosocial questionnaires for those who took part in COMPASS and consented to research.*

	Total sample				**Diabetes service**				**Talking Therapies**			
Self-reported questionnaires	***Baseline*** (*n*=9)		***Follow up*** (*n*=9)		***Baseline*** (*n*=4)		***Follow up*** (*n*=4)		***Baseline*** (*n*=5)		***Follow up*** (*n*=5)	
	Mean (SD) Number (%)	Median (IQR)	Mean (SD) Number (%)	Median (IQR)	Mean (SD) Number (%)	Median (IQR)	Mean (SD) Number (%)	Median (IQR)	Mean (SD) Number (%)	Median (IQR)	Mean (SD) Number (%)	Median (IQR)
PHQ-9	9.56 (3.91)	11 (7,12)	8.6 (4.03)	8 (5, 12)	11.5 (1.71)	11.5 (10, 12.5)	9 (3.74)	8.5 (6.5,11.5)	8.2 (4.82)	7 (6,12)	8.2 (4.7)	7 (5,12)
GAD-7	11.11 (5.40)	12 (6,14)	10.33(6.26)	6 (6, 16)	14.25 (2.06)	14 (13,15.5)	12 (7.12)	11 (6,18)	8.6 (6.11)	6 (5,9)	9 (6.0)	6 (5,10)
PHQ-ADS	20.67 (8.67)	23 (16,27)	18.88 (9.6)	15 (12, 25)	25.5 (3)	25 (23,28)	21 (10.55)	19.5 (12.5,29.5)	16.8 (10.08)	16 (10,18)	17.2 (9.6)	15 (12,18)
DDS-17	3.34 (1.30)	3.29 (2.24, 4.76)	3.2 (1.3)	3.2 (2.12,4.4)	3.31 (1.20)	3.06 (2.38, 4.24)	3.22 (1.13)	3 (2.44, 4)	3.36 (1.52)	3.29 (2.18,4.76)	3.2479 (1.54)	3.53 (1.8, 4.4)
WSAS	17.89 (6.29)	19 (15,21)	19.3 (8.4)	19(15,26)	20.25 (4.11)	20.5 (17.5, 23)	17.5 (3)	17 (15,20)	16 (7.52)	18 (9,19)	20.8 (11.30)	26 (15, 27)
EQ-5D	6.78 (0.97)	7 (6,7)	7.1 (1.05)	7 (6,8)	6.75 (0.5)	7 (6.5, 7)	7.25 (1.26)	7 (6.5, 8)	6.8 (1.30)	7 (6,8)	7 (1)	7 (6, 8)

Table 6. *Preliminary analyses exploring pre-post treatment effects of COMPASS on self-reported outcomes.*

Self-reported outcome	Group	*n*	Estimated pre-post difference	se	95% lower limit	95% upper limit	Cohens D
Depression (PHQ-9)	**All patients**	9	-1.00	0.70	-2.54	0.54	-0.50
	Talking Therapies	5	0	0.55	-1.52	1.52	0
	Diabetes service	4	-2.25	1.11	-5.78	1.27	-1.01
Anxiety (GAD-7)	**All patients**	9	-0.80	1.40	-3.92	2.40	-0.20
	Talking Therapies	5	0.4	0.24	-0.28	1.08	0.73
	Diabetes service	4	-2.25	3.12	-12.17	7.68	-0.36
General psychological distress (PHQ-ADS)	**All patients**	9	-1.8	1.93	-6.22	2.66	-0.31
	Talking Therapies	5	0.4	0.51	-1.02	1.82	0.35
	Diabetes service	4	-4.5	4.17	-17.78	8.78	-0.54
Diabetes distress (DDS-17)	**All patients**	9	-0.11	0.30	-0.73	0.50	-0.14
	Talking Therapies	5	-0.13	0.38	-0.61	0.35	-0.34
	Diabetes service	4	-0.10	0.61	-2.04	1.86	0.07
Functioning (WSAS)	**All patients**	9	1.44	2.50	-4.30	7.20	0.20
	Talking Therapies	5	4.80	3.14	-3.91	13.51	0.68
	Diabetes service	4	-2.75	3.20	-12.93	7.43	-0.43
Health Related Quality of Life (EQ-5D)	**All patients**	9	0.33	0.33	-0.44	1.10	-0.33
	Talking Therapies	5	0.2	0.37	-0.84	1.24	0.24
	Diabetes service	4	0.5	0.65	-1.55	2.55	0.40
Self-reported HbA1c mmol/mol	**All patients**	6	-4.42	4.13	-15.05	6.21	-0.22
	Talking Therapies	4	-2.75	2.75	-37.70	32.19	0.04
	Diabetes service	2	-5.25	6.39	-25.57	15.07	0.31

Implementation

Implementation was assessed by the number of *online* and *therapist support* sessions completed by the participant. Therapist time (minutes) spent supporting the participant and the mode of support (e.g., teleconference vs in-site messaging) was also collected.

Out of the twelve people who consented into the research study, one participant (*n*=1; 8.33%) did not register on the COMPASS platform and therefore did not access any sessions. The reason for disengagement prior to registration was low mood. Additionally, another three people with diabetes (*n*=3; 25%) who registered on the platform did not access any online sessions. The reasons for this were low mood (*n*=1), learning difficulties impacting ability to use COMPASS (*n*=1) and already receiving psychological support which was not identified at the eligibility assessment (*n*=1). When we removed these participants from the analyses, rates of engagement increased. Therefore, below we present ITT analysis on the twelve participants who consented to the study. Per-protocol analysis on the eight participants (*n*=8; 66.66%) who logged into ≥1 COMPASS online sessions is presented in Appendix B.

Across the whole sample, (*n*=12), the median number of online COMPASS sessions accessed was 2 (IQR=0 – 3.5; mean =2.3; se = 0.72; 95% CI = 0.75 – 3.92). Further, the median number of therapist support sessions that were attended on COMPASS was 1 (IQR= 0-4; mean =1.75 se=0.57; 95% CI = 0.50 – 3.00) and therapists supported participants for a median of 45 minutes (IQR = 0-90; mean = 64.08; se= 22.34; 95% CI = 14.90-113.26) across the study.

Mode of support provided.

COMPASS therapist support was delivered via either telephone, video conferencing or in-site messaging depending on patient and service preference. Telephone and video-conferencing support was received by n=5 (45.45%) participants. In-site messaging support was received by n=2 (18.18%) participants. One participant (n=1; 9.09%) received unguided COMPASS treatment. This was agreed with the patient prior to commencing COMPASS treatment. The reason for this was external barriers; lack of resource meant that COMPASS guided support was no longer available in the diabetes service.

Diabetes service vs *Talking Therapies*.

In both analyses the number of online COMPASS sessions completed appeared to be higher for patients from the diabetes service than the Talking Therapies services.

The median number of online COMPASS sessions completed was 3 (IQR: 0-3) (mean =2.33; se=0.80; 95% CI; 0.30 to 4.4) in the diabetes service. This was slightly higher than in Talking Therapies median = 1; IQR =0-4) (mean = 2.33; se=1.3; 95% CI =-0.96 to 5.6). Similarly, in the diabetes service the number of therapist sessions tended to be higher (median = 1.5 IQR = 0-4; mean =2; se =0.86; 95% CI; -0.20 to 4.2) than the Talking Therapies services (Median = 0.5 IQR = 0-4; mean 1.5; se=0.81; 95% CI; -0.57 to 3.6). Therapists in the specialist diabetes service spent longer supporting patients, for example therapist supported patients in the diabetes service had a median duration of 62.5 minutes (IQR =0-193) (mean =91.5 minutes; se=40.94; 95% CI; -13.8 to 196.8) and 37.5 (IQR=0-60) (mean =36.67 minutes; se=14.81; 95% CI; -1.4 to 74.75) in Talking Therapies. Exploring differences in mode of therapist support between the diabetes service and talking therapy services, in site messaging was the only form of support was used to support patients in South London and Maudsley Talking Therapies. A similar pattern was observed in per protocol analyses (see appendix B).

4.5 Qualitative results

We qualitatively explored potential barriers and facilitators to the ***adoption*** of COMPASS from the perspective of people with diabetes (see *Table 7*).

A total of twelve (*n*=12) people with diabetes were interviewed. Of these, eight (*n*=8; 66.7%) engaged with COMPASS (completed ≥1 online sessions) and four (*n*=4; 33.3%) did not engage.

Six interviewees received care from the diabetes service (50%) and six from one of the two Talking Therapies services (50%). *Table 7* lists information on setting, COMPASS engagement status and diabetes type.

Table 7. *Participant recruitment setting, compass status and diabetes type.*

Setting	COMPASS status	Diabetes Type
Diabetes Service	Engaged	Type 1
Diabetes Service	Engaged	Type 1
Diabetes Service	Did not engage	Type 1
Diabetes Service	Did not engage	Type 1
Diabetes Service	Engaged	Type 1
Diabetes Service	Engaged	Type 1
Talking Therapies	Engaged	Type 2
Talking Therapies	Did not engage	Type 2
Talking Therapies	Did not engage	Type 2
Talking Therapies	Engaged	Type 2
Talking Therapies	Engaged	Type 2
Talking Therapies	Engaged	Type 1

Table 8 summarises the key themes derived from the inductive thematic analysis highlighting barriers and facilitators to uptake and engagement with COMPASS. These are described below with supporting quotes and participant number in brackets.

Table 8. *Themes and subthemes identified through thematic analysis.*

Theme	Sub-theme
1. *The undefined route to mental health support.*	
2. *Internet-enabled therapy, novel but not as good?*	*1.1* COMPASS sold as a substitute. *1.2* Defining COMPASS. *1.3* Expectations and experiences of moving to the digital world.
3. *The role of human contact in digital therapy.*	
4. *Finding the balance in tailoring digital treatment.*	*4.1* Tailored content supports engagement and understanding. *4.2* COMPASS lacks diabetes self-management tools *4.3* The challenges of an individualised intervention for all

Theme 1: The undefined route to mental health support.

The journey to receiving emotional support varied across two contexts. In the diabetes service, participants recalled how the diabetes health care professionals actively raised the topic of distress and managed the onward referral; this was valued by participants.

> *"it was the [healthcare professional], I don't actually know her last name….But she was great. And yeah, it just felt overall at [service]. That there was a lot of focus on mental health with diabetes and it was amazing."* – Diabetes service; engaged; type 1 diabetes.

> *"No, they [healthcare team] mentioned it [psychological support], and I usually would be like, Oh no, no, no, it's fine, because in my head that's gonna take a lot of time…. I want to get out because I'm so, like, anxious about those appointments, that, in my head, if I start taking extra help, I'm going to be there longer…But that time it was quite straightforward and then he [the doctor] was like, Oh, yeah, I'll just put the referral through..."* – Diabetes service; engaged; type 1 diabetes.

There was also a sense that participants in the diabetes service felt confident to advocate for their own needs of mental health support in the context of their diabetes.

> *"I'd had the Libre [blood glucose monitor] for the best part of a year at that point, and I raised the sort of mental health side of it with her [the doctor] and said, Look it's stressing me out a little bit"* – Diabetes service; engaged; type 1 diabetes.

However, in Talking Therapies participants felt that their previous interactions with health care professionals prior to accessing Talking Therapy services had been a missed opportunity to raise the topic of distress.

> *"you get the initial diagnosis [of diabetes], and then you get obviously medication. But in terms of actual emotional support, that didn't seem to be offered as standard… Although it's the symptoms are mainly physical, I feel like it does have quite a large emotional connection…. There had previously not been emotional support offered."* – Talking Therapies; engaged; type 2 diabetes.

This was confirmed by others reflecting on the need to proactively seek out psychological treatment independent of their health care team:

> *“I didn’t know about [Talking Therapies services] it was a leaflet through the door about [Talking Therapies] in [region], so in terms of the process, I got the leaflet, I went online and registered my interest in [receiving treatment from] [Talking Therapies]. And then I think I got an email back, like a day or two later”* – Talking Therapies; engaged; type 2 diabetes.

Theme 2: Internet therapy, novel but not as good?

Subtheme 2.1: COMPASS sold as a substitute.

Despite COMPASS being a routinely offered mental health treatment, there was a sense that internet-enabled therapy was offered as a second choice or substitute option, often coinciding with negative perceptions of the programme and its credibility.

> *“I was only aware of the online COMPASS thing because I did request to someone to be, like, in a face to face, that made more sense. But even they [service] couldn’t fix me an appointment because they were also quite busy”* – Talking Therapies; engaged; type 2 diabetes.

> *“it was made quite clear to me that because of pressure on the system, because of COVID-19, COMPASS was the only way I was probably going to get something quickly because the person I spoke to was very up front and said, Look demand for the counsellors is massive at the moment, you’re going to be sat around for a few months if you want to go down that route.”* –Diabetes service; engaged; type 1 diabetes.

> *“To be brutally honest, I didn’t feel like there was much else [on offer] except COMPASS.”* – Diabetes service; engaged; type 1 diabetes.

Subtheme 2.2: Defining COMPASS.

In both settings there seemed to be a lack clarity on what COMPASS was and what the treatment would entail. The description of COMPASS to patients appeared to lack a clear explanation of the digital element. Additionally, in Talking Therapies there seemed to be a lack of awareness of the integrated mental and physical health focus of COMPASS.

> *“I didn't really know it was going to involve the website thing.”* – Diabetes service; engaged; type 1 diabetes.

> *"She said [the clinician conducting the assessment], well, COMPASS really is about dealing with the health side of it, you know, with living with health, long term health conditions. So, it's not really for depression, which I was going through…. I was told from the start, she [the clinician conducting the assessment] said, Look, this isn't really geared up to the emotional side of it as much as it is to the medical side. So, I went in with that expectation "*- Talking Therapies; engaged; type 2 diabetes.

Some participants described feeling unclear around taking part in a research study in the context of routine care.

> "I was quite confused about who was helping me, what was the difference between you [COMPASS research team] and the service [Talking Therapies] , I still don't know the answer.– Talking Therapies; did not engage; type 2 diabetes.

> "They [Talking Therapies] say that I can stay with them or they can refer me for the [COMPASS] research" – Talking Therapies; did not engage; type 2 diabetes.

Subtheme 2.3: Expectations and experiences of moving to the digital world.

Almost all the participants indicated that they had little expectation of what digital treatment might be. However, some participants described novelty as a pull factor for choosing to uptake it.

> *"I've had, I've had one to one therapy before. So, I thought, well, let's try a different one where I'm sort of participating in a way where I can see in black and white because what I've said, because when you have one-to-one sessions, it's great but you often come out of the session and you've got so upset during it, you think, "What did I say?" It's like it's all gone"* –Talking Therapies; engaged; type 2 diabetes.

> "the only other CBT that I've had was [face-to-face], as I said when I was [age] I can't remember much of it, but I was given a sheet of like, a booklet …Okay, and it was just, like, a wad of paper, and it had, like, so much to work through. And I was like, Okay, I want to get better, but this is hell. This is actual hell." –Diabetes service; engaged; type 1 diabetes.

Specifically, some participants indicated that the digital nature of COMPASS integrated well into other aspects of their diabetes care, and this was a benefit of online treatment. However, others described that this treatment option added to their self-management burden.

> *"I have grown up with obviously devices. I use my phone for my diabetes. I'm on a CGM and have been on flash glucose. So, and also carbs and cals like I always use my phone and I always have done."* - Diabetes service; engaged; type 1 diabetes

> *"so I've got my sensor, I've had four hypos in the last couple of days and it just -- but I have to have my phone charged up – it [COMPASS] is another thing to manage."* – Talking Therapies; engaged; type 1 diabetes

This tended to coincide with later disengagement.

> *"I mean, I spend like, 20 hours or at least 16 hours of my daily routine on digital media anyway. So I'm like, really, I just wanted to get out of all that self-help, and like all the [digital] tools"*- Talking Therapies; engaged; type 2 diabetes.

> *"I just lost track of it [COMPASS]. And, yeah, it's just basically I forgot about it."* - Diabetes service; did not engage; type 1 diabetes.

Theme 3: The role of human contact in digital therapy.

All participants found that the added element of therapist support enhanced engagement and motivation. However, it seemed that the therapist support received (e.g., format of sessions and perceived connection with COMPASS guide) varied across patients and services. This tended to impact the overall appraisal of COMPASS. Some participants described finding little therapeutic benefit of the guide.

> *"I kind of felt that [via message] she [COMPASS guide] had a list of questions that there was a tick box exercise, really. It wasn't, it wasn't in depth, and it was like, Oh, you've done really well, again …and I didn't feel really connected with her [COMPASS guide]"* –Talking Therapies; engaged; type 1 diabetes.

> *"I suppose greater integration of the self-paced with the actual therapist led part. That might maybe make the two feel closer together…I only had a few sessions with the guide, so it's hard to say.* – Talking Therapies; engaged; type 2 diabetes.

Whereas other participants identified therapeutic benefits of the guide.

> *"I think she [COMPASS guide] knew me quite well…. She was good at making links and things, like, I previously said to stuff I was currently talking about…. I'm gonna*

> *lose my leg, nobody's gonna talk to me, I'm not gonna get married, da, da da. So I'd say all those things, but then, ... she [COMPASS guide] was able to ground me and do the whole, like, challenging that thought with me"* - diabetes service; engaged; type 1 diabetes.
>
> *"what was helpful about having a guide was that I was able to get some of what I was talking about [on COMPASS] the guide would look at what I was what I was putting down and she'd say, like, Right I noticed you put this. Explain that to me. Give me an example of that. And then we'd kind of talk it through, and we'd get to a point where we kind of addressed it a little bit"* - diabetes service; engaged; type 1 diabetes.

Additionally, in the diabetes service many participants praised their guide for their flexibility in the constraints of the current NHS system. This tended to be appraised as a factor that maintained engagement.

> *"with my work, I get meetings put in last minute and get messed around quite a lot, so it was nice to know that [COMPASS Guide] was able to, she probably went above and beyond it, accommodating to like finding a time that worked. So she was great"* – diabetes service; engaged; type 1 diabetes.
>
> *"I reckon if [COMPASS guide] wasn't, like, I don't want to say persistent because persistent implies like, consistent would be the word. If she wasn't as consistent, I reckon I would have stopped doing it, purely because I was feeling anxious and stuff like that, yeah"* – diabetes service; engaged; type 1 diabetes.

Theme 4: *Finding the balance in tailoring digital treatment.*

Subtheme 4.1: Tailored content supports engagement and understanding.

The content of the COMPASS platform in and of itself was something that participants described as both a barrier and facilitator of engagement with COMPASS. Some participants commented on how COMPASS helped them to identify links between their diabetes and psychological distress that they were not aware of prior to starting treatment.

> *"When I actually started the COMPASS thing, number one, when I started doing the task, I was like, Okay, so people actually do know that there's actually a big link in this link to all these behaviours it's quite in depth. Two, it helped me pick up things that I didn't even realise were linked to ...–* diabetes service; engaged; type 1 diabetes.

> "*I think that that's why having something like COMPASS was really useful because it gave me the resources to think about that more than just if I was seeing someone [for mental health treatment], not about it [diabetes].* – diabetes service; engaged; type 1 diabetes.

Others explained that they were able to apply some of the tools they had learnt on COMPASS to their diabetes.

> *"I had a diabetic low when I was out ..... So I had a panic at the beginning, and then I thought, No, calm down, okay, this is the situation. What are you going to do about it? How are you going to deal with it? Right, you need to go and get something to eat or drink. And that was kind of based on what I'd read on COMPASS about breaking down the problems, which was good, because, in the past I would have just panicked and thought, Oh, my God, what's happening to me...."* –Talking Therapies; engaged; type 2 diabetes.

Subtheme 4.2: COMPASS lacks diabetes self-management tools.

Some participants felt that COMPASS could have been more in-depth or included more diabetes education or self-management tools to help them manage their diabetes.

> *"for me, COMPASS didn't go the kind of whole hog in terms of, what I wanted to …. it kind of opened Pandora's box ….There was a lot of explaining of feelings, but that didn't' translate to -- for me that didn't translate into sort of coping mechanisms. –* diabetes service; engaged; type 1 diabetes.

> *"[COMPASS] just felt more like as I said, like, it's just a theoretical tool rather than being practical….If you know, maybe the diet plans, or like the cooking patterns …. if you had more practical solution of like the tips that would help, you know, like foods, different portion sizes … you know,".* –Talking Therapies; engaged; type 2 diabetes.

> *"I think maybe it would just be, some of it would just be some more information and support. I think maybe also, like I said, maybe, …. I suppose support in making lifestyle changes…. Diet or your exercise or your medication….It would definitely be in those three areas….I also went back to my GP to get a referral for more, is it better health [leisure centre]? So where they're able to refer you to your local gym for exercise and help. So, I think maybe a more practical way, might be more useful to me."* –Talking Therapies; engaged; type 2 diabetes.

Subtheme 4.3: The challenges of an individualised intervention for all.

Participants empathised with the challenges around creating a tailored intervention in diabetes, describing the individualised nature of the condition.

> *"how do you make something that is specific yet unspecific to each person?" –* Diabetes service; engaged; type 1 diabetes.

4.6 Discussion

Summary of findings

We used mixed methods and the RE-AIM framework (Glasgow, Vogt, & Boles, 1999) to understand how COMPASS; a therapist supported internet-enabled CBT programme is implemented in routine care for people with diabetes across two NHS care settings.

In terms of Reach, the conversion rate of people with diabetes who were referred for psychological support to those who were willing to use COMPASS was low, with a 20% conversion rate in the diabetes service and 0.7% conversion rate in Talking Therapy services. Missing data in clinical records meant it was not possible to understand the reasons for the poor reach of COMPASS in relation to ineligibly or lack of acceptability. However, our qualitative findings highlighted that integrated care settings may increase uptake, but more work is needed to explain the value of digital therapies and COMPASS specifically in both settings.

Regarding Effectiveness, our findings demonstrate trends indicating that COMPASS is an effective treatment for improving mental health outcomes for adults with diabetes in routine care. Additionally, COMPASS appears to hold promise for improving HbA1c. Further, treatment effects appear larger in secondary care diabetes services. However, we were unable to control for baseline outcome scores in our analyses which were also higher in the diabetes service so these findings should be interpreted cautiously.

Considering Implementation, overall rates of usage were low. However, a greater number of online and therapist sessions were completed in the diabetes service (online = 3; therapist= 1.5) compared to talking therapies (online =1; therapist=0.5). In line with this, therapists in the diabetes service spent longer supporting patients (62.5 minutes) compared to those in talking therapies (37.5 minutes). This is far below the intended use of protocol (Hulme et al.,

2021) which considers a person adherent if they complete ≥ 5 online session and 90 minutes with a therapist (e.g. ≥ 3 x 30 minute telephone support calls). Qualitative findings highlighted that some participants were dissatisfied with the therapist support they received and identified that sites were not implementing in line with the published protocol used in the RCT (Hulme et al., 2021; Picariello et al., 2024b).

Comparisons with existing literature

As highlighted above the rate of reach of COMPASS from all referrals across the two settings in our study was low. Further, the rate observed in the current study was much lower than in the RCT of COMPASS (Picariello et al., 2024b). In the RCT, there was a 59% conversion rate seen between total referrals and uptake. However, this study was not conducted within an NHS context. Indeed, the COMPASS trial used a centralised "hub" style delivery model where patients could self-refer through charities (Hulme et al., 2021). Additionally, the trial was conducted during COVID-19 when there was no alternative to remote therapy, and people with diabetes were not included in this study. These factors may explain the diverging findings.

Regarding routine NHS care contexts, previous work has explored the implementation of remote telephone delivery within Talking Therapies services (Rushton et al., 2020; Saxon et al., 2023). In this work, the conversion rate between total referrals to uptake was 16%, suggesting that COMPASS performed worse in terms of reach than telephone therapy in Talking Therapies services. However, our findings demonstrate greater reach of COMPASS in the diabetes service, posing the potential that COMPASS may have greater reach for people with diabetes when offered as part of an integrated care pathway. Our qualitative findings align with this; within the diabetes service participants valued the normalisation of the link between mental and physical health and thus referrals to psychology.

However, it should be noted that in both settings participants described that the explanation of COMPASS by therapists was unclear, leading to confusion about what the treatment was. This is an important consideration as previous qualitative work has evidenced that the explanation of treatment influences treatment initiation and outcome expectancy (Bowker et al., 2024). Furthermore, patients commonly perceive internet-enabled CBT as less credible and useful than face-to-face treatment (Apolinário-Hagen et al., 2018; Jardine et al., 2023). Our qualitative findings also indicated that COMPASS was sold as a substitute. Therefore, this likely reinforced patient’s treatment beliefs and expectations. Indeed, the explanation of COMPASS may be a key barrier to long-term implementation. However, it is unclear if the explanation of the digital element of COMPASS is the only barrier. Our qualitative findings indicate that the LTC-specific element of COMPASS was also unclear. Indeed, existing qualitative evidence indicate that therapists in Talking Therapies perceive that they lack knowledge around specific LTCs and their treatments, impacting their confidence to communicate about them (Carroll et al., 2021).

Our qualitative findings also suggest that barriers and facilitators to implementing COMPASS occur prior to entering psychological services. Participants in Talking Therapies described that the discussion of emotional wellbeing and thus the routine offer of psychological support prior to reaching Talking Therapies was lacking. Additionally, they described a need to proactively seek this support out. However, previous qualitative work has indicated that people with diabetes require support to make sense of this multimorbidity (Mc Sharry et al., 2013). Training clinicians to better understand eligibility for COMPASS may improve care pathways and ultimately improve the reach of COMPASS.

Our effectiveness findings highlight the potential of COMPASS as an effective treatment for improving depression, anxiety, general psychological distress, and diabetes-related distress in adults with diabetes aligning with COMPASS RCT findings (Picariello et al., 2024b).

However, in this study, quality of life and social functioning did not improve following COMPASS treatment. This diverges from the COMPASS RCT, yet it should be acknowledged that despite observed improvements in quality of life and functioning in the RCT, COMPASS produced the smallest treatment effect on these two outcomes. Given the small sample size and the uncertainty around effect estimates presented in this study, all effectiveness findings should be interpreted with caution.

However, one reason for these diverging findings may be that the hub delivery model utilised in the RCT allowed therapists to support patients to better integrate their mental and physical health challenges. Indeed, a study by Wroe et al. (2018) found that a CBT intervention that that linked mood to the management of diabetes improved psychological distress when delivered in Talking Therapies. This aligns with our qualitative findings indicating that patients with diabetes would like greater integration between their mental and physical health. Hence, taking a more integrated approach specific to diabetes management may enhance treatment effects.

Usage of COMPASS online and therapist sessions in our study was lower than observed in the COMPASS RCT (Picariello et al., 2024b), reinforcing the research to practice gap our study is aiming to explore. One reason for the discrepancy is likely lack of fidelity to the COMPASS protocol (Hulme et al., 2021) by therapists delivering COMPASS. Although, it appears that the protocol was more readily adhered to in the diabetes service than Talking Therapies. The potential lack of fidelity to the protocol in our study is consistent with other research on digital CBT interventions to treat psychological distress conducted in routine care (Gilbody et al., 2017; Hudson et al., 2017). These mixed findings may be accounted for by individual and contextual factors such as diabetes diagnosis or study setting. Additionally, the inconsistent findings surrounding adherence to and engagement with digital therapies may be compounded by how published literature defines these outcomes. In a recent review, Forbes et al. (2023) highlighted that more standardised assessments and reporting of engagement and adherence in digital therapy research would enable greater comparison across studies, populations and contexts. However, this review did not suggest a standardised way of defining these outcomes, therefore this needs further considering in future work.

However, our qualitative findings indicate that human contact was one factor that enhanced the usage of COMPASS, aligning with other review evidence (Baumeister et al., 2014; Borghouts et al., 2021). Indeed, participants in this study positively appraised having a human to guide their online work. However, some participants expressed dissatisfaction with the support they received, highlighting that they received minimal support. This therefore indicates that the suggested protocol was not applied. Participants also expressed appreciation for therapist and service flexibility with appointment scheduling. This is an important consideration when implementing COMPASS in this population, as flexible working is often challenging due to constraints such as policy and lack of resource (O'Reilly et al., 2017).

Strengths and Limitations

As far as we are aware this is the first implementation study of an LTC-specific digital CBT treatment for adults with diabetes, delivered with routine NHS care. This naturalistic observational study was conducted in both primary and secondary care settings providing insights into the feasibility of implementing COMPASS into distinct care pathways. Additionally, the use of real-world data provides insight into the current implementation context of COMPASS. In the current study we were able to include patients that may be underrepresented in traditional research, such as those from diverse ethnic and social backgrounds. Specifically, over half of the participants who completed our study questionnaire were from a minoritised ethic background, showing greater representation than seen in this COMPASS RCT (Picariello et al., 2024b). However, missing data on participant eligibility and acceptability made it hard to draw concrete conclusions about the reach of COMPASS. Additionally, we were unable to include people who were offered COMPASS and declined it in our interviews as this data was not available which adds bias to our findings.

The reliability of effectiveness estimates in this study should be acknowledged. The confidence intervals surrounding the treatment effects were wide hence these findings should be interpreted cautiously. Furthermore, when exploring effectiveness, we were unable to control for potential moderators of effect (e.g. baseline distress and/or engagement with COMPASS and/or therapist support time). Additionally, in this study over half of the sample accessed COMPASS treatment prior to completing the baseline questionnaire. This was due to the naturalistic study design but this many have positively influenced treatment effect sizes because patients had the opportunity to be gain beneficial treatment effects prior to reporting their mood at baseline. Future studies should aim to ensure that data on research outcomes is collected prior to COMPASS access Taken together, these limitations highlight the need for more research to draw first conclusions concerning the effectiveness of COMPASS for adults with diabetes. We were also unable to determine if poor implementation rates were due to low motivation and/or acceptability by patients or lack of appropriate screening and application of COMPASS by therapists due to data reporting challenges. Additionally, adherence to digital therapies when delivered within routine care is poorly defined across the literature (Forbes et al., 2023), therefore this makes it challenging to quantify implementation outcomes outside of RCT contexts. Finally, regarding the qualitative exploration of adoption, data collection stopped pragmatically once all consenting participants had been interviewed rather than when it was deemed that the data collected had sufficient depth and richness to address the research question in this study (Braun & Clarke, 2021b). Therefore, this should be considered as it may have influenced the validity our qualitative findings (Fusch & Ness, 2015).

4.7 Chapter conclusion

This chapter used mixed-methods to explore outcomes related to the Reach, Effectiveness, Adoption and Implementation of COMPASS in line with the RE-AIM framework (Glasgow, Vogt, & Boles, 1999). The findings presented in this chapter demonstrated limited reach and implementation of COMPASS. Moreover, many barriers exist surrounding adoption and overall implementation from the perspectives of patients with diabetes. Preliminary treatment effects are promising regarding improvements in psychological outcomes. Further, COMPASS appears to have a positive influence on HbA1c. However, more robust analyses are needed to confirm this. Additionally, more work is needed to explore factors influencing the implementation of COMPASS beyond the patient-level. Indeed, future research should aim to explore contextual, service, and systemic level factors influencing the implementation of COMPASS. Currently, little is known about the acceptability and uptake of digital CBT treatment (irrespective of LTC status). Therefore, future work should aim to investigate this to understand wider barriers to compass implementation. These areas of future work will be explored in the subsequent two chapters of this thesis.

Chapter 5. Cross-sectional Talking Therapies study [manuscript under review]

5.1 Chapter overview

The preceding chapter explored the implementation of COMPASS for adults with diabetes and co-morbid psychological distress. The chapter highlighted the limited reach, adoption and implementation of COMPASS and further outlined barriers and facilitators to the implementation of COMPASS from the perspective of patients with diabetes. However, it is unclear if the barriers and facilitators are unique to COMPASS. Additionally, it is unclear if these factors are unique to people with diabetes. More investigation is needed to ascertain if barriers exist commonly in psychological care for people with LTCs and/or are specific to digital CBT treatments in routine NHS care. Therefore, this chapter presents a cross-sectional study investigating the association between LTC status with assessment attendance, treatment engagement, and internet-enabled therapy receipt within Talking Therapies services. This study also explores if receipt of internet-enabled treatment bolsters engagement. At the time of submission of this thesis, the manuscript presented in this chapter had been peer reviewed and is undergoing revisions with BJPsychOpen.

Please note the Supplementary Tables for this manuscript under-review are presented in Appendix C rather than in the main body of the thesis. Due to journal requirements at BJPsychOpen, the referencing style follows journal requirements (Vancouver). However, for the purpose of the referencing style had been amended to APA referencing.

5.2 Manuscript under review

Title: Assessment attendance and treatment engagement with talking and internet-enabled therapies of people with and without a long-term physical health condition. An analysis of Talking Therapies service data.

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Word count (excluding title page, abstract, tables, references): 4993

Essential references beyond those describing statistical procedures, psychometric instruments and diagnostic guidelines used in the study: 37

Abstract

Background

Research indicates that treatment outcomes are poorer for people with Long-Term physical health Conditions (LTCs) in Talking Therapies services (formerly known as Improving Access to Psychological Therapies). However, the impact of having an LTC on attendance at assessment and treatment appointments within Talking Therapies remains unclear. Internet-enabled therapies may be one way to overcome barriers to treatment engagement in Talking Therapies. However, the impact on engagement and the influence of LTC status on receipt of internet-enabled therapies is unknown.

Aims

To explore the association between LTC status with assessment attendance, treatment engagement, and internet-enabled therapy receipt within Talking Therapies services. Secondly, to explore if receipt of internet-enabled treatment bolstered engagement.

Method

We used anonymous patient level data from two inner-London Talking Therapies services during January-December 2022 (n=17,095 referrals). Binary logistic regression models were constructed to compare differences between LTC and non-LTC groups on 1) assessment attendance 2) engagement 3) internet-enabled therapy receipt. In our regression models we controlled for key clinical and demographic covariates.

Results

There were no differences between LTC and non-LTC patients in assessment attendance or treatment engagement, after controlling for covariates. Across the whole sample, receiving

internet-enabled treatment increased engagement. Patients who reported a LTC were less likely to receive an internet-enabled treatment.

Conclusions

Having an LTC does not negatively impact assessment attendance and engagement with talking therapies. However, receiving an internet-enabled treatment bolstered engagement in our regression models. Patients who reported a LTC were less likely to receive internet-enabled treatment.

Introduction

Talking therapies LTC-initiative

The Improving Access to Psychological Therapies (IAPT) programme, now named the Talking Therapies programme was introduced in England to provide equitable access to psychological therapy for people living with common mental health conditions such as depression and anxiety (Clark et al., 2009). Talking Therapies was founded based on the economic argument that increasing access to evidence-based psychological therapies would reduce cost burden to the National Health Service (NHS) and welfare benefit system (Layard & Clark, 2014). In 2016, the Five Year Forward View policy document set out the need for the prioritisation of psychological support for people with long-term physical health conditions (NHS England, 2016). Talking therapy services use the abbreviation LTC to refer to long-term physical health conditions which they define as conditions that currently cannot be cured and require ongoing management, for example but not limited to cardiovascular disease, chronic obstructive pulmonary disease and diabetes(National Collaborating Centre for Mental Health., 2018; NHS Data Model and Dictionary). LTCs affect approximately 30% of the population and people with LTC(s) are 2-3 times more likely to experience a mental health condition than those without an LTC(Boast & Lancet, 2018). Co-occurring physical and mental health needs have been consistently associated with poorer clinical outcomes, reductions in quality of life, and increased healthcare costs (Das, Naylor, & Majeed, 2016; Naylor et al., 2012; Toffolutti et al., 2021).

In response to the Five Year Forward View (NHS England, 2016), Talking Therapies services were commissioned to develop care pathways offering integrated mental and physical health-care (National Collaborating Centre for Mental Health., 2018). However, treatment outcomes in the Talking Therapies programme are poorer for people with LTCs compared with their non-LTC counterparts (Delgadillo et al., 2017). These findings remain following the introduction of LTC care pathways within Talking Therapies services, albeit this evaluation was performed relatively soon after the LTC specific guidance was introduced (Seaton et al., 2022). Talking Therapies services are constantly refining the types of treatment interventions offered to people with LTCs to increase their efficacy. Indeed, two different Talking Therapies services have compared the efficacy of treatment interventions tailored to the needs of people with LTCs relative to a non-tailored standard treatment. Both services report larger treatment effects on depression and anxiety outcomes for patients who accessed tailored LTC interventions (Kenwright et al., 2017; Wroe et al., 2018). Pre-post analysis of a therapist supported digital intervention developed specifically to treat distress in the context of LTCs implemented in routine Talking Therapies care reported large treatment effects on depression and anxiety outcomes for people with LTCs who were considered to have clinically significant baseline levels of depression and anxiety (Seaton et al., 2023). Thus, despite poorer outcomes for patients with LTCs in Talking Therapies services, treatments can be adapted for people with LTCs which a may enhance treatment effects.

Usage outcomes in Talking Therapies

What remains unclear from the literature is whether LTC status impacts a person's ability to attend an assessment and remain continually engaged with treatment within Talking Therapies services. In addition, internet-enabled therapy is a treatment delivery method used by Talking Therapies. From April-21 to March-22, 648,617 sessions of internet-enabled therapy were reported but whether this enhances or lessens engagement with treatment is unclear (NHS Digital., 2022). Previous factors associated with attendance in Talking Therapies services indicate that being from a minoritised ethnic background (Harwood et al., 2023; Sweetman et al., 2022), living in a more socially deprived area (Sweetman et al., 2022) and coming to the services through the GP rather than self-referral route (Davis et al., 2020;

Sweetman et al., 2022) have been associated with reduced assessment and/or treatment attendance at Talking Therapies services. Additionally, higher depression scores at baseline and not meeting criteria for a common mental health disorder were risk factors for treatment non-engagement (Sweetman et al., 2022).

We are aware of three studies that have examined the explanatory effect of LTC status on attendance at initial appointments within Talking Therapies services (Davis et al., 2020; Di Bona et al., 2014; Saxon et al., 2023). One study showed first appointment attendance was less likely to occur if a person had an LTC (Di Bona et al., 2014). The other studies showed no effect of LTC status on first appointment attendance (Davis et al., 2020; Saxon et al., 2023). However, these studies did not consider the recorded purpose of the appointment in their analysis. Instead, one study (Davis et al., 2020) looked at first appointment attendance only. The other study (Saxon et al., 2023) defined any attended appointment within the first contacts as an assessment. Two studies have examined the explanatory effect of LTC status on treatment attendance within Talking Therapies services (Saxon et al., 2023; Verbist et al., 2023). The first study (Saxon et al., 2023) showed that LTC status had no effect on attendance at treatment appointments. The authors defined treatment as any attended appointment after the first two appointments. Within the second study (Verbist et al., 2023), the authors did consider the appointment purpose. Here treatment engagement was defined as attendance at ≥2 treatment sessions and a planned discharge status (e.g., ending treatment after agreement with a therapist). This study reported a statistically significant effect of LTC status on treatment engagement, but this only occurred when analyses were restricted to the cohort accessing treatment during the COVID-19 pandemic (2020). No statistically significant effect of LTC status was observed in this study when analyses were restricted to cohorts attending Taking Therapies pre (2019) or post (2021) the pandemic.

These mixed findings are likely attributable to several factors including the number of Talking Therapies sites included in the analyses, the way in which key variables were defined, and the variables controlled for in statistical analyses. Additionally, differences in the time frames in which cohorts were studied may have also contributed (e.g., pre/post the implementation of the Talking Therapies LTC guidance, COVID-19 pandemic). Thus, there remains the need to study the role of LTC status on assessment attendance and treatment engagement within Talking Therapies post-covid pandemic lockdown and post the publication of the LTC guidelines. Further, considering the recorded purpose of the appointment may provide a more nuanced insight into the influence of LTC status on usage outcomes in Talking Therapies services.

Internet-enabled therapies in Talking Therapies

In addition, the National Institute for Health and Care Excellence (NICE) (National Institute for Health and Clinical Excellence, 2009) recommend the delivery of therapy using remote delivery methods such as telephone and internet. Indeed, research evidence suggests that remote therapies may bolster engagement to psychological therapies by overcoming barriers to attendance (Bee et al., 2008; Knowles et al., 2014). Attendance may be a particular challenge for people with LTCs because of multiple hospital appointments and mobility challenges associated with certain LTCs. However, a recent analysis of data from seven Talking Therapies services showed people with a LTC were less likely to receive a telephone assessment compared with their non-LTC counterparts, despite a telephone delivered assessment being associated with higher attendance rates overall (Saxon et al., 2023). LTC status had no effect on attendance at treatment appointments. However, irrespective of LTC status people who were offered telephone delivered treatment sessions were less likely to attend treatment (Saxon et al., 2023). The potential of internet-enabled therapy treatment platforms, as one way to bolster treatment engagement and improve outcomes within the Talking Therapies programme is recognised (Clark, 2018). However, the findings from the study by Saxon et al. (2023) investigating telephone delivery raises questions as to whether the same patterns may be found for internet-enabled modalities given the lack of face-to-face contact. To our knowledge, no studies have quantitatively explored the impact of internet-enabled therapy on engagement in Talking Therapies services and whether a person's LTC status influences the mode of treatment received. Qualitative data from therapists working in Talking Therapies services (Carroll et al., 2021) suggests digital interventions may be perceived as a potential barrier to treatment engagement for people with LTCs, however this hypothesis is yet to be tested quantitatively.

Aims

Therefore, the aims of this study were to use routinely collected data to investigate the following:

1) Does LTC status impact on assessment attendance when controlling for potential demographic and clinical confounders?
2) Does LTC status and mode of treatment delivery impact on attendance at ≥2 treatment sessions when controlling for potential demographic and clinical confounders?
3) Does LTCs status impact on a person's likelihood of receiving internet-enabled therapy?

Methods

This paper is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology guidelines (STROBE) (Vandenbroucke et al., 2007). All procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. This research was part of an NHS Quality Improvement project, approval granted by London NHS Quality Improvement Board (Signed off by Director of Nursing at the relevant hospital trusts on 07/01/2019 (service A) & 28.01.22 (service B).

Data

All data analysed in this study were collected as part of routine care for reporting to NHS digital (NHS Digital., 2023b). NHS Talking Therapies services are required to collect data on all patients as part of the Minimum Dataset at the first attended contact and at each attended session thereafter. Outcome data includes scores on depression, anxiety, and social functioning (see below for measures). Services also collect usage data such as the purpose, attendance, and delivery modality of appointments in line with the Talking Therapies dataset (v 2.0)(NHS Digital., 2023b). The current study analysed data from two inner-London adult Talking Therapies providers between 1st January 2022- 31st December 2022. Raw demographic and clinical data were collected from any individual referral to the two services during the stated timeframe. It is possible that some individuals received more than one referral within the analysis timeframe. All care episodes were included in the analysis meaning that an individual could be included in the analysis more than once. The data used was anonymous and the research team had no contact with patients at this service.

Participants

We included data from any individual aged 18 or over with a referral to the included services over the 12-month period. The sample was restricted to referrals with complete information on LTC status. Cases where LTC status was reported as ‘not stated’ were excluded from the sample. Patients who were still in active treatment were excluded for data completion reasons and to avoid misclassifying a patient as either not attending either and assessment or treatment when they have not had the opportunity to do so because they are still in active treatment. After missing cases were removed, a final sample of n= 17095 remained (see Table 1). Verbal consent to data access was provided by participants and was recorded by healthcare professionals at the services, however as the data was anonymous at the point of access informed consent was not required. This is consistent with national guidelines for data reporting of Talking Therapies services to NHS Digital(NHS Digital., 2023b).

Outcome variables

Objective 1: Assessment Attendance

Attendance at assessment was defined as cases with at least one contact with Talking Therapies where the purpose of the session was coded as ‘assessment’, or ‘assessment and treatment’ and it was attended (1=attended assessment 0= did not attend assessment). The timeframe for assessment attendance was restricted to appointments 1-4, based on service do not attend (DNA) policies and the assumption that assessments will have been conducted within this timeframe.

Objective 2: Engagement with treatment

Engagement with treatment was defined as cases with two or more contacts with Talking Therapies where the purpose was coded as ‘treatment’ (1=engaged 0= did not engage). The Talking Therapies manual defines patients who have received a ≥2 treatment sessions as having “completed treatment” (NHS Digital., 2023b). In this study we have relabelled this as treatment engagement. The timeframe for treatment engagement was pragmatically restricted to appointments 1-10 to manage the number of observations per case.

Objective 3: Receipt of internet enabled therapy

We defined internet-enabled therapy as delivery of therapy through an internet-based programme, which is accessed by the patient in their own time. This definition is consistent with the definition in the NHS data dictionary and Talking Therapies(NHS Digital., 2023a, 2023b). Intervention modality is recorded by in-service clinicians during each contact meeting. It is possible for clinicians to select more than one intervention in one meeting. Due to this method of recording, we defined receipt of internet-enabled therapy as cases with at least one contact meeting where an internet-enabled intervention had been recorded by the clinician regardless of any other activity (1=yes 0=no).

Explanatory variables

LTC status

LTC status is a self-reported outcome collected at the point of (self)-referral or during the first contact appointment. In the current study LTC status was defined as a binary variable (0 = LTC absent 1=LTC present).

Internet-enabled therapy receipt

Receipt of internet-enabled therapy was an explanatory variable only in the analysis where engagement was the outcome variable.

Covariates

Age, gender, ethnicity, social deprivation decile, Talking Therapies service, whether the participant had a GP referral and baseline clinical scores were included as covariates. Age (years), gender (female=0 male 1) and ethnicity were self-reported and recorded at referral, or assessment. Ethnicity categories were based on Office of National Statistics categories and were as follows: White, Black, or Black British, Asian, or Asian British, mixed ethnicity and other. These ethnicity categories were then collapsed into a binary variable for the main analyses (0= white 1= minoritised ethnicity). We included data from 2 Talking Therapies service's (0=service A, 1=service B). Referral source is routinely collected. For this study GP referral source was derived as a binary variable (0=not referred by GP 1= GP referral). Social deprivation decile was calculated based on postcode data. Patients' postcodes were inputted into a publicly available government tool (English indices of deprivation 2019: Postcode Lookup (opendatacommunities.org)) that gives a deprivation rank based on the Lower Super Output Area (LSOA) that each postcode falls under (McLennan. et al., 2019). The index of multiple deprivation decile is calculated by dividing the LSOAs into 10 equal groups, with a lower decile indicating greater social deprivation. Baseline clinical scores are self-reported and collected routinely at the initial appointment using three standardised questionnaires within the Talking Therapies programme: the Patient Health Questionnaire-9 (PHQ-9) (Kroenke, Spitzer, & Williams, 2001), The Generalised Anxiety Disorder assessment-7 (GAD-7)(Spitzer et al., 2006) and the Work and Social Adjustment Scale (WSAS)(Mundt et al., 2002). The PHQ-9 is a nine-item depression questionnaire. Scores on the PHQ-9 range from 0-27; higher scores indicate greater depressive symptoms (a score of $\geq$ 10 indicates clinically relevant symptoms)(Kroenke, Spitzer, & Williams, 2001). The GAD-7 is a seven-item anxiety questionnaire. The GAD-7 has a scale range of 0-21; higher scores indicate greater anxiety symptoms (a score of $\geq$ 8 on GAD-7 indicates clinically relevant symptoms) (Spitzer et al., 2006). The WSAS measures functioning and is a five-item self-report questionnaire. The WSAS has a scale range of 0-40; high scores indicate greater impairments in functioning (Mundt et al., 2002).

Statistical Analysis

Analyses were performed on STATA (version 17). Descriptive and clinical characteristics of the sample were compared using t-tests for continuous variables and $\chi 2$ tests for categorical variables by LTC status. Due to the consistent application of the data monitoring system within the Talking Therapies programme cases of missing data were low. Therefore, any missing data were treated as blanks. To investigate the association between LTC status and a) assessment attendance b) treatment engagement and c) receipt of an internet-enabled therapy, binary logistic regression models were used to determine the relative contribution of LTC status to the three outcome variables. For the internet-enabled therapy logistic regression, only participants who attended an assessment were included in the analyses. This was because patients cannot be offered an intervention prior to attending an assessment in Talking Therapies. For each research objective four regression models were tested. Analyses were run using complete cases. Model 1 was unadjusted. Model 2 adjusted for age, gender, ethnicity, and deprivation decile. Model 3 additionally included baseline PHQ-9 (depression), GAD-7 (anxiety) and WSAS (social functioning) scores and GP referral (no/yes) and site (A or B).

Results

The demographic and clinical characteristics of the sample are shown in Table 1. Across the 17,095 participants the mean age was 36.73 years (SD= 12.74), 53.65% were female and over half (55.48%) were of white ethnicity. The average deprivation decile was 2.9, which suggests that the average participant lived in a postcode in the 10%-20% most socially deprived areas in England. In our sample, 25.57% of participants identified as having an LTC. Participants with a LTC were significantly older on average, lived in more deprived areas, were more likely to be from a minoritised ethnic background and were more likely to be referred to Talking Therapies by their GP. They had significantly higher baseline depression (PHQ-9), anxiety (GAD-7) and social functioning (WSAS) compared to the non-LTC group; see *table 1* for details.

Table 1. Demographic and clinical characteristics of final sample

Variable:	Total sample n (%)/mean (sd)	Non-LTC group n (%)/mean (sd)	LTC group n (%)/mean (sd)	Mean diff	95% CI	Statistical test	p-value
Baseline referrals	17,095	12, 724 (74.43%)	4, 371 (25.57%)				
Age (years); n= 17,095	36.73 (12.74)	34.41 (11.01)	43.47 (14.85)	-9.06	-9.48 to -8.65	t=-42.6814	p<.001
Gender (% Female); n=16,911	11735 (69.39%)	8661 (68.07%)	3074 (70.33%)			x^2 7.5966	p=0.006
Ethnicity; n=16,176						$x^2(4)$ =113.7642	p<.001
Asian or Asian British	1,227 (7.59%)	903 (7.10%)	324 (7.41%)				
Black or Black British	3,483(20.40%)	2,341 (18.40%)	1,142 (26.13%)				
Mixed	1,330 (7.78%)	980 (7.70%)	350 (8.01%)				
Other	1,161 (6.79%)	878 (6.90%)	283 (6.47%)				
White	8975 (52.50%)	6,864 (53.95%)	2,111 (48.30%)				
Minoritised ethnicity (% yes) n=16,176	7201 (44.52%)	5,102 (42.63%)	2,099 (49.86%)			$x^2(2)$ =65.7280	p<.001
Deprivation decile; n=16,991	3.39 (1.67)	3.46 (1.71)	3.19 (1.54)	0.27	0.21 to 0.33	t=9.1835	p<0.001
GP referral: (% Yes); n= 17021	2,040 (11.99%)	1317 (10.35%)	723 (16.54%)			x^2 =120.1492	p<0.001
PHQ-9; n=14,674	13.93 (6.19)	13.43 (6.14)	15.36 (6.13)	-1.93	-2.16 to -1.70	t=- 16.6995	p=<0.001
GAD-7; n=14669	12.52 (5.29)	12.26 (5.29)	13.24(5.22)	-0.98	-1.18 to -0.79	t=-9.8788	p=<.001
WSAS; n=13459	18.14 (9.38)	17.55 (9.11)	19.92 (9.91)	-2.37	-2.74 to -2.01	t=-12.7970	p<0.001
Service; % referred to service A	10,048 (58.78%)	7,722 (60.69%)	2,326 (53.21%)			x^2 =75.0079	p<0.001
Attended assessment (% yes)	13,549 (79.26%)	10,003 (78.62%)	3546 (81.13%)				
Engaged (of those attended assessment, % Yes)	4622 (34.11%)	3468 (34.67%)	1154 (32.54%)				
Internet-enabled therapy received (of those attended assessment, % Yes)	861 (6.41%)	727 (7.27%)	141 (3.98%)				

CI= Confidence Interval; LTC= Long-term physical health Condition.

Association of LTC status with outcomes

Attended assessment.

The demographic and clinical characteristics of the sample who attended an assessment in Talking Therapies are shown in Appendix C Table 1. A total of 79.26% (*n*=13,549) of participants attended a Talking Therapies assessment following a referral (*n*=17, 095) and of these, 26.17% had an LTC and 73.82% did not. Patients who reported having an LTC were significantly more likely to attend an assessment than those without in Model 1 (OR: 1.17; unadjusted) and Model 2 (OR= 1.12; adjusted for socio-demographic characteristics). When clinical characteristics and site were entered into the model no statistically significant effect of LTC status on assessment attendance was observed. Other statistically significant explanatory variables of assessment attendance indicated that individuals who were female (OR: 0.83; p=0.011), from minoritised ethic groups (OR: 0.82; p=0.003), those with better functioning (OR: 0.99; p=0.040) were less likely to attend an assessment at Talking Therapies (see Appendix C Tables 3 and 4 for adjusted regression models). Patients who had higher baseline anxiety (OR: 1.02; *p*=0.021) and were a patient within service A (OR: 4.29 *p*=<0.001) were more likely to attend their assessment. Age, social deprivation, baseline depression scores or being referred by a GP did not significantly influence assessment attendance within our two services (see Appendix C)**.**

Treatment engagement.

Only 34.11% (n=3468) of those who attended an assessment in our sample went on to engage with treatment (n=4,622). Of these who engaged, 24.97% had an LTC and 75.03% did not. The demographic and clinical characteristics of the sample who engaged are presented in Appendix C table 2. Patients with an LTC were statistically less likely to engage in treatment in the unadjusted model (OR: 0.91). However, when sociodemographic (model 2) and clinical characteristics and site (model 3) were statistically accounted for the effect of LTC status on treatment engagement was no longer statistically significant. Individuals from a minoritised ethnic background (OR: 0.81; *p*<0.001), those with a higher baseline depression (OR: 0.98; *p*<0.001) and those referred by a GP (OR 0.77; *p*<0.001) were significantly less likely to engage with treatment. Individuals from a less socially deprived area (OR 1.03 *p*=0.010), those with a higher baseline anxiety score (OR: 1.03 *p*<0.001) and those referred to service A (OR: 1.19; *p*<0.001) were significantly more likely to engage in treatment. No other covariates were statistically significant explanatory variables of treatment engagement (see Appendix C table 3 &4).

Internet-enabled therapy receipt

When investigating rates of internet-enabled therapy receipt in our sample who attended an assessment (n=13,549), we found that 6.41% (n=868) of patients received internet-enabled therapy at some point across their care pathway. Of those who received this, n=141 (3.98%) had an LTC and n=727 (7.27%) did not. See Appendix C table 5 for the demographic and clinical characteristics of the sample who received internet-enabled treatment. Across all three models, LTC status was associated with a decreased likelihood of receiving internet-enabled therapy even after adjusting for demographic and clinical characteristics (OR: 0.74, *p*=0.003). Older patients (OR:0.98, *p*<0.001), those from a minoritised ethnic group (OR: 0.79, *p*=0.003), those with poorer functioning (OR: 0.98 *p*=0.002) and those referred to service B (OR: 0.16 *p*<0.001) were significantly less likely to receive internet-enabled treatment (See Appendix C table 3 &4).

Internet-enabled therapy receipt on treatment engagement

Across all three of our regression models, those who received internet-enabled therapy were significantly more likely to engage treatment even after adjusting for demographic and clinical characteristics *(see Table 3*). Being older (OR: 1.00, *p*=0.021), from a minoritised ethnic background (OR: 0.81, *p*<0.001), being referred by a GP (OR: 0.76, *p*<0.001) and having higher baseline depression scores (OR: 0.98 *p*<0.001) and poorer social functioning (OR: 0.99, *p*=0.005) predicted reduced likelihood of engagement irrespective of internet-enabled receipt. Having higher baseline anxiety scores (OR: 1.02, *p*<0.001), lower deprivation score (OR: 1.03, *p*<0.001) and being referred to service A (OR:1.30, p=<0.001) was associated with increased likelihood of engagement irrespective of internet-enabled therapy receipt. See Appendix C tables 6&7

Table 2: Binary logistic regressions of LTC status on assessment attendance, treatment engagement, and receipt of internet-enabled therapies.

Regression	Attended assessment			Engaged			Received internet-enabled therapy		
	Odds ratio	P-value	95% CI	Odds ratio	P-value	95% CI	Odds ratio	P-value	95% CI
Model 1	1.17	<0.001	1.07 -1.28	0.91	0.022	0.84- 0.99	0.53	<0.001	0.44 - 0.64
Model 2	1.12	0.018	1.02- 1.24	0.94	0.141	0.86 -1.02	0.67	<0.001	0.55 - 0.82
Model 3	1.16	0.062	0.99 -1.35	0.97	0.563	0.86- 1.07	0.74	0.003	0.60 - 0.90

CI= confidence interval; LTC= long-term physical health condition. Model 1: unadjusted. Model 2: Adjusted for age, gender, ethnicity, and deprivation decile. Model 3: Adjusted for age, gender, ethnicity, deprivation decile, baseline PHQ-9 (depression), GAD-7 (anxiety) and WSAS (social functioning) scores, GP referral and site.

Table 3: Binary logistic regressions of receipt of internet-enabled therapies on treatment engagement.

Regression	Engaged		
	Odds ratio	P-value	95% CI
Model 1	2.95	<0.001	2.57 -3.39
Model 2	2.78	<0.001	2.40 – 3.21
Model 3	2.68	<0.001	2.31 – 3.10

CI= confidence interval; Model 1: unadjusted. Model 2: Adjusted for Long-term physical health condition status, age, gender, ethnicity, and deprivation decile. Model 3: Adjusted for long-term condition status age, gender, ethnicity, deprivation decile, baseline PHQ-9 (depression), GAD-7 (anxiety) and WSAS (social functioning) scores and GP referral.

Discussion

This study used patient data from two London adult NHS Talking Therapies services to explore potential variations in assessment attendance, treatment engagement, and use of internet-enabled therapies amongst those with and without an LTC. Additionally, we explored whether use of internet-enabled therapies bolstered treatment engagement. Our findings indicate that individuals with a LTC were no more likely to attend an assessment appointment than those without an LTC when we controlled for demographic factors, clinical factors, and site. Likewise, LTC status did not influence engagement after controlling for covariates. Individuals offered an internet-enabled therapy were more likely to engage in treatment, but people with LTCs were less likely to receive this treatment method compared to their no-LTC counterparts.

We found that LTC status did not affect rates of assessment appointment attendance. This is consistent with previous quantitative evidence (Davis et al., 2020; Saxon et al., 2023) showing that LTC status does not influence initial appointment attendance. This lack of association is promising for Talking Therapies services as it suggests that once referred, these services are successfully supporting LTC clients to attend their assessment. However, similar to other studies, we found that individuals from more deprived areas (Saxon et al., 2023; Sweetman et al., 2022) and those from minoritised racial and ethnic groups (Harwood et al., 2023; Sweetman et al., 2022) were less likely to attend assessment appointments irrespective of LTC status. Additionally, we found that patients with poorer social functioning and higher levels of anxiety were significantly more likely to attend their assessment. This finding regarding anxiety has been seen elsewhere (Sweetman et al., 2022). However, it should be highlighted that the effect sizes found in our study were small suggesting that the role of baseline anxiety severity and social functioning should be interpreted with caution. Odds ratios of, or near to, one are small and therefore unlikely to be meaningful to clinical practice (Haddock, Rindskopf, & Shadish, 1998). Individuals who were referred to service A were significantly more likely to attend their assessment, with large effect. This is likely due to the variability between services based on their location, culture, and commissioning. We can only speculate reasons for this effect; however one reason may be that Talking Therapies services have different links with local organisations for signposting patients out to access support within the community thus influencing assessment non-attendance in Talking therapies. Providing information to patients and referrers on local organisations that could offer support outside of Talking Therapies services may help patients to contact services that are appropriate for their needs.

Having an LTC was not significantly associated with treatment engagement in our study when service, demographic, clinical factors were controlled for. This suggests that engagement with treatment sessions did not vary by LTC status. Our findings align with previous work conducted before the COVID-19 pandemic (Saxon et al., 2023; Verbist et al., 2023). This may suggest that the association between LTC status and increased engagement seen during the COVID-19 pandemic (Verbist et al., 2023) was due to other factors unrelated to LTC status. We hypothesise that one reason for this contrasting finding may have been due to heightened levels of mental health difficulties specifically for people with LTCs (Frank et al., 2020). Additionally, a transition to remote appointments may have removed additional barriers to engagement for LTC patients. Our findings are encouraging as they suggest that efforts by Talking Therapies services to engage patients, including those with LTCs have been successful at reducing potential inequalities. However, we found that overall patients referred by a GP were less likely to engage in treatment, as seen elsewhere (Davis et al.,

2020) . Conversely, other work has shown that individuals who self-refer are more likely to attend treatment appointments within Talking Therapies (Saxon et al., 2023). Our findings also indicate that patients with higher baseline levels of anxiety were more likely to engage with treatment appointments, and those with higher levels of depression were less likely to attend irrespective of LTC status as has been seen in other studies (Sweetman et al., 2022).

Our study demonstrated that patients with an LTC had a significantly reduced likelihood of receiving a internet-enabled therapy compared to their non-LTC counterparts, yet receipt of internet-enabled therapies improved engagement. Internet-enabled therapies are effective for patients with LTCs (Carlbring et al., 2018; Seaton et al., 2023). However, qualitative evidence suggests that patient (Patel et al., 2020; Seaton et al., 2023) and therapist views (Carroll et al., 2021) on the value of digital treatment are mixed. It has been indicated that Talking Therapies clinicians feel that internet-enabled treatment is acceptable for patients with LTCs and may be advantageous for engagement (Carroll et al., 2021). However, referral patterns to internet-enabled therapy across the two sites in our study did not mirror this pattern and suggest that potential biases may be in place that are preventing referrals to internet-enabled treatment for LTC clients. The “digital divide” is well established and postulates that some demographic groups including older adults and those from an minoritised ethnic groups may be disproportionally excluded from using digital treatment due to reduced confidence, skill and/or access to digital products (Greer et al., 2019). Our findings correspond with this as people who were older, from an minoritised ethnic group were significantly less likely to receive internet-enabled treatment (regardless of LTC status). However, our findings remained after controlling for these demographic factors suggesting that other LTC-specific barriers may influence this relationship over and above these factors.

From the data available to us, it is unclear if differences in internet-enabled intervention receipt are a result of LTC patients declining to uptake internet-enabled treatment or that this treatment option was not considered by clinicians. Other work has indicated that clinicians feel less confident explaining the role of psychological therapy within LTCs (Carroll et al., 2021). This may be due to perceived complexities such as increased physical health demands. Hence, assessing clinicians may default to other options such as LTC-specific groups rather than digital treatment. Therefore, more work may be needed to educate clinicians on the value of internet-enabled treatments as a suitable and effective option for people living with an LTC. It has been suggested that speciality LTC roles such as "LTC-champions" increase patient engagement within Talking Therapies and provide support for non-LTC clinicians (Panchal et al., 2020) therefore, Talking Therapies commissioners should aim to develop and promote these roles.

We found that across all patients, those who received a internet-enabled intervention at some point across their care pathway were more likely to engage with treatment with moderate effect. This was irrespective of LTC status. To our knowledge this is the first study to quantitatively investigate if internet-enabled therapies bolster engagement within Talking Therapies settings. Qualitative studies have shown that patients identify benefits in internet-enabled therapies including flexibility, convenience, and accessibility (Seaton et al., 2023) potentially accounting for our findings in part. Additionally, internet-enabled therapies have been shown to be effective for treatment outcomes in within Talking Therapies services for patients with (Seaton et al., 2023) and without LTCs (Richards et al., 2020). This suggests the benefits of internet-enabled treatment to both patients and services could be two-fold. However, we were unable to quantify the dose of internet-enabled therapy receipt within our study due to current reporting and therefore more work is needed to explore this.

It is well established that internet-enabled treatment is one way in which Talking Therapies services can scale up delivery and provide accessible, evidence-based, and potentially cost-effective (Richards et al., 2020) psychological therapies. Current evidence indicates that outcomes are poorer for LTC patients than their non-LTC counterparts within Talking Therapies services (Seaton et al., 2022). Therefore, internet-enabled treatments may be a solution to improve this and support engagement for LTC clients. Consistent work shows that LTC-specific CBT protocols with greater therapeutic relevance produce better treatment outcomes (Seaton et al., 2023; Wroe et al., 2018; Yardley et al., 2016) and increased engagement (Panchal et al., 2020). Hence, Talking Therapies guidance recommend that treatment protocols are adapted for LTC patients (National Collaborating Centre for Mental Health., 2018). Despite this guidance, qualitative work suggests that this still remains a challenge for therapists within Talking Therapies due to service and system level constraints (Carroll et al., 2021; Hassan, Bennett, & Serfaty, 2018). Digital treatments may be one way in which services can provide more tailored support to patients in a cost-effective manner. Additionally, through using a internet-enabled modality such as a guided support platform, clinician burden may be reduced. A real-world implementation study has indicated that digital therapist-guide interventions, tailored to the needs of those with LTCs may be effective and acceptable to patients when delivered in Talking Therapies care (Seaton et al., 2023).

Strengths and Limitations

To our knowledge this is the first study to explore the influence of having an LTC on usage outcomes in Talking Therapies in a post UK- COVID-19 lockdown cohort. The use of NHS real world Talking Therapies data in this study, provides insight into these outcomes in current clinical practice. Additionally, through considering the recorded purpose of appointments we were able to distinguish between attendance at assessments and treatment sessions. This allows for a more nuanced understanding of usage outcomes across the treatment pathway. Further, we were able to include patients that may usually be underrepresented in traditional research, such as those from diverse ethnic and social backgrounds. However, the use of data from inner-London based services makes it difficult to generalise to a broader UK context. In this study we relied on self-reported LTC diagnoses and treated it as a binary variable which has been done in other studies using Talking Therapies data (Delgadillo et al., 2017). However, missing data on LTC status and the exclusion of patients without data means that we were unable to capture all referrals. Further we selected cut offs for our outcome variables. We restricted assessment attendance to the first four and treatment engagement to the first ten Talking Therapies appointments. These restrictions were pragmatically and clinically selected considering service DNA policies, and data management challenges. However, these restrictions may present a level of bias in our analyses. Additionally, the missing data present for baseline clinical outcomes may also present biases in our analyses. We were unable to report reasons for non-assessment attendance, non-engagement and intervention receipt in our study, and therefore more work should be done to explore these reasons. Indeed, the reporting of some of the variables within the current dataset was reliant on practitioner and administrator accuracy, thus some uncertainties surrounding the reliability of the reporting remain.

Conclusion

There were no differences between LTC and non-LTC patients in assessment attendance or treatment engagement once we controlled for key confounders. Across the whole sample, receiving internet-enabled treatment bolstered engagement. However, LTC patients were less likely to receive internet-enabled treatment. Is important to note that, under a quarter of patients went on to engage with treatment irrespective of LTC status in our study. This suggests that further work may be needed engage patients in Talking Therapies interventions generally. One way evaluation research could support this is through using implementation science methods to gain insights into the gap between treatment guidelines and clinical practice. Recent research (Faija et al., 2023; Faija et al., 2020) has used implementation theory to evaluate real-world clinical practice in Talking Therapies services. Evaluating feedback from key stakeholders, alongside the using theoretical frameworks may provide services with clear recommendations for implementing practice change, thus supporting engagement.

The supplementary material for this article can be found at the online appendix.

Acknowledgements

The authors gratefully express their appreciation to the clinical and administrative staff at the London Talking Therapies services, whose support and guidance enabled the project.

Funding statement: This research received no specific grant form any funding agency, commercial or not-for-profit sectors.

Conflict of Interest: None

Data availability: The data used in the study are available on request from the corresponding author, JH. The data are not publicly available they could compromise the privacy of the participants.

5.3 Chapter Conclusion

This chapter demonstrates that assessment attendance and treatment engagement in Talking Therapies is equitable for people with and without a reported LTC when key confounders are controlled for. Rates of internet-enabled therapy receipt appear low across the total sample. However, the findings in this chapter indicate that people living with an LTC are less likely to receive an internet-enabled intervention, despite the potential of digital treatment to bolster treatment engagement. Therefore, this may suggest that LTC-specific barriers to the receipt of digital treatment in Talking Therapies may exist. This provides context to the findings presented in chapter 4 which highlight the limited reach of COMPASS for adults with diabetes and co-morbid psychological distress. It should be noted that this chapter calculated the frequency of people who received internet-enabled therapy by studying all those who received internet therapy relative to all those who “attended for assessment”. However, Chapter 4 explored the receipt/reach of COMPASS from all those referred to each respective service because data on assessment and triage data was unavailable.

Therefore, to provide comparable estimates regarding the reach of COMPASS compared to those generated in chapter 4, the reach of internet-enabled treatments in Talking Therapies, has been quantified using the internet-enabled therapy variable from chapter 5 as the numerator and total referrals as the denominator (see chapter 5 table 1). The reach of internet-enabled therapy in Talking Therapies for the non-LTC sample is 5.71% (n=12725/727) and the reach for those with an LTC is 3.23% (n=141/4371). The implications will be discussed in the wider discussion (chapter 7).

Chapter 6. Stakeholder qualitative study

6.1 Chapter overview

The preceding chapter highlighted that receipt of internet-enabled therapy is not equitable between those with and without an LTC that remained after controlling for key confounders. This suggests that barriers unique LTCs (including diabetes) barrier may exist regarding internet-enabled therapy receipt that may be influencing the overall implementation of COMPASS. Alongside this, chapter 4 explored barriers and facilitators to COMPASS implementation from the perspective of patients and the findings indicated that contextual, service, and systemic level factors may be influencing the implementation of COMPASS. Hence, this chapter will explore the barriers and facilitators to the implementation of COMPASS from the perspective of key stakeholders. This chapter is to be submitted for publication hence the researcher will use the pronoun “we” to refer to the research team included in this study.

6.2 Introduction

Diabetes is a chronic condition that requires constant self-management. It is estimated to affect ~7% of the UK population and this is increasing (Whicher, O'Neill, & Holt, 2020). Robust research evidence shows that depression, anxiety and psychological distress related to living with diabetes (named diabetes-related distress) are prevalent in people living with diabetes. Specifically, adults with diabetes have ~2x greater odds of experiencing depression (Farooqi et al 2022) and 1.5x greater odds of experiencing anxiety than the general population (Amiri & Behnezhad, 2019). Additionally, diabetes-related distress is estimated to affect up to 40% of people with diabetes (Skinner, Joensen, & Parkin, 2020)

Co-morbid psychological distress in diabetes is related to worsened quality of life (Carper et al., 2014; Schram, Baan, & Pouwer, 2009), increased risk of complications (Nouwen et al., 2019; Pintaudi et al., 2015) and poorer glycaemic control (Schmitt, Bendig, et al., 2021). Additionally, comorbid depression in diabetes has been associated with increased healthcare costs through increased service utilisation, work absence and disability leave (Hutter, Schnurr, & Baumeister, 2010; Molosankwe et al., 2012). However, treating mental health for people with physical Long Term Health Conditions (LTCs) such as diabetes is estimated to reduce healthcare costs by 15-20% (Layard & Clark, 2015; Mental Health Taskforce, 2016).

For adults with diabetes, currently depression and anxiety can be treated through drugs and/or psychotherapy (Gold et al., 2020). However, the National Institute of Health and Care Excellence (NICE) favours psychotherapy as the first line interventions due to risk benefit-ratios in diabetes (Baumeister, Hutter, & Bengel, 2014; National Institute for Health and Care Excellence [NICE], 2023a, 2023b). Moreover, meta-analytic evidence has demonstrated the efficacy of psychotherapy such as Cognitive Behavioural Therapy (CBT) for improving mental health outcomes such as depression, anxiety and diabetes-related distress in diabetes (Jenkinson et al., 2022).

In line with this, NICE guidelines recommend Cognitive Behavioural Therapy (CBT) as a psychological treatment for the management of depression in the context of LTCs (National Collaborating Centre for Mental Health, 2010). Furthermore, in 2016 the English National Health Service (NHS) talking therapies services were commissioned to develop care pathways to provide Talking Therapies for people with LTCs such as diabetes in routine care (National Collaborating Centre for Mental Health., 2018).

However, consistent research evidence indicates that individuals who have an LTC such as diabetes have worsened depression and anxiety outcomes than those without an LTC when treated within routine care (Ewbank et al., 2020; Seaton et al., 2022; Wakefield et al., 2021). One reason for this may be that CBT treatment protocols often fail to account for concerns specific to having an LTC like diabetes. Preliminary evidence indicates that CBT protocols which integrated diabetes-specific concerns may produce better treatment outcomes (Nobis et al., 2015). Additionally, tailoring treatment protocols for people with diabetes may increase treatment acceptability and engagement through increased relevance (Clarke et al., 2018). However, providing access to tailored CBT is challenging for patients (via time and mobility) and NHS services (via treatment costs and trained therapists) (Gandy et al., 2018; May et al., 2001). Additionally, there is a need for a scalable treatment model in diabetes as demand for psychological support is currently outweighing supply (Diabetes UK, 2019; Sachar, Breslin, & Ng, 2023). Thus, internet-enabled therapy may be a solution for this.

To this end, our team developed a therapist-guided digital CBT intervention called “COMPASS – navigating your long-term condition” using the Medical Research Council (MRC) framework (Skivington et al., 2021). The development of COMPASS was informed by the transdiagnostic model of adjustment (Carroll et al., 2022; Moss-Morris, 2013), which proposes that distress in LTCs such as diabetes is triggered and perpetuated, by mechanisms specific to having a LTC that psychiatric protocols to treat depression and anxiety do not account for.

The efficacy of COMPASS to improve clinical outcomes has been evaluated through a robust randomised controlled trial (RCT). The RCT findings demonstrated that compared to standard-charity support, COMPASS improved general psychological distress (measured via the Patient Health Questionnaire Anxiety depression Scale PHQ-ADS (Kroenke et al. (2016) with a large effect (SMD= 6.82; 95% Confidence Intervals CI = 4.55–9.10; p<0.001), depression (measured via the PHQ-9 Kroenke, Spitzer and Williams (2001) with moderate effect (SMD= 3.49; 95% CI = 2.25-4.72; p<0.001), and anxiety (measured via the GAD-7; Spitzer et al. (2006) with moderate effect (SMD= 3.26; 95% CI= 2.00-4.51; p<0.001) , work and social functioning (measured via the WSAS; Mundt et al. (2002) (SMD= 2.58; 95% CI = 0.61-4.56; *p*=0.010) and illness-related distress (SMD= 1.01; 95% CI= 0.57-1.45; *p*<0.001) (Picariello et al., 2024b).

The effectiveness and acceptability of COMPASS has also been evaluated in the real-world within NHS routine care, Talking Therapies services and Secondary Care services (Seaton et al., 2023). This effectiveness study demonstrated that COMPASS produced significant improvements in in psychological distress, depression, anxiety, and functional impairment for patients with a range of LTCs including those with diabetes when treated in NHS routine care.

However, in chapter 4 of this thesis, we report findings exploring the feasibility of implementing COMPASS. Our quantitative study findings demonstrated that only 1.80% of our sample who were referred for psychological support chose to uptake COMPASS. From missing data in chapter 4, we were unable to quantitatively determine if this was due to ineligibility or non-acceptability of COMPASS by adults with diabetes. However, this conversion rate seen in routine practice is much lower than the 59% consent to study rate seen in the COMPASS RCT described above. Additionally, the rate of usage of the online and therapist sessions was much lower (online =2, therapist support sessions =1) than stated for intended use in the COMPASS protocol (Hulme et al., 2021) (≥5 online and ≥3 telephone sessions/contacts) the rates observed in the RCT (Picariello et al., 2024b). Our findings demonstrate a clear gap between research, and usage in routine clinical practice. This research to practice gap has been demonstrated widely in interventional research in psychology (Lipschitz et al., 2019). However, little is known about the specific factors influencing this gap in the implementation of an internet-CBT intervention for adults with diabetes specifically. As presented in chapter 4 of this thesis, we interviewed adults with diabetes who used COMPASS. The qualitative findings indicated mixed appraisal of COMPASS by patients. Additionally, users experienced barriers and facilitators to using COMPASS at every stage of the care pathway. Specifically, participants described that their route to accessing mental health support was not clearly defined. Additionally, the explanation of COMPASS by healthcare professionals appeared to be confusing to participants and inaccurate. Taken together our findings indicated that the implementation of COMPASS is influenced by multi-level and contextual factors, not the intervention alone.

The influence of context and wider stakeholders on the implementation of internet-enabled CBT has been highlighted before (Folker et al., 2018; Jardine et al., 2023). However, qualitative evidence indicates that there may be additional factors to consider when trying to implement an internet-enabled therapy into routine care for adults with diabetes specifically. These include therapist beliefs about LTC therapy, practical barriers to embedding COMPASS into current care pathways and the use of digital intervention in diabetes care (Carroll et al., 2021; Clarke et al., 2018).

Therefore, in the current study we aimed to gain an insight into the barriers and facilitators of implementing COMPASS into routine care for adults with diabetes from stakeholders (psychologists, therapists, healthcare professionals, commissioners). We qualitatively interviewed stakeholders who had and had not been exposed to COMPASS to explore how an internet-enabled CBT intervention may align with existing service provision.

6.3 Methods

The study is reported in accordance with the American Psychological Society (APA) Journal Article Reporting Standards (JARS) for qualitative research.

6.3.1 Study design

We employed a qualitative design using in-depth semi-structured interviews to explore stakeholder perceptions of the barriers and facilitators to implementing an internet-enabled CBT intervention named COMPASS into healthcare services for adults with diabetes. Purposive sampling was used to capture the varied professional roles and experiences. The study received NHS ethical approval (REC: 22/WA/0017).

6.3.2 Settings and participants

This qualitative study was nested within a wider implementation study (presented in chapter 4). The wider study was a implementation study of COMPASS, digital CBT, conducted across three inner London NHS services; two Talking Therapies service (primary care mental health), and a Diabetes and Endocrinology service (secondary care physical health).

6.3.3 Study eligibility

In this qualitative study, individuals who worked in one of the three services using COMPASS and therefore had been exposed to the intervention were eligible for inclusion. This included therapists who had experience of conducting assessments for treatment suitability and/or had been involved in the delivery of COMPASS. Other stakeholders that worked in, or alongside the study sites supporting the care of adults with diabetes such as commissioners, policy makers, doctors, nurses, or psychologists who may make referrals one of our study sites were also eligible for inclusion. These stakeholders had varied knowledge of COMPASS.

For context, therapists within the diabetes service work in a physical health setting and are part of the multi-disciplinary team. Supervision is received from a health psychologist who has specialist expertise in clinical health psychology and diabetes. Therapists within Talking Therapies work within a primary mental health team and therefore their expertise in working with patients with diabetes and other LTCs likely varies.

6.3.4 Procedure

Recruitment and data collection

Participants were approached and recruited via email. A total of twenty-one (n=21) were approached to take part. Of those two (n=2) declined and two (n=2) did not respond to contact. Therefore, a final sample of seventeen remained. All participants provided informed consent prior to the interview. During the interviews, only EJ and the participants were present. All interviews followed a semi-structured interview schedule and were conducted on MS teams. The interviews were transcribed using a secure transcription service approved by the university and NHS ethical sponsor. Data collection and analysis happened in parallel. Data collection concluded once the research team determined that the interviews provided sufficient depth and richness to address the research question in this study (Braun & Clarke, 2021b).

6.3.5 Data analysis

Data was analysed using inductive thematic analysis following the steps outlined by Braun and Clarke (2006, 2019) to ensure that the analysis remained grounded in participant's experience and reflexivity was considered. Recordings were listened to, and transcripts read repeatedly so that the authors could familiarise themselves with the data. Line by line coding was employed across all transcripts. Using these codes the first author (EJ) began to identify and develop themes and sub-themes by examining the codes for patterns of shared meaning. These codes were then grouped into sub-themes and overarching themes. The themes were then discussed, refined and agreed on in relation to the entire dataset, ensuring that they accurately represented the data as a whole and addressed the research question.

6.3.6 Characteristics of the research team and reflexivity

In line with Braun and Clarke (2019) approach to thematic analysis, we recognise that the researcher's personal experiences, beliefs, and values inevitably influence the interpretation of data. For example, EJ conducted and analysed all the interview data. EJ has an MSc in Health Psychology, previous experience in qualitative interviewing and these interviews formed part of her doctoral thesis. Hence, the background and experiences of EJ shaped the way she engaged with and interpreted the data. Specifically, E.J has worked on the COMPASS project as a researcher for four years and has been involved in relationship building, training and working with the NHS services implementing COMPASS. Therefore, these experiences likely influenced how the stakeholders' narratives were interpreted.

Additionally, RMM and JLH are responsible for the original and ongoing development of COMPASS: navigating your long-term condition. Furthermore, all authors have experience of working in research and clinical practice with people with LTCs (such as diabetes) across a range of settings. Taken together, these experiences will have led to assumptions about the implementation of COMPASS into routine NHS care which may be presented in the analysis. However, throughout the analysis, EJ maintained reflexive field notes, and the codes, subthemes, and themes were discussed amongst the research team and her peers, throughout each stage of analysis and transcripts re-read to ensure that the codes sub-themes and themes accurately represented the data.

By embracing subjectivity as a resource (Braun & Clarke, 2021a) rather than a limitation, the analysis was enriched, allowing for a deeper understanding of the nuanced barriers and facilitators to implementing COMPASS into routine NHS care whilst acknowledging the impact my experiences and positionality may have had on the themes presented in this analysis.

Table 9. *Interview schedule.*

Topic	Key questions	Prompts
Referral	• What do you consider when referring someone with diabetes to psychological support?	• Could anything be done to improve the referral process? What?
Suitability for treatment	• How do you establish if someone's psychological distress is linked to their diabetes? • How do you find working with patients with DM (LTCs)? • When thinking about who is versus who isn't appropriate for a digital intervention, what factors influence your decision?	• Do you feel that there are any important factors that need to be considered when explaining psychological therapy to people with LTC's such as diabetes?

Topic	Key questions	Prompts
Uptake and engagement	• What factors do you think influence the uptake and engagement of psychological therapy in patients with DM/LTCs. • Do you think online CBT is a useful tool for your service?	Prompt COMPASS specifically If not, why not?
COMPASS specific	• How did you find using the COMPASS platform as a therapist?	• Would you change anything?
Wider system	• To what extent do you think [name of service] is ready for a digital-LTC specific intervention? • Do you feel that there are any factors that need considering when looking to embed a new digital CBT intervention specifically for people with a LTC like DM? • Are there any external factors that may influence then implementation of COMPASS. • What suggestions would you have for implementing a digital CBT intervention such as COMPASS to support people with diabetes and their mental health?	

6.4 Results

A total of 17 stakeholders were interviewed. This comprised three men and fourteen women. Participants were recruited in London, from Talking therapies services currently using COMPASS (*n*=9) and psychological support services within diabetes services (*n*=4; *n*=2 currently using COMPASS; *n*= 2 not using COMPASS). Additionally, we recruited participants in community diabetes teams (*n*=1), those working in the mind-body NHS trust policy team (*n*=2) and in commissioning (*n*=1). A description of participant roles, the settings in which they worked and their exposure to COMPASS are shown in *Table 10*.

Table 10.*Participants role and employment settings.*

Role	Setting	Exposed to COMPASS
Clinical health psychologist	Physical health setting	Yes
Trainee clinical psychologist	Physical health setting	Yes
Psychological Wellbeing Practitioner	Primary mental health service Talking Therapies	Yes
CBT therapist	Primary mental health service Talking Therapies	Yes
Psychological Wellbeing Practitioner	Primary mental health service Talking Therapies	Yes
CBT therapist	Primary mental health service Talking Therapies	Yes
CBT therapist	Primary mental health service Talking Therapies	Yes
CBT therapist	Primary mental health service Talking Therapies	Yes
CBT therapist	Primary mental health service Talking Therapies	Yes
Clinical psychologist	Primary mental health service Talking Therapies	Yes
Psychological Wellbeing Practitioner	Primary mental health service Talking Therapies	Yes
Commissioner	Local Clinical Commissioning Group	No
Clinical health psychologist	Physical health setting	No
Implementation researcher	Academic Health Science Centre	No
Clinical health psychologist	Physical health setting	No
Implementation researcher	Academic Health Science Centre	No
Diabetes Specialist Nurse and Health Psychologist	Physical health setting	No

The themes are displayed in **Figure 3**. Themes captured participants' perceptions of barriers and facilitators to implementing the COMPASS intervention into routine NHS care from the perspectives of stakeholders. As some participants had not been exposed to COMPASS, they discuss barriers and facilitators of implementing internet-enabled CBT into current routine care for adults with diabetes.

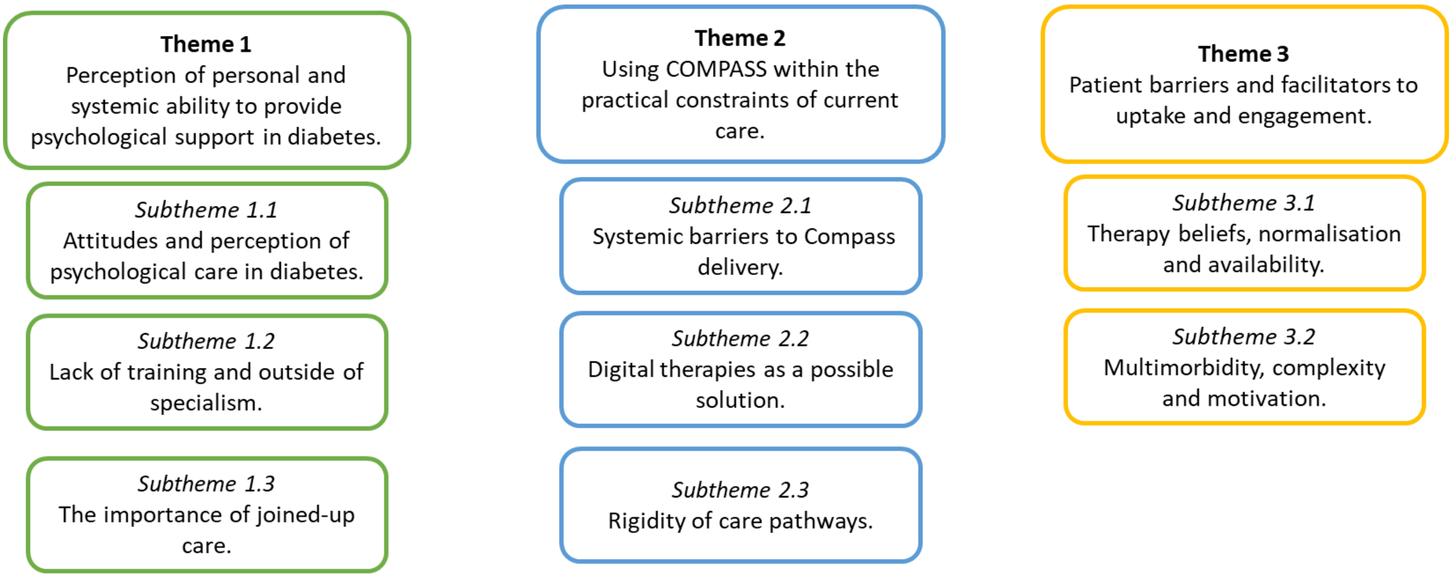

Figure 3. *Themes and subthemes generated from inductive thematic analysis.*

Theme 1: Perception of personal and systemic ability to provide psychological support in diabetes.

Subtheme 1.1: Attitudes and perception of psychological care in diabetes.

Participants reported both positive and negative attitudes towards mental health support within their workplaces for people with diabetes. In physical health settings, this was focused on the value placed on mental health in the context of a medical model. Generally, the participants in the physical health settings appeared to positively appraise the input of psychology and have a good awareness of the need for this support, potentially facilitating the implementation of COMPASS.

> *"I think for most of the nurses that I worked with quite closely and most of the doctors and the dietitians, I think most of us are quite switched on. In terms of, you know, does this person need psychological help and support"* - Community Diabetes nurse; not exposed to COMPASS.

Further, psychologists in physical health settings generally perceive other members of the team as confident to discuss mental health with their clients but noted that experience may influence confidence:

> *"There's some very experienced and very knowledgeable staff in the service who are more confident and would have conversations at a deeper level with patients than others. But I think some of the newer staff [would not]... we also have quite a lot of rotating doctors who don't necessarily always know the referral process"* – Clinical Health Psychologist; exposed to COMPASS.

However, within Talking Therapies where people with diabetes are being treated within a mental health model, participants highlighted that LTC specific therapy often appears to be an area that clinicians tend to avoid:

> *"we've got a bit of a bad name the long-term condition services. It's not very like fun, and I don't know, like a sexy area to work. ...I think maybe long-term conditions just gets a bit of a bad press. Maybe it's a bit kind of Oh, well, there's not much we can do in the area, So I think it depends on the clinician and their views as to how kind of interested they are." – CBT therapist; exposed to COMPASS.*

> *"I have to say I was previously quite avoidant of LTC . It was, uh, um, I think, quite often linked to sort of very depressed chronic pain patients. Um, and and just being sort of very stuck"* - CBT therapist; exposed to COMPASS.

Further, participants described that they felt some clinicians lacked confidence around physical health elements when assessing and treating patients with diabetes:

> *"most of our assessments are done by PwPs [Psychological Wellbeing Practitioners]. Yeah, I think with newly trained, uh, with PwPs in training or or very recently qualified. My sense is that they often aren't that confident with it [assessing and treating people with LTCs]"*– CBT therapist; exposed to COMPASS.
>
> "sometimes people within IAPT [Talking Therapies] never worked with [someone with] tinnitus [for example]. So [they think] how on Earth am I going to do that? …. I've never had a whatever it might be condition, and the patient expects me to understand it. ….So so there's the the clinician confidence base and and and knowledge base." - CBT therapist; exposed to COMPASS.

Subtheme 1.2: Lack of training and outside of specialism.

All participants discussed the importance of mental health training when working with people with diabetes but lack of time and resource was identified as the common obstacles:

> "I was at one point providing kind of monthly teaching sessions [with the diabetes team], but, um, the that that that was when we didn't, we weren't having as many direct referrals…if I had more time, I would like to do that. But there's there's is not the resource at the moment to do that." - Clinical health psychologist; not exposed to COMPASS.

Alongside this, in Talking Therapies participants explained that LTC training was a "top up" rather than a core part of their therapeutic qualification training, potentially impacting their confidence and knowledge of the psychological needs in diabetes:

> "*it needs to be included within the core [talking therapies training] …. I remember struggling with that when when I did the CBT training that it needs to be a top up… I mean, I've been in the service for [a number of] years. Uh, and before this [LTC top*

> *up course], I had one training around Medically Unexplained Symptoms 10 years ago, and another training on diabetes. It was like a two-hour thing, again over a decade ago. So it's fairly minimal."* – CBT therapist; exposed to COMPASS.

This tended to link to clinicians feeling less confident to recommend and explain LTC treatments like COMPASS:

> *"personally, I don't feel like I know enough about it [COMPASS] to be able to explain and give it probably enough justice of what it is."*– Psychological Wellbeing Practioner; exposed to COMPASS.

Subtheme 1.3: The importance of joined-up care.

There was a unanimous sense from participants that integration with physical health teams is helpful to better manage the psychological care of people with diabetes and support clinicians:

> *"What I think is really helpful is kind of being in, the clinician, the psychological clinician, being embedded in a clinic. And so they [physical health team] know your face, they know who to approach, they know who to have a chat with. And also they know that you're, they can just knock on your door and kind of approach you that way. And I think it's those informal chats as well that help people to kind of know why psychology and psychiatry is there"* - Clinical Health Psychologist; exposed to COMPASS

However, many participants felt that this integration and communication between different services and healthcare teams was lacking:

> *I think if there if there were, if there was better communication and tighter links [between services], I think that would really support, um, clients with LTCs in [place]..."* – CBT therapist; exposed to COMPASS.

For example, in one of the Talking Therapies services, participants expressed the benefits of having LTC "champions". These champions are therapists who have been allocated a specialised role in their team to link in with physical health services and provide other clinicians support:

> *“ it's really helpful to have the champions because they have really good links with the hospital teams or with any multidisciplinary team meetings that are going on.”* - CBT therapist; exposed to COMPASS.

Theme 2: Using COMPASS within the practical constraints of current care.

Subtheme 2.1: Systemic barriers to Compass delivery

Participants described systematic barriers to implementing COMPASS, such as high staff turnover which can lead to information getting missed by clinicians:

> *“There's vast sort of turnover of PwPs. They've got so much to learn in such a short period of time, and as soon as they get experience, they move on.”* – CBT therapist; exposed to COMPASS.
>
> *“because the guides are the trainees [on rotating placements]...But I suppose [I wonder] in terms of the actual model of Compass, whether having trainees is always the best.”* – Clinical Health Psychologist; exposed to COMPASS

Similarly, changes in service provisions mean that the available resources for diabetes patients often change, making it challenging for clinicians to remember new interventions and/or referral pathways:

> *“I don't know if you've heard of that [intervention].... That was great while it was available, and then the [Organisation] didn't commission it.....So there's so many changes to keep up with all the time.”* - Diabetes community nurse; not exposed to COMPASS.

In the current study Talking Therapy employees or Trainee psychologists provided the guided support on COMPASS within routine care, however participants queried the sustainability of this delivery model and cited funding as a barrier to the longer-term implementation of COMPASS in NHS services:

> *“paying for for something ...yeah, it is a big barrier because, um, it's it's not like it. It's not like there's just a kind of budget freely available to to just commission things. If that makes sense, it has to go through a lot of like it has to go through a lot of bureaucratic processes. So if the money were available for it, it .... would require time and energy to to to get the money for it.”* - Clinical Health Psychologist; not exposed to COMPASS

Therapists using COMPASS also indicated that service requirements in physical health settings were a barrier to implementation:

> *"...that was the struggle, the implementation of, like, a programme that's separate from the service, but is also integrated, trying to be implemented in the service, created more admin than I personally would have liked.... also like, you know, how to communicate with them if you book it through Compass messaging or, like, they would also then receive a text from the service, but then the service would be the wrong time than we'd agreed on Compass...."* - Clinical Health Psychologist; exposed to COMPASS

Subtheme 2.2: Digital therapies as a possible solution.

All participants tended to appraise internet-enabled CBT treatments positively in general and acknowledged the potential of internet-CBT like COMPASS to increase resources, and therefore access to psychological therapy for people with diabetes.

> *"If I was using it (COMPASS) in my practise, it would be, you know, I I like I say if they're on the waiting list, I'd say, why don't you have a go at that? And then I would be very say, when they, um, reach the top of my waiting list and I'm going to start therapy with them. I .... I think that it could [also] be used to to to supplement the sessions I'm doing with them.."* – Clinical health psychologist; not exposed to COMPASS

Additionally, COMPASS was cited as an intervention that could be given to diabetes patients earlier in the care pathway therefore reducing workload in specialist diabetes services:

> *"it creates more of a stepped-care service than we have .. And I think that's important, because if we've got to reserve our time for the people that need it most, it means that we're not then offering the people who, if we intervene, excuse me, early, we're actually preventing further problems in the future"* – Clinical health psychologist; exposed to COMPASS

> *"I think if there was an intervention that people could use, um, straight away at the point of referral, um, I think that could be beneficial...."* – Clinical health psychologist; not exposed to COMPASS

Participants also indicated that internet-CBT gave them variability within their diary which positively impacted their relationship to their work overall:

> *"And from a PWP perspective, it means that we get like, variety in our diaries as well. So you're not doing kind of back to back telephone calls all day, but you can kind of*

> *break it up and do some online reviews, and I think that's just so important. Like variety as a PWP in terms of minimising burnout"*– Psychological Wellbeing Practitioner; exposed to COMPASS

Also some participants described benefits of the platform such as providing tailored information to scaffold for their work and ease their workload:

> *"I would [usually] put a lot of time, a lot of time of my day into planning sessions and making my own resources, and really trying to understand it. Whereas Compass, it was there, so it took away that extra time, but also took away the, like, it meant you started the model, right? You didn't do anything off, I didn't have to figure out what the model was, how I could implement it properly, how I could make sure I was sticking to the protocol, because it's all there on Compass, and that for someone who is less experienced or less confident in the use of a model, I think it's really helpful and beneficial."* – Clinical Health Psychologist; exposed to COMPASS

However, there did appear to be some resistance from therapists to use digital interventions. Specific to delivering COMPASS some therapists were worried about delivering a novel or unknown intervention:

"There is something about digital work.. there's just absolute resistance to digital work" – CBT therapist; not exposed to COMPASS.

"I think it creates a lot of anxiety when there's a new programme that they have to learn the ropes of... the anticipation is big.....Once, you know, you've had that training and suddenly you've been told to have a COMPASS client that get creates quite a lot of anxiety.." - CBT therapist; exposed to COMPASS.

Subtheme 2.3: Rigidity of care pathways.

Participants expressed a need to be more flexible when working psychologically with people with diabetes, however rigid national objectives and individual service targets were a barrier to this, especially in talking therapies:

> *"…[In Talking Therapies] there's more pressure and maybe a little bit less flexibility.. an issue we we have, that one of our KPIs [key performance indicator] is our recovery. at least it's something that the commissioners very much want to know about…that's why we [in talking therapies] have much tighter structures so that the throughput can be maintained and our waiting lists are managed...that might be restrictive especially for an LTC population."* – CBT therapist; exposed to COMPASS.

Some participants described the presence of diabetes-specific biological criteria within current care pathways. This was cited as a barrier to treatment suitability, potentially influencing the long-term implementation of COMPASS for people with diabetes:

> *"there's a few, um, points that the client needs to meet to be able to be eligible for our service. So one, for example, is the Hba1c has to be, um, below, uh, 9%. ..so that would suggest that the diabetes is quite well managed…Um, but if the numbers getting above nine, it would suggest that they're struggling to manage that. So in that case, they probably benefit from a kind of more holistic approach…."* - CBT therapist; exposed to COMPASS.

Alongside this, participants described feeling unsure of how to adapt their work to integrate digital treatments that don't conform to their understanding of the current pathway:

> *"So, and because they have LTC, they can be quite some distress about their situation. They can also, you know, need, so maybe they need a lot more hand holding. But by definition, computerised programme is not hand holding in Talking Therapies… because this is digital, this is computerised programme. This is not supposed to be hands-on. It's like one to one. That's how I implement it anyway. And this is what the digital meant to be..."* – Clinical psychologist; exposed to COMPASS.

Theme 3: Patient barriers and facilitators to uptake and engagement.

Subtheme 3.1: Therapy beliefs, normalisation and availability.

Stakeholders described practical patient barriers and facilitators to uptake of COMPASS such as access to the internet and confidence with technology.

Additionally, participants expressed that the introduction and description of psychological support in diabetes influenced uptake:

> *"One of the things that are, um, important to explain to patients is, I think a lot around, just kind of normalising some of the emotions that come with, um, diabetes as well. Um, because..if I think about when I first started off in the role, people thought that if they were referred to psychology, it meant that there was, You know, I remember one patient put it as something wrong in the in my head.."* – Clinical health psychologist; not exposed to COMPASS.

In line with this, participants indicated that patient beliefs and expectations of therapy may influence the uptake of COMPASS:

> *"I guess, like beliefs, as I mentioned earlier, like what they hold about therapy itself and like psychological support and whether or not that's going to help them if they're struggling with a long term condition."* – CBT therapist; exposed to COMPASS.

> *"People kind of come in with fixed ideas about what they should be getting. And that's often a face to face….so there might be quite a big difference in terms of their expectation."* – CBT therapist; exposed to COMPASS.

Many participants acknowledged that the availability of COMPASS was a patient facilitator to the uptake of COMPASS.

> *"One of the main things that I think helped uptake was that there were limited options in terms of the support that they could have from our service…Compass could be offered immediately to them, they could start pretty much instantly, … yeah, immediately having a therapist and access to the content, people like that idea"* - Clinical Health Psychologist; exposed to COMPASS.

Additionally, the relevance of COMPASS to diabetes was something that participants perceived to be a patient facilitator to the uptake of COMPASS:

> *"I do know of several people, more than several, who have come into the diabetes psychology service and they've had previous talking therapies and the conclusion of that talking therapies is that it might be helpful for them to have some diabetes specific support. So it's kind of like they've done a piece of work around, say, anxiety, and now they want to apply it to diabetes."* – Clinical Health Psychologist; exposed to COMPASS.

> *"I think it will be very frustrating. I think if you're referred to somebody who's got no idea or doesn't really understand what it's like [to live with diabetes]."* - Diabetes community nurse; not exposed to COMPASS.

Patient choice was cited as both a facilitator and barrier to the uptake of COMPASS:

> *"think it is important to take into account patient preference. I worked in an old service, and they would kind of just offer [name] [digital treatment] for certain patients, then people start to resent and don't engage with it, so I don't think that's good. But the problem, we then have is there's not as much uptake with it when there is patient choice."* - Psychological Wellbeing Practitioner; exposed to COMPASS.

Subtheme 3.2: Multimorbidity, complexity and motivation.

Complex personal circumstances were cited as a barrier to engagement with psychological therapy overall and COMPASS specifically:

> *"So some clients, um, they've got they might they might have quite chaotic or very challenging, um, social contexts. So, like, issue issues with housing or caring responsibilities or all sorts of things that mean that, um, they they they don't have the kind of space to engage with the psychologist"*– Clinical Health Psychologist; not exposed to COMPASS.

Specific to adults with diabetes, participants expressed that the challenges and demands of living with diabetes may influence engagement with COMPASS:

> *"often what we notice is that someone particularly with diabetes type one, it is such a full on [condition]. Um, it's like an extra job, basically organising their condition, their appointments...They want therapy, they want everything. And then just as quickly, something else might take priority. And they haven't got the time to kind of keep up with that... And the energy to put into using a programme [like COMPASS] would be a really important factor."* - CBT therapist; exposed to COMPASS.

Motivation was also cited as a key factor influencing patient engagement with COMPASS:

> *"For some patients, a big motivator can be a a deterioration in their physical health. So they might have had, um, diabetes related complications like retinopathy or neuropathy or something like that. And that's been a motivator for them to want to, um, make changes ... Um, For some people, the motivator might be, um, the yeah, they they just they to know that something might have happened where they they kind*

of reached a point like a bit of a crisis point with with the the distress related to it." - Clinical Health Psychologist; not exposed to COMPASS.

"I think perhaps.. people don't like self-directed learning so they can find that quite difficult. And I think what we do find as well if people are feeling quite depressed. The last thing they want to do is to log on to a programme, um, and be in charge of their learning." - Psychological Wellbeing Practitioner; exposed to COMPASS.

6.5 Discussion

This study provided insight into the barriers and facilitators to implementing COMPASS; an internet-enabled CBT intervention into routine NHS care, from the perspectives of stakeholders responsible for diabetes care. The study demonstrated that generally stakeholders working in diabetes care acknowledge the need for a scalable psychological treatment that can meet the needs of adults with diabetes. Participants acknowledged that digital therapies such as COMPASS are one way to increase access to psychology and support clinicians to provide tailored psychological support in diabetes care. However, barriers and facilitators to implementing COMPASS in routine care were multi-layered and existed at the patient, therapist, service, and system-level.

Comparison of study findings to previous literature

The importance of knowledge and understanding around the link between mental and physical health within diabetes care was acknowledged by all participants as a factor influencing the implementation of COMPASS. In our subtheme '*attitudes and perceptions of psychological care in diabetes'* we highlighted that knowledge appeared to influence stakeholders' attitudes and confidence towards working psychologically with people with diabetes. Further, stakeholders' confidence and attitudes towards working psychologically with patients with diabetes varied across settings.

Generally, participants working in physical health settings tended to have greater awareness of the importance of the link between mental and physical health. However, in Talking Therapies participants expressed a perception that many therapists have an aversion to LTC working, due to a lack of personal interest, confidence, and knowledge of how to support people living with diabetes.

Lacking knowledge, confidence and negative perceptions of LTC working has been cited as key barrier to implementing integrated care (Knowles et al., 2013; O'Reilly et al., 2017; Wakida et al., 2018) from the perspective of psychological therapists (Carroll et al., 2021) and diabetes nurses (Benton et al., 2023; Hadjiconstantinou et al., 2020) despite their acknowledgement of its value to bolster confidence and knowledge. Indeed, in our study participants positively appraised co-located psychology in physical health teams. Hence, Talking Therapies LTC guidelines (National Collaborating Centre for Mental Health., 2018) recommend joined up, co-located working.

It has been acknowledged that another way to overcome this barrier is through training (Benton et al., 2023; NHS Digital., 2023b). However, our study suggests healthcare professionals do not feel adequately trained to provide support outside of their respective mental or physical health specialism, which aligns with previous findings (Benton et al., 2023; McCrae et al., 2015). Specific to Talking Therapies services, despite a policy push for Talking Therapies to support patients with co-morbid LTCs such as diabetes (Mental Health Taskforce, 2016; National Collaborating Centre for Mental Health., 2018), therapists still described minimal LTC training as part of their core competencies for qualification (Roth & Pilling, 2008) and only optional "top up" training post-qualification (National Collaborating Centre for Mental Health., 2018). This systemic view of LTC training as an afterthought may overtly influence clinician knowledge, skill and confidence, and covertly influence their attitudes towards an LTC intervention such as COMPASS (Gask, 2005; Knowles et al., 2015).

Although, the distinction between skills and knowledge should be considered. Knowledge does not always translate to changes in behaviours or beliefs (Sligo & Jameson, 2000). Therefore, the development of skills should be prioritised alongside knowledge. Skill development is ongoing and can be enhanced by LTC and COMPASS-specific clinical supervision (Richards, 2014). However, despite the potential of training as a solution, it should be noted that as part of the implementation of COMPASS, training and clinical supervision was provided to clinicians, and uptake and adoption was still low (see chapter 4). Therefore, suggesting that there are other contributing barriers to the implementation of COMPASS.

The potential to increase access and reduce short term (e.g. less input needed) and long term (e.g. reducing waitlists) workload were cited as facilitators to the implementation of COMPASS by both psychological and non-psychological stakeholders. However, psychological stakeholders expressing this view tended in more senior roles. Furthermore, the value of digital did not tend to be acknowledged as readily by more junior clinicians, perhaps due to low confidence and poor knowledge discussed above. Having said that, some clinicians indicated that COMPASS may provide a solution to overcome some of the barriers highlighted above regarding confidence and knowledge. For example, in general, therapists who used COMPASS, positively appraised the intervention explaining that the embedded-LTC protocol bolstered their understanding and confidence to work with people with diabetes. Additionally, in Talking Therapies therapists expressed that COMPASS added variety to their workload which may be protective for future burnout (Westwood et al., 2017).

However, this was not a unanimous opinion as some clinicians working in psychological role highlighted that they perceived a common resistance to digital working within their service. Similarly, other research outside of diabetes and LTC populations, has highlighted that attitudes are a key factor to implementing e-health interventions (Ross 2016). Indeed, research has shown that negative clinician attitudes towards internet-enabled CBT (Duffy et al., 2023) indicating that this is not a barrier unique to COMPASS. Previous research indicates that lack of familiarity with internet treatment (Wilhelmsen et al., 2014) and/or beliefs about how therapy should be delivered (Folker et al., 2018) may be a key driver of this resistance. Our findings align with this as therapists expressed anxieties around COMPASS delivery.

Therefore, there is potential that attitudinal barriers and facilitators to the implementation of COMPASS are operating at two levels: LTC-specific and digital-specific.

Participants expressed concerns about how COMPASS, a digital treatment for adults with diabetes fit into the current pathways. Specifically in talking therapies, some participants indicated that the current conceptualisation of internet-CBT is that it is a self-guided, low-intensity intervention. In contrast, it seemed that the perception of LTC clients is that they are complex. Hence, they described that this incompatibility made it challenging to see how successful implementation could occur. The perception that internet-CBT should be used as a treatment for mild depression only is not uncommon and has be seen previously (Topooco et al., 2017). Currently, internet-CBT is recommended for mild-to-moderate depression (National Institute for Health and Care Excellence [NICE]. 2022). However, preliminary evidence indicates that in the absence of suicidal risk the effectiveness of internet-CBT is not moderated by symptom severity. This finding has been shown in diabetes (van Bastelaar et al., 2012) and with COMPASS treatment (Picariello et al., 2024b). Therefore, more work may be needed alter these perceptions.

Additionally, participants in talking therapies expressed the need to work flexibility with people with diabetes but highlighted that national objectives and thus service targets make this challenging. This misalignment between patient-centred psychological treatment and national targets has been observed elsewhere (Rushton et al., 2019).

Additionally, our theme '*Using COMPASS within the practical constraints of current care'* described numerous physical barriers to the implementation of COMPASS across their settings, such as staff turnover, changing service provision, funding, and service requirements (e.g. admin and performance targets). Currently COMPASS is run in the context of a research project. This may contribute to the changing service provisions, but without funding and services that can infrastructurally support adults with diabetes and therapists to use and deliver COMPASS, this will continue to be the case. Compatibility with current systems, available resource and cost have all been identified as key factors to influence implementation of internet-interventions (Ross et al., 2016).

Internet access, technical literacy and patient beliefs/expectations were identified as key barriers to uptake and engagement with COMPASS from the perspectives of stakeholders. Furthermore, the normalisation of psychological support provisions appeared to facilitate access and engagement to COMPASS for diabetes patients. This aligns with wider literature suggesting that stigma and negative perceptions around help-seeking and mental health support in general are key barriers to psychological support access in the general population (Salaheddin & Mason, 2016). Additionally, specific to people with diabetes, clinicians cited the demands of living with diabetes as a barrier to implementation of COMPASS. However, the availability and relevance of the programme for adults with diabetes as a facilitator for its implementation. This builds on findings presented in study 4 indicating that the relevance of COMPASS is positively appraised by patients and identified as a facilitator to usage by stakeholders.

Recommendations for future implementation

Training and supervision.

As highlighted above training and supervision are crucial for the future implementation of COMPASS to address negative perceptions and attitudinal barriers digital and LTC specific CBT. However, training should focus on both knowledge and skill development. Ongoing clinical supervision is one way to enhance skills, promote confidence and reflect on attitudinal barriers.

Having clear indications of use.

As discussed above, despite training and education, some clinicians hold inaccurate beliefs about patient suitability for COMPASS often in regard to mood severity. This is despite quantitative research evidence indicating that clinical severity does not moderate the effectiveness of COMPASS (Picariello et al., 2024b) indicating that COMPASS holds potential to benefit patients with higher mood scores. Therefore, future work should aim to address these inaccurate beliefs through clearer indications of use, better education, and provision of accurate treatment information for clinicians.

Co-located working.

The value of co-located, collaborative working is recognised at an individual and policy level as one way to improve mental health care for people living with diabetes and other LTCs (Knowles et al., 2015). As highlighted in this study, the benefits of co-located care extend beyond the patient and are another way to increase clinician confidence and knowledge. Hence, Diabetes UK (Sachar et al 2023) recommend that Talking Therapies-LTC pathways are embedded within diabetes services. However, many system level challenges exist around co-located care as it currently stands. Therefore, when co-location is not possible “champion” roles may help to bridge this gap in each respective setting (Miech et al., 2018). For example, in physical health settings a psychology and/or COMPASS champion and in Talking Therapies, an LTC and diabetes and digital champion (Panchal et al., 2020; Valente & Pumpuang, 2007).

Offering digital CBT interventions across the whole of care pathway.

Offering digital CBT across the whole of stepped care may tackle the challenges faced by current, rigid care pathways. In the current study, alongside Talking Therapies (primary care), COMPASS was delivered in a diabetes service through a specialist psychology team (secondary care). The implementation of COMPASS appeared more feasible here than in Talking Therapies, hence where possible, secondary care diabetes services may use digital interventions to increase access to psychological support. This could be offered in numerous formats e.g. a as a stand-alone treatment or as an adjunct to face-to-face therapy (Newby et al., 2021).

Alternatively, diabetes commissioners may look towards a hub model of care as highlighted within the COMPASS trial (Picariello et al., 2024b) as a way to improve access to psychological treatment for people with diabetes. However, future studies are needed to confirm the use of digital CBT interventions across patients and stages of care as currently NICE only recommend internet-therapy for mild-to-moderate distress (NICE., 2013).

Stability of resource.

To improve stability of resources key decision makers must acknowledge the value of both LTC-specific and digital interventions and provide adequate funding to ensure consistency of resources. From our findings it appears that overall, service leads acknowledge this, yet there seems to be misalignment with wider funding decisions, clinician guidelines, and service targets set by NHS decision makers, as seen elsewhere (Rushton et al., 2019). Thus, from a funding perspective more health economic arguments may be needed to highlight the benefits of internet-enabled therapies such as COMPASS.

Specific to diabetes, the importance of commissioning has been recognised as a paper by Sachar et al (2023) outlined key recommendations for local implementation of mental health care in diabetes and cited better commissioning as key to increasing access to psychological treatment in diabetes care.

Strengths and limitations

Participants represented a wide range of stakeholders with different perspectives and responsibilities for implementing services for adults with diabetes. This is a strength as we were able to triangulate insight from psychological clinicians and non-psychological clinicians, those who had been exposed to COMPASS and those who had not. This allowed us to explore wider barriers and facilitators to the implementation of COMPASS for adults with diabetes within routine care beyond the intervention and one setting. Additionally, the inclusion of stakeholders with a range of experience across primary and secondary care added to the generalisability of our findings. However, there may have been selection bias in our sample as although we were exploring barriers to implementation, the participants chose to take part. Additionally, stakeholders were recruited from settings in London England only, therefore steps should be taken to explore the perspectives of more diverse groups in different locations as the findings will likely differ.

6.6 Chapter conclusion

Findings from this chapter indicated several barriers to COMPASS implementation at two levels: i) working with people with LTCs and ii) using a digital intervention. Implementation strategies to address the barriers were outlined in this chapter including: i) extra training and supervision for working with LTCs and using digital tools, ii) co-located working, iii) expanding digital implementation across the care pathway, iv) having clear indications of use. This has implications as there is a clinical need to improve access to psychological support for adults with diabetes in routine care (Sachar, Breslin, & Ng, 2023) and to bolster treatment outcomes (Seaton et al., 2022). One scalable way to achieve this is using digital CBT that considers the challenges of living with an LTC such as COMPASS (Picariello et al., 2024b;

Seaton et al., 2023). Therefore, future work should future explore and test these strategies as a way of addressing the barriers and enhancing the facilitators presented in this chapter.

Chapter 7. General Discussion

7.1 Chapter overview

As highlighted in the preceding chapters, psychological distress is prevalent in adults with diabetes and is associated with poorer health outcomes and increased healthcare costs (Diabetes UK, 2019). The need for accessible and effective psychological support in routine care for adults with diabetes is well recognised. Robust evidence has demonstrated the potential of CBT as a treatment option to improve psychological distress in adults with diabetes (Jenkinson et al., 2022). Further, research evidence indicates that CBT adapted to consider the challenges of living with diabetes enhances treatment effects, acceptability, and engagement (Nobis et al., 2018; Wroe et al., 2018). However, tailoring interventions is costly, time consuming and challenging to deliver at scale (Gandy et al., 2018). Internet-enabled CBT is one solution to this.

Internet-enabled CBT is an effective and potentially cost-effective treatment for adults with LTCs (Mehta, Peynenburg, & Hadjistavropoulos, 2019; White et al., 2022) and specifically diabetes (Jenkinson et al., 2022). Hence, a research team a Kings College London developed COMPASS, a therapist-guided digital CBT intervention to treat psychological distress related to living with an LTC. COMPASS has demonstrated efficacy in a robust RCT context (Picariello et al., 2024b) and effectiveness in routine NHS primary and secondary care (Seaton et al., 2023). However, gaps in the literature remain, particularly regarding the translation of research into practice for internet-enabled CBT in routine care for adults with diabetes. Therefore, the overarching aim of this thesis was to explore the feasibility of implementing COMPASS, an internet-enabled CBT intervention into routine NHS clinical practice tailored specifically for adults with diabetes and co-morbid psychological distress. To address this, a systematic review and three empirical research studies were conducted:

1. Study 1 (Jenkinson et al 2022; presented in chapter 2) was a systematic review with meta-analysis. It aimed to test the efficacy of CBT and third-wave CBT interventions on: diabetes distress, depression, anxiety, and HbA1c. A secondary objective of the review was to examine which intervention components are most useful in treating diabetes-related distress.
2. Study 2 (presented in chapter 4) used mixed methods (qualitative and quantitative). It explored the implementation of COMPASS into routine NHS care for adults with diabetes and co-morbid psychological distress. The specific research objectives for this study were defined using the RE-AIM framework of implementation (Glasgow, Vogt, & Boles, 1999). As part of this study, the barriers and facilitators to implementing COMPASS were qualitatively explored from the perspective of patients with diabetes.
3. Study 3 (presented in chapter 5) used a cross-sectional observational design and routinely collected service data from NHS digital. It examined if people with LTCs (including diabetes) were less likely to attend and engage with Talking Therapies services compared to people without an LTC. It also explored if LTC status influenced the receipt of internet-enabled therapy.
4. Study 4 (presented in chapter 6) used qualitative thematic analysis to examine the barriers and facilitators to implementing COMPASS from the perspective of those implementing COMPASS (e.g. health-care professionals) and wider stakeholders (e.g. commissioners).

This final chapter will provide an overall discussion across the four studies in each chapter of this thesis. It will highlight the research strengths and the novel contributions made to the literature. Limitations to the body of research, and clinical implications will then be discussed within the broader context of implementation science research. Future research to continue this work moving forward will then be outlined alongside an overarching conclusion.

7.2 Summary of findings and contributions to the literature

The overall aim of this thesis was to explore the implementation of COMPASS; an internet-enabled CBT intervention to treat psychological distress in two routine NHS care settings for adults with diabetes. Collectively the studies identified novel factors that need considering when implementing digitally delivered psychological interventions to adults with diabetes.

The systematic review (with meta-analysis) (Jenkinson et al 2022; see chapter 2) was the first systematic review and meta-analysis to focus on diabetes-related distress as the primary outcome of interest with depression, anxiety and HbA1c listed as secondary outcomes. This enabled the effectiveness of CBT and third-wave CBT on each of these outcomes to be examined. A novel finding of the review was that CBT significantly improved diabetes-related distress. Of note, when diabetes distress was listed as the primary outcome, the trial effect sizes were larger. This may be because these trials tailored their interventions more specifically to address the emotional response to living with diabetes, but poor reporting of intervention content made this difficult to ascertain. However, wider diabetes literature (Nobis et al., 2015; Wroe et al., 2018) and research in other LTCs (Moss-Morris et al., 2013) has shown that tailoring interventions increases treatment effectiveness.

The review also demonstrated that larger treatment effects were observed on diabetes-related distress outcomes when CBT was: i) digitally delivered, ii) was supported by a trained psychological practitioner and, iii) included behavioural activation. Thus, the outcomes of the review, confirmed that using a therapist supported digital intervention like COMPASS to treat psychological distress in diabetes is warranted given the statistically significant treatment effects observed across the included studies. However, none of the studies included in the review were conducted in routine clinical practice. This identified a clear need to explore how feasible it is to effectively improve psychological outcomes using COMPASS in the NHS. The review also acknowledged that whilst CBT improved diabetes distress, treatment effects remained small. Thus, a consideration for study two (presented in chapter 4) was to explore potential adaptions that could be made to COMPASS to target the emotional needs of people with diabetes specifically.

Study two used mixed methods (see chapter 4) to answer the overarching question of this thesis, specifically is it feasible to implement COMPASS into routine NHS care for adults with diabetes and co-morbid psychological distress. As discussed in chapter three, there is a need to consider both the effectiveness of an intervention alongside its adoption in the real-world (Lipschitz et al., 2019).

A strength of this study (see chapter 4) was the incorporation of the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework (Glasgow, Vogt, & Boles, 1999). Specifically, RE-AIM helps to define outcomes when studying complex interventions in the real-world. Thus, a novel finding of this thesis was the ability to explore the population "reach" of a digital mental health intervention. The study findings highlighted the disappointing reach of COMPASS as the conversion rate of adults with diabetes who were referred for psychological support to those accessing COMPASS was 20% in the diabetes service, and only 0.70% in the Talking Therapies services.

This is lower than what was observed in the RCT of COMPASS (Picariello et al., 2024b) and an RCT of another diabetes-specific web-based CBT intervention aiming to reducing depression and diabetes-related distress (Van Bastelaar et al., 2011). Additionally, this is lower than the observed reach of other remote therapy delivery in Talking Therapies (such as telephone delivery; reach = 16%) (Saxon et al., 2023). However, the use of mixed-methods and conducting qualitative interviews with patients provided further insight into potential barriers patients face in selecting a digitally delivered intervention.

Indeed, participants expressed that the way COMPASS was explained to them by clinicians was confusing and that there was a lack of clarity around the digital element of COMPASS. Unclear explanations of treatment have been observed as a key barrier to implementation of remote therapy delivery in NHS care in other qualitative work (Rushton et al., 2020). Additionally, across both settings, COMPASS appeared to be explained to patients as a substitute for face-to-face treatment. Much rhetoric around digital therapies exist, including the perception that they are less useful, credible, or effective (Beatty & Binnion, 2016; Borghouts et al., 2021). Therefore, this description may have reaffirmed the rhetoric surrounding digital therapy and was likely another barrier to the overall implementation of COMPASS.

Additionally, participants in Talking Therapies expressed a lack of clarity around the LTC-specific nature of COMPASS which may have been a barrier for adults with diabetes to use and/or accept the intervention as they were unclear on its relevance. The explanation of psychotherapy interventions has been cited as a key facilitator to treatment initiation and long-term usage (Bowker, Saxon, & Delgadillo, 2024). Therefore, taken together, an important target to improve the implementation of COMPASS is likely the clinician "sell" of both the integrated and digital nature of the intervention.

One way to mitigate confusion may be through targeting system level-change. Specifically, in chapter 4, patients emphasised that the normalisation of referrals to psychological support within diabetes care facilitated access and engagement to psychological services. Therefore, this is a target to support future implementation. This patient finding aligns with current guidelines that demonstrate the importance of integrated care in diabetes (Sachar, Breslin, &

Ng, 2023). However, the experiences of integration and normalisation did not appear to be standardised and fluctuated across settings.

The "implementation" findings defined by the RE-AIM framework, also identified the importance of examining the implementation of COMPASS following the RCT protocol (Hulme et al., 2021). In the RCT, the COMPASS protocol was considered to have been implemented appropriately if patients completed five out of the eleven online modules and attended a minimum of three therapist sessions. However, findings in chapter 4 demonstrated that both online and therapist session usage were poorer than observed in the COMPASS RCT (Picariello et al., 2024b). Again, using mixed methods was of value as qualitative interviews identified adherence and fidelity challenges to the COMPASS protocol from the patient perspective. Indeed, many participants acknowledged the value of COMPASS and highlighted the LTC tailored content was a facilitator to engagement with the intervention. However, others expressed a desire for more practical diabetes management tools to be included. A misalignment between treatment expectations (e.g. believing COMPASS can support diabetes self-management) versus the intended purpose of COMPASS (e.g. to treat psychological distress in the context of diabetes) may have led to a lack of adherence. Some participants expressed disappointment with the therapist support and felt as though clinicians provided poor patient-centred, protocol-focused care. Previously the patient-clinician relationship has been highlighted as a key facilitator to digital treatment success in previous literature (Beatty et al., 2017; Lawler et al., 2021). Therefore, the lack of perceived support may have account for poor engagement with COMPASS therapist support sessions if patients were not perceiving an added benefit.

Furthermore, other research in the context of providing telephone therapy have reported that performance targets (e.g. delivering care efficiently) can conflict with the clinical needs of a patient (Rushton et al., 2019). This may have applied here in that COMPASS was being implemented as an efficient model of care to the detriment of patient-centred care. This is despite the COMPASS RCT findings showing 2.25 hours (S.D. = 1.07) of therapist time was effective whilst remaining efficient, and acceptable to patients (Picariello et al., 2024b).

Despite low rates of reach and usage, preliminary analyses exploring pre-post change trends suggested that COMPASS is an effective treatment for improving psychological outcomes for adults with diabetes in routine care. This aligns with previous work conducted in NHS settings (Seaton et al., 2023) but illuminates the research to practice gap that the thesis aimed to explore. COMPASS also appeared to hold potential for improving HbA1c which is a novel finding of this thesis. However, due to a small sample size we were not adequately powered for significance testing. Furthermore, confidence intervals around the treatment estimates were wide, hence these findings need to be confirmed with more work. As highlighted above, the qualitative findings revealed that patients expressed a desire for COMPASS to incorporate more diabetes self-management tools. Addressing this feedback could serve as a strategy to enhance integrated care and foster synergistic improvements in both mental and physical health outcomes.

Taken together these findings indicate that currently the reach, adoption, and implementation of COMPASS in practice is poor despite clinical need (highlighted in chapters 1 and 3), and the potential effectiveness of the intervention. However, chapter 4 findings identified further research questions to help elucidate the challenges linked to the reach, adoption, and implementation of COMPASS. Specifically, these outstanding questions were:

1) Are these barriers to the reach of COMPASS specific to the intervention or:
    a. do they exist commonly across psychological treatment for people living with LTCs including diabetes?
    b. do they exist commonly across digital interventions?

2) Are clinician, service and system level barriers and facilitators influencing the implementation of COMPASS and if so, what are these barriers and facilitators?

The quantitative cross-sectional study (presented in chapter 5) used large (*n*=17,095 referrals), routinely collected service-level data from two Talking Therapies services to explore if having a LTC including diabetes (vs not having an LTC) influenced engagement with psychological therapy which was defined as two different outcomes: i) assessment attendance and ii) treatment engagement (attending two or more treatment sessions). The study also explored if LTC status impacted on a person's likelihood of receiving internet-enabled therapy.

A strength of this study was that the analysis offered valuable context to the low reach of COMPASS observed in Chapter 4. Analysing a larger dataset (not limited to COMPASS) enabled a more nuanced understanding of the barriers contributing to the interventions limited reach. This analysis provided insight on the nature of these barriers and their placement within the broader care pathway.

The findings showed that across all referrals to the Talking Therapies services, there were no significant differences between those with an LTC vs those who did not have an LTC in terms of attendance at assessments and treatment engagement (all modes of delivery), after controlling for key confounders. Further, irrespective of LTC status receiving a digital treatment appeared to bolster engagement. This is promising, although, people who reported having a LTC were less likely to receive a digital intervention in Talking Therapies.

To our knowledge this is the first study to robustly explore how LTC status impacted assessment attendance, treatment attendance, and receipt of digital therapy in Talking Therapies whilst controlling for key sociodemographic and clinical characteristics.

For completeness, the population reach of digital interventions in NHS Talking Therapies was calculated in chapter 5 using the same method of calculation used in chapter 4. Specifically, for people without a LTC, digital interventions reached 5.71% of the referred population. For those with an LTC the reach of digital interventions was 3.23%. This is higher than the 0.70% reach observed for COMPASS implemented in NHS Talking Therapies (see chapter 4). However, this is still low, adding to the limited reach of digital therapies across LTC and non-LTC patients. Hence this suggests that barriers to engaging with COMPASS outlined in this thesis may not be unique to people living with an LTC. However, it appears that having an LTC adds a further level of complexity which reduces their likelihood of receiving and/or engaging this mode of treatment.

Finally, the stakeholder qualitative study (presented in chapter 6) provided an additional opportunity to gain insight into the poor rates of reach and implementation of COMPASS observed in chapter 4, from the perspective of key professionals working in diabetes care. A strength of this study was the inclusion of clinicians and wider stakeholders. Although patient perspectives offer tremendous value into barriers and facilitators to implementation, they do not afford insights into all the factors influencing this. It is commonly understood that implementing new healthcare interventions into dynamic systems (i.e. the NHS) affects individuals, organisations and wider system context (Flottorp et al., 2013). Hence, it is crucial to consider stakeholder perspectives.

Stakeholders recognised the necessity for more accessible and scalable psychological treatment for adults with diabetes and appreciated that COMPASS is one way to achieve this, yet through these interviews many barriers were identified. The barriers predominantly surrounded two main areas: 1) COMPASS as a digital CBT intervention, 2) challenges of integrated mental-physical health working. Furthermore, these barriers appeared to be operating at patient, clinician, service, and system-level.

Despite the acknowledgement that COMPASS, a tailored, digital CBT intervention may increase access for patients, findings in chapter 6 highlighted key deficits in clinician knowledge, skills, and confidence as a barrier to implementation. This finding is consistent with previous research surrounding remote therapy delivery (Faija et al., 2020) and specifically for people with LTCs (Carroll et al., 2021). Specific to Talking Therapies, findings presented in chapter 6 revealed a reluctance to using digital treatment particularly amongst junior clinicians. Negative therapist attitudes towards digital working has been highlighted as a consistent barrier to implementation (Pote et al., 2021). Partially, this may be due to a misalignment between digital therapy and clinician expectations of their role as a therapist (i.e. to build therapeutic alliance and deliver face to face therapy) (Faija et al., 2020; Meisel, Drury, & Perera-Delcourt, 2018; Mol et al., 2019).

Furthermore, some psychological clinicians appeared to hold inaccurate beliefs about the effectiveness, usefulness, and suitability of digital interventions for patients, as other research has likewise found (Andrews & Williams, 2015; Topooco et al., 2017). For example, the belief that they are only appropriate for patients with lower psychological symptomology and less complexity. This finding is not novel (Duffy et al., 2023), yet consistent research has shown that the treatment effects observed for digital CBT interventions (including COMPASS) are not moderated by symptom severity (Meyer et al., 2015; Picariello et al., 2024b). In contrast, other therapists recognised the value of COMPASS as a tool to support their work and reduce their preparation time. Therefore, if enhanced, this may be one way to support less experienced clinicians to deliver LTC-tailored treatment and facilitate future implementation of COMPASS.

Additionally, clinicians in Talking Therapies appeared to hold inaccurate beliefs about working with people with LTCs such as diabetes (e.g. that they are inherently more complex). These beliefs may have led to hesitation around working with a CBT protocol that considers the challenges of an LTC such as COMPASS. In-turn this may contribute to lack of clarity around the explanation of the LTC element of the treatment and thus the limited reach of COMPASS seen in Chapter 4. Previous research indicates that providing treatment rationales enhances the acceptability and update of internet CBT (Molloy et al., 2021) therefore, this may be one target to facilitate the implementation of COMPASS.

Most stakeholders cited structural barriers to the implementation of COMPASS; a digital LTC specific intervention. These barriers included incompatibility of COMPASS with current care pathways and service targets. Furthermore, a lack of resource and funding was cited as a key barrier. In light of this, some participants questioned the collective readiness for an intervention such as COMPASS, not only at the level of the healthcare service but also within the current constraints of wider care pathways.

In sum, this thesis demonstrated that an LTC-specific digital CBT intervention such as COMPASS has the potential to increase access to tailored psychological support and effectively improve outcomes for adults with diabetes and co-morbid psychological distress. However, challenges between research evidence and clinical practice remain and do not only impact patients but clinicians and wider stakeholders.

7.3 Clinical implications

From the three empirical studies of the PhD thesis, it is clear, that in implementing COMPASS in its current format without any infrastructure to support its adoption is unfeasible. Hence, clinical implications of this body of research exist.

As discussed throughout this chapter, despite consistent evidence indicating a clinical need for integrated, accessible psychological support in diabetes care (Diabetes UK, 2019; Sachar, Breslin, & Ng, 2023), the reach of COMPASS was low.

Routine mental health screening in clinical practice may be one way to enhance access to psychological support and promote joined up-care. Currently, routine mental health screening is recommended in outpatient healthcare settings (National Collaborating Centre for Mental Health., 2018). However, as demonstrated in chapter 4, no COMPASS users in the diabetes service were identified via routine mental health screening. Further, no COMPASS user in Talking Therapies was identified via a diabetes specific screening measure, despite recommended use of illness-specific screening tools in practice (National Collaborating Centre for Mental Health., 2018). Screening tools like the diabetes-distress screening measure (Fisher, Glasgow, et al., 2008) could support clinicians to accurately identify sources of distress and tailor treatment pathways, leading to improvements in outcomes (National Collaborating Centre for Mental Health., 2018). Additionally, screening may normalise integrated care and reduce stigma for patients. As supported by findings in chapter 4, patients highlighted that the normalisation of referrals to psychological support fosters access and engagement to therapy, and the long-term implementation of COMPASS.

However, it should be acknowledged that uncertainties surrounding the effectiveness of routine mental health screening in a primary care context exist. Evidence suggests that screening for depression does not lead to improvements in depression outcomes (Gilbody, Sheldon, & House, 2008; Thombs et al., 2021). Additionally, some healthcare professionals question the utility of mental health screening for people with LTCs without accompanying care pathways and treatment options (Barley et al., 2012; Roberge et al., 2016). Therefore, mental health screening in diabetes should only be implemented if there are care pathways in place to support onward referrals.

Despite long-standing policy prioritisation and guidelines (National Collaborating Centre for Mental Health., 2018) integrated working from the perspective of stakeholders remains a challenge. Indeed, findings presented in chapter 6 indicate that many clinicians expressed a lack of confidence and knowledge with working outside of their specialism. Additionally, Talking Therapies clinicians described minimal training in working with people with comorbid LTCs. This has significant clinical implications. People living with diabetes are likely to continue experiencing poor mental health, leading to ongoing clinical demand, affecting both clinical and economic outcomes. Further, where Talking Therapies services do provide psychological support, mental health outcomes will likely continue to be poorer for those with LTCs than those without as has previously been shown (Seaton et al., 2023).

One way to ameliorate this, is to improve training and supervision surrounding both digital and LTC specific working. This emphasis on workforce development is consistent with UK policy (National Collaborating Centre for Mental Health., 2018; NHS, 2019; Topol, 2019). Previous work has echoed the workforce challenges identified in this thesis such as therapist reluctance, lack of expertise and infrastructural barriers to LTC and digital working (Carroll et al., 2021; Pote et al., 2021). Therefore, NHS and University Commissioners should focus on workforce development by integrating LTC and digital competencies into core training for psychological clinicians. Findings presented in chapter 6 indicate that teaching and training around these areas is currently lacking and relies on individual service initiatives. Alongside skill and knowledge development, improvements in training and teaching may support the modification of negative perceptions surrounding digital and LTC.

At the service level employing principles of clinical case management and supervision (e.g. collaboration, reflectivity and empowerment between supervisor and trainee) can support implementation and adherence to psychotherapy protocols (Richards, 2014). Furthermore, ongoing clinical supervision should focus on problem-solving, skill development, and boosting confidence for clinicians working digitally with people with diabetes and other LTCs.

Taken together, improvements in training and supervision may combat two of the main barriers identified in chapter 6 of this thesis: i) clinician understanding of the value of digital treatment ii) clinician understanding of how CBT protocols and therapeutic working can be adapted for people with LTCs and co-morbid psychological distress. In turn this may support the “sell” of COMPASS to patients which this thesis identified as a barrier to implementation. However, taken together findings of this thesis highlight the multi-layered complexity of implementing COMPASS. Hence, relying on training for clinicians alone to bridge the implementation gap is likely insufficient and ongoing supervision can address challenges in real-time when they arise.

Therefore, NHS decision makers should consider increasing resources, adapting guidelines and altering service targets to align with their LTC (Mental Health Taskforce, 2016) and digital policy priorities (NHS, 2019) to increase the feasibility of COMPASS implementation. These policy documents promote patient-centred care, however findings in this thesis highlighted misalignment between patient and clinician needs, policy initiatives and service level requirements as seen elsewhere (Rushton et al., 2019).

Based on the findings of this thesis, one way to support this may be allocating more funding towards connecting services to promote collocated working. Co-location has challenges, but has been shown to increase clinician confidence and benefit patients (Knowles et al., 2015). Furthermore, as highlighted in chapter 6 of this thesis, joined-up care appears to be valued by clinicians. Where this is not feasible, dedicated champion roles may help to facilitate the implementation of both digital and LTC-mental health care pathways (see chapter 6).

7.4. Implications for implementation literature

As highlighted above, some of the findings presented in this thesis align with existing literature. For example, specific to digitally delivered interventions, negative perceptions (Beatty & Binnion, 2016; Borghouts et al., 2021), lack of clarity around the intervention (Rushton et al., 2020) and a lack of clinician confidence (Faija et al., 2020) have been seen as barriers to implementation previously. Furthermore, other literature has identified the importance of a clear explanation clinician confidence and knowledge in the implementation of psychological therapy (Bowker, Saxon, & Delgadillo, 2024) and LTC specific interventions (Carroll et al., 2021) confirming existing implementation findings.

However, this body of work not only confirms these findings but also expands the literature by exploring the implementation of a digital, LTC-specific intervention aiming to treat psychological distress (COMPASS) in routine diabetes care, a combination which has not been previously examined. Furthermore, the research explores implementation across primary and secondary care settings. Therefore, this body of work provides new insights into how implementation differs across contexts and individuals involved in the implementation process.

Additionally, this thesis extends existing literature by employing the RE-AIM framework, which offers a comprehensive structure to assess multiple dimensions of implementation. The use of this framework allowed for a broad and nuanced understanding of how the COMPASS intervention is currently integrated into clinical practice, highlighting novel strengths and limitations of the implementation process in ways that previous studies have not captured. Specifically, analysing service-wide quantitative Talking Therapies data (study 3) alongside COMPASS specific data, enabled comparison between the implementation of COMPASS and all digital products across Talking Therapies services. This provided greater understanding surrounding COMPASS implementation, revealing that digital implementation remains a challenge irrespective of interventions and populations. However, this appears to be further exacerbated by having an LTC. Moreover, studies 2 and 4 identified COMPASS-specific factors contributing to these challenges and suggested potential solutions from stakeholders within the service. Thus, the triangulation of these data sources provided a novel comprehensive view of the implementation landscape.

By applying RE-AIM, this thesis also introduces a more systematic approach to evaluating digital interventions in the context of diabetes care, enabling the comparison of outcomes across existing research and providing a blueprint for future research in this area.

7.5 Limitations not already discussed.

7.5.1 Systematic review (chapter 2)

The systematic review in this thesis aimed to examine the impact of the content and mode of delivery on treatment effects. However, the quality of reporting of intervention content was mixed. For example, some of the published RCTs included lots of detail about their intervention where others did not. This is a limitation as it may have added bias to the findings presented in chapter 2 as a study may have been coded as not having a specific intervention component when in fact it was not reported. Therefore, publishing treatment protocols alongside RCT findings would enhance understanding of active treatment ingredients.

Additionally, in the review CBT interventions were defined in line with the definition used by Fordham et al. (2021) in their large meta-review of existing systematic reviews (recently published at the time of conducting the work in chapter 2). Likewise, third-wave CBT interventions were defined as those that include techniques such as mindfulness meditation, acceptance of unwanted thoughts and increasing flexibility (Hunot et al., 2013) such as Acceptance and Commitment therapy (ACT) and mindfulness-based therapy. As no reviews had explored the active ingredients used to treat diabetes-related distress at the time of the review presented in chapter 2, these definitions felt appropriate to capture all relevant literature, to address the research questions and represent the CBT and third-wave interventions identified through the search. However, these intervention definitions lack objectivity which is a limitation. To reduce bias posed by these broad definition's consensus discussion with other members of the research team occurred when classifying an intervention that had been unclearly reported.

As discussed in chapter 2, more intervention studies aiming to improve diabetes-related distress are needed. The review included twenty-two RCTs overall, but the inclusion of multiple outcomes and analyses based on intervention type (traditional CBT vs Third-wave CBT) meant that in some analyses, the number of included studies was small. Therefore, the potential of type II error occurring should be considered. Type II error is where the sample sizes may have been too small to detect significant effects.

7.5.2 Implementation study (chapter 4)

To reiterate, the implementation study was conducted within routine care. Hence, infrastructures did not exist to collect eligibility and acceptability data concerning COMPASS. Therefore, accurately quantifying the reach of COMPASS and the reasons for this were not possible. These data acquisition challenges add uncertainty to the findings presented in chapter 4. Furthermore, the small sample size adds to the uncertainty and generalisability of the findings.

Additionally, effectiveness analyses focused on pre-post change scores. Quantifying effectiveness from change scores, increases the bias as there is no comparator group (Hariton & Locascio, 2018). Hence, it cannot be confirmed if the observed differences in outcomes presented in chapter 4 relate to COMPASS or other factors such as natural improvements in psychological outcomes over time that would have occurred without an intervention. A study looking at change over time on the PHQ-9 in a population without diabetes showed that 11.1% of sample reported a decrease in their score whilst 5.6% reported an increase in their score. Hence, a similar pattern may have occurred in this study (Round et al., 2020).

7.5.3 Use of self-reported measure across studies across studies

A limitation across the studies presented in chapter 4 and 5 was the use of self-reported measures of psychological and psychosocial outcomes.

However, as discussed in chapter 1, self-reported measures of these outcomes are common, and the measures used in this study are all validated to be used in adults with diabetes. Additionally, in the context of this thesis, self-report was arguably the most appropriate way to measure psychological and psychosocial outcomes as data collection aimed to mirror routine care as much as possible. Indeed, most of the self-reported measures collected for the purpose of study 4 by the research team are collected routinely in Talking Therapies service and make up their mandated minimum dataset (NHS Digital., 2023b).

However, specifically in chapter 4, social desirability may have influenced the responses to these questionnaires. Further, baseline responses may have been subject to acquiescence bias if patients felt that their scores would determine their access to psychological treatment (Hinz et al., 2007).

Additionally, chapter 4 utilised self-reported measures to assess disease characteristics such as HbA1c levels and diabetes type. The use of subjective measures rather than objective measures is a limitation. These disease characteristics may have been assessed more accurately by taking blood samples and/or or accessing patient records. However, taking blood samples as part of this thesis was not feasible due to financial constraints. Further, the researcher did not have access to all patient medical records. To mitigate this, participants were asked to report the date and means of ascertaining the results e.g. from memory or medical records.

Another limitation is that adults with diabetes were included if they self-reported or had an objective diagnosis of diabetes. The reason for this was that study inclusion was at the services discretion and Talking Therapies only require self-reported diagnoses (NHS Digital., 2023b). Although, previous evidence has shown a substantial concordance between both clinical and self-reported diagnoses of diabetes (Haapanen et al., 1997).

Another limitation is the exclusion criteria necessary for this study. COMPASS is an intervention that requires an ability to speak and read the English Language, own a computer, and access the internet. Therefore, this likely limits the reach of the intervention. Due to poor data reporting concerning eligibility and acceptability, we were unable to explore the influence of digital literacy, ethnicity, deprivation status and other socio-demographic factors influencing the reach of COMPASS. Therefore, this limits the overall generalisability of the findings concerning COMPASS reach. However, over half of the sample reported their ethnicity as being from a minoritised group. This is slightly higher than the sociodemographic profiles of patients attending the talking therapy sites that were recruited from (see Chapter

5). However, this was based on a crude way of defining ethnicity (e.g. binary minoritised group vs not) due to small sample size. Therefore, this may account for the differences between the ethnicity breakdown seen in chapter 4 compared to chapter 5. Further, quantifying ethnicity using a binary definition does not give a detailed insight into the specific ethnic minority groups who were accessing COMPASS.

7.5.4 Cross-sectional study; Talking Therapies (chapter 5)

The analysis conducted in this study was not limited to people with diabetes and included all LTCs. Therefore, the generalisability of the findings for all people with LTCs to people with diabetes specifically remains uncertain. However, this decision to include all LTCs was made to enable a broader exploration of the reasons for the low reach of COMPASS. For example, to explore if the challenge of low reach was common across psychological treatments for people with LTCs or to the challenges which surround digital interventions more broadly. However, it should be noted that 6.80% of all LTC referrals were made up of adults with diabetes, aligning with current UK prevalence rates (Diabetes UK., 2019, 2023b). This therefore indicates that the sample in chapter 5 was representative of the diabetes population.

Another limitation of the study is that LTC status was defined using a binary variable. This was selected pragmatically considering Talking Therapies data reporting guidelines. However, consequently, multimorbid LTCs were not accounted for in the analysis. Multimorbidity in health conditions is common (Barnett et al., 2012). Therefore, number of LTCs may have impacted outcomes and future work could explore this.

The challenging nature of the real-world data meant that restrictions were placed on the analyses. For example, engagement with treatment was defined as cases with two or more contacts with Talking Therapies where the purpose was coded as ‘treatment’. However, engagement may have been more accurately represented by quantifying the number of treatment sessions attended. Although, poor and inconsistent reporting by clinicians of usage data meant it was not possible to reliability quantify treatment dose, therefore making it challenging to explore this.

7.5.5 Stakeholder interview study (chapter 6)

The stakeholder interview study focused only on diabetes care delivered in London only limiting its generalisability to other contexts. Additionally, the influence of the researcher on qualitative findings in this thesis should be acknowledged. In both qualitative studies (see chapter 4 and chapter 6) the researcher who conducted the interviews was known to participants as the lead researcher which may have introduced social desirability bias into their responses. Moreover, many stakeholders (chapter 6) were employed at the settings involved in this research which may have introduced bias. To manage this, all participants were reminded in the study information sheet and consent form that the qualitative interview was optional and that all responses would be anonymised. Additionally, participants were given time to decide whether to take part.

Moreover, qualitative interviews are subject to personal interpretation, hence the analysis is naturally influenced by the researcher’s prior experience and knowledge. This inherently influences data interpretation. However, to try to reduce any biases introduced by the researcher, data was collected using a semi-structured interview guide to facilitate the exploration of participant perspectives rather than restricted to rigid questions designed by the researchers. To further reduce any biases, the researcher allowed guidelines by Braun and Clarke (2006) for conducting systematic and rigorous thematic analysis. Furthermore, themes were consistently cross checked against the data and discussed with the wider research team. However, other methods such as contacting participants to check the accuracy of themes may have been useful to reduce biases.

7.6 Future research

This thesis provided novel and necessary contributions to the literature. Of note it highlighted that without infrastructures to support COMPASS, it is unfeasible to implement it in routine NHS care, in the same way that was observed in the RCT (Picariello et al., 2024b).

A plausible next step for future work would be draw on novel implementation-effectiveness trial designs (Curran et al., 2012). Hybrid implementation-effectiveness trials combine research focussed on assessing the effectiveness of an intervention whilst also testing implementation strategies to support a complex intervention to be embedded in routine care sufficiently.

The effectiveness component of the trial would apply the same protocols as those used in the COMPASS RCT. However, based on patient feedback identified in chapter 4 adaptations are needed to COMPASS to make it more specific to diabetes. The tailoring of COMPASS will be further discussed below.

The value of a hybrid trial is their potential to allow for testing of the implementation strategies identified in the clinical implications section above. Firstly, utilising screening for distress would support the normalisation of distress when offered as a routine appointment. Routine screening would also support objective data collection on patient eligibility whilst providing infrastructures to collect data on patient acceptability. Hence, the reach question of COMPASS could be answered in more detail than was achieved in the current thesis.

Additionally, future work should aim to develop training and supervision informed by the findings in this thesis. Ongoing delivery of training and supervision could address therapist concerns about working with people with LTCs and the use of a digital therapy. Specifically, supervision should focus on supporting fidelity to the protocols. This may help to address the challenges of implementing COMPASS observed in this thesis.

Lastly having an LTC champion in the services in which COMPASS is implemented would help foster integration and provide a named point of contact to further enhance the integration. Additionally, the inclusion of a digital "champion", specifically in Talking Therapies services where other digital treatments are used would help to support the ongoing use of digital therapies. However, before launching a full-scale hybrid trial it is important to feasibility test the implementation strategies and likewise pilot data collection protocols.

Supporting engagement with digital interventions

Adherence and engagement to digital CBT interventions is poorly defined (Forbes et al., 2023). Further, as identified within this body of work personal, contextual, and methodological factors may influence engagement. Likewise, there may also be technological strategies that can promote engagement. For example, systematic reviews have shown that prompts such as push notifications or email reminders help to foster engagement (Alkhaldi et al., 2016). It would be helpful to explore and test the value of such approaches with COMPASS.

Tailoring the content of COMPASS further for people with diabetes

Qualitative interview findings from patients with diabetes appear to suggest a need to adapt COMPASS to make it more specific to diabetes through including more self-management tools. This may enhance the overall acceptability of the intervention. Therefore, future work could focus on tailoring the content of COMPASS for people with diabetes. Co-adaptation with a patient advisory group may support this work. Indeed, utilising the person-based approach (Yardley et al., 2015) including think-aloud methodologies and patient focus groups may gather insight into where necessary changes are needed.

Patients identified a need for more illness self-management strategies, hence future work should consider how diabetes management could successfully be embedded into COMPASS. This may ultimately improve both mental and physical health outcomes. Across type 1 and type 2 diabetes, the inclusion of more tailored behavioural strategies surrounding diet and exercise may be important targets to consider. However, the distinct differences in self-management strategies (e.g. use of insulin vs not) and aims that commonly exist between people with type 1 diabetes and type 2 diabetes should be considered in any content adaptation. Furthermore, ethnic, social, cognitive, literacy, and cultural factors are important to consider here (Chatterjee et al., 2018).

Indeed, if adaptations resulted in a change to hypothesised mechanisms of action, mediation analyses could provide insight into what elements of the intervention may be most beneficial for adults with diabetes. This would ultimately allow even further refinement of the COMPASS intervention similar to work performed in other trials of CBT (Goldsmith et al., 2020) .

Digital inclusion

As highlighted in the limitations section of this thesis, it was not possible to explore the influence of digital exclusion on the reach of COMPASS specifically, and its long-term implementation. However, findings presented in chapter 5 from a large sample, demonstrate that certain socio-demographic characteristics such as older age and being from a minoritised ethnic group reduced the likelihood of receiving an internet-enabled therapy. This needs considering if COMPASS were to be adopted and sustained in diabetes care, as older age and ethnicity are risk factors for the development of type 2 diabetes (Whicher, O'Neill, & Holt, 2020) and these factors are commonly associated with digital exclusion (Department of Health, 2014; Serafino, 2019). Therefore, future work should prioritise exploring the wider influence of socio-demographic factors on COMPASS implementation.

One way to do this is to partner with community organisations and embed community outreach within research to explore the sociodemographic relevance of COMPASS and its content. For example, Beck and Naz (2019) utilised a steering group approach to identify the needs and relevance of a current psychological services for minoritised groups. Indeed, the authors of this study established a steering group made up of community representatives with different demographic backgrounds (e.g. age, generation born in the UK, sexuality and religious backgrounds). This was approach differed to traditional patient involvement work as linking in with a variety of representatives within the community the researchers were able to not only consider those using services or willing to take part in research but the wider community.

Additionally, research should explore strategies to support access and engagement to COMPASS for these groups. For example, in one Talking Therapies service in East Midlands, partnerships have been established with local authorities and organisations to increase access to psychological therapy for underrepresented groups such as asylum seekers Through this partnership, clinicians in Talking Therapies have been trained in culturally responsive communication to adapt the explanations of Talking Therapies services and their treatments to support patient understanding and reduce stigma (Beck et al., 2019).

Additionally, work is being done to adapt interventions and make them more responsive to individual demographic needs. For example, in this thesis one person with diabetes was not able to engage with COMPASS as they had dyslexia. Therefore, future work should explore ways to support the practical accessibility of COMPASS and the impact of this on its reach.

7.7 Thesis conclusion

This PhD thesis demonstrated a clear research-to-practice gap regarding the implementation of COMPASS, an internet-enabled CBT intervention to treat psychological distress, among adults with diabetes in two English NHS care settings.

The findings presented in this body of research provide important and novel contributions to the literature. It has highlighted the efficacy of CBT as a treatment for diabetes-related distress from meta-analysed studies. However, the empirical research studies highlighted that offering CBT digitally via COMPASS was faced with numerous challenges to implementation whilst also identifying facilitators, albeit in their minority.

Across the thesis, facilitators to implementation included COMPASS' consideration of LTC-specific challenges, consistent therapist support and the normalisation of the need for and availability of psychological support for people with diabetes within NHS services. Barriers included digital therapies being viewed as inferior treatments when compared with face-to-face therapies, a lack of understanding of what COMPASS offered patients, and a greater need for diabetes self-management to be addressed in COMPASS. Service level pressures also meant that therapists and managers felt unable to offer COMPASS as per the protocol intended. Of note, this thesis was able to further contextualise the findings of COMPASS by taking a broader perspective; specifically, it identified that usage of digital therapies in talking therapy services is low but that people with LTCs have a lower chance of receiving a digital treatment.

Taken together these findings highlight a clear need to focus on the implementation strategies required to ensure an evidence-based digital interventions like COMPASS are used in practice. Putting in place implementation strategies are complex interventions in and of themselves, therefore robust research methods are needed to evaluate their value alongside testing the efficacy of the intervention being delivered. The use of implementation-effectiveness hybrid designs allow such goals to be achieved and offer a sensible next step for researching the use of COMPASS in routine diabetes care.

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Appendix

Appendix A: Systematic review

A1) Publication supplementary material

Table S1. Search strategy for the systematic review of Cognitive Behavioural Therapy interventions to treat diabetes-related distress

Population	Intervention	Study	Outcome
MEDLINE (Ovid) • exp Diabetes Mellitus/ • exp Diabetes Mellitus, Type 2/ • Exp diabetes mellitus, Type 1/ • Diabetes mellitus.mp • Diabetes.mp • Diabetes mellitus type 1.mp • Diabetes mellitus type 2.mp • Type 1 diabetes.mp • Type 2 diabetes.mp	**MEDLINE (Ovid)** • Cognitive Behavio?ral Therap* • Exp Cognitive behavioral therapy/ • (cognitive adj2 behav$).mp. • Cognitive therap*.mp • exp Mindfulness/ • mindfulness.mp • exp psychotherapy/ • (Behavio?r* adj3 (therap* or intervention* or train* or modif* or strategy*)) • CBT.mp • MBCT.mp • Psychotherapy.mp. • Psychological intervention*.mp • acceptance adj2 (commitment therap*) • Acceptance and commitment therap*.mp • Talking therap*.mp • ACT.mp	**MEDLINE (Ovid)** • randomized controlled trials as topic/ • clinical trials as topic/ • randomized controlled trial/ • Random Allocation/ • clinical trial/ • clinical trial, phase i.pt • clinical trial, phase ii.pt • clinical trial, phase iii.pt • clinical trial, phase iv.pt • controlled clinical trial.pt • randomized controlled trial.pt • randomly allocated.tw • (allocated adj2 random$).tw • randomi? Controlled trial*.mp	**MEDLINE (Ovid)** • Diabetes distress.mp • Diabetes related distress.mp • Diabetes adj2 distress • Problem areas in diabetes.mp • Diabetes distress scale.mp • Exp psychological distress
PsycINFO (Ovid) • Exp diabetes mellitus/ • Diabetes Mellitus.mp • Exp type 2 diabetes/ • Type 2 diabetes.mp • Type 1 diabetes.mp • Exp diabetes/ • Diabetes.mp • Exp diabetes mellitus/ • Diabetes mellitus type 1.mp • Diabetes mellitus type 2.mp • T2DM.mp	**PsycINFO (Ovid)** • Exp cognitive behavior therapy/ • Exp cognitive therapy/ • Cognitive behavio* therap*.mp • CBT.mp • (cognitive adj2 behav*).mp. • Exp Psychotherapy/ • Psychotherapy.mp • Exp “acceptance and commitment therapy”/	**PsycINFO (Ovid)** • Exp clinical trials/ • Exp Randomized controlled trials/ • Exp intervention/ • Intervention.mp • RCT.mp • Randomi?ed controlled trials.mp • (random* adj allocat*).ab. • randomi?ed.ab. • randomly allocated.mp	**PsycINFO (Ovid)** • Exp diabetes/ and exp distress/ • Diabetes distress.mp • Diabetes related distress.mp • (diabetes adj2 distress).mp • Problem areas in diabetes.mp • Diabetes distress scale.mp

• T1DM.mp	• acceptance adj2 (commitment therap*).mp • exp mindfulness/ • exp mindfulness-based interventions/ • mindfulness.mp • cognitive therap*.mp • MBCT.mp • Talking therap*.mp • ACT		
PubMed • Diabetes mellitus [mh] • Diabetes • Type 1 diabetes • Type 2 diabetes	**PubMed** • Cognitive behavio* therap* • Therapy, cognitive behavio* • Behavio* therapies, cognitive • Cognitive behavio* therapies • Therapies, cognitive behavio* • CBT • Mindfulness-based cognitive therapy [mh] • Mindfulness • MBCT • ACT • “Acceptance and commitment therapy” [mh]	**PubMed** • Randomized controlled trials as Topic [mh] • Clinical trials, randomized • Trials, randomized clinical • Controlled clinical trials • Randomised • Randomized • Randomized controlled trial [publication type] • RCT • Random allocation	**PubMed** • Diabetes distress • Diabetes related distress • Problem areas in diabetes • Diabetes distress scale
CENTRAL 1. ("diabetes mellitus"):ti,ab,kw 2. (Diabetes):ti,ab,kw 3. MeSH descriptor: [Diabetes Mellitus] explode all trees OR 4. (“type 2 diabetes”):ti,ab,kw 5. (“type 1 diabetes”):ti,ab,kw 6. MeSH descriptor: Type 1 diabetes 7. MeSH descriptor:type 2 diabetes	**CENTRAL** • MeSH descriptor: [Cognitive Behavioral Therapy] explode all trees • (Cognitive behav* therap*):ti,ab,kw • (CBT).ti,ab,kw • MeSH descriptor: [Mindfulness] explode all trees • Mindfulness:ti,ab,kw • (MBCT):ti,ab,kw • MeSH descriptor: [Acceptance and Commitment Therapy] explode all trees • (ACT):ti,ab,kw • (Cognitive behav* therap*) full text • Psychological intervention*	**CENTRAL** • MeSH descriptor: [Randomized Controlled Trial] explode all trees • (RCT):ti,ab,kw • (Randomized controlled trial):ti,ab,kw **Limit set on ‘trials only’**	**CENTRAL** • (diabetes distress):ti,ab,kw • (Diabetes distress) full text • MeSH descriptor: [Psychological Distress] explode all trees
EMBASE (Ovid)	**EMBASE (Ovid)**	**EMBASE (Ovid)**	**EMBASE (Ovid)**

- exp Diabetes Mellitus/ - diabetes mellitus.mp - diabetes.mp. - type 2 diabetes.mp - type 1 diabetes.mp - diabetes mellitus type 1.mp - diabetes mellitus type 2.mp - exp non-insulin dependent diabetes mellitus/ - exp insulin dependent diabetes mellitus/ - T1DM.mp - T2DM.mp	• Exp cognitive behavior therapy/ • exp behavior therapy/ • exp cognitive therapy/ • cognitive behav* therap*.mp • exp mindfulness • mindfulness.mp • CBT • ACT • MBCT • ((cogniti* or relaxation or acceptance or commitment or adaptation) adj6 (therap* or behavio* or strateg* or intervention* or approach* or psychotherap* or training or treatment or technique* or program* or counselling).mp • ((behavio*) adj6 (strateg* or intervention* or therap* or approach* or psychotherap* or technique* or counselling).mp • Exp psychotherapy/ • Psychotherapy.mp • Talking therap*	**From SIGN** • Exp Clinical Trial/ (505836) • Exp randomized Controlled Trial/ (430740) • Exp controlled clinical trial/ (91696) • exp RANDOMIZATION/ (88833) • randomi?ed controlled trial$.tw (118033) • rct.tw (13355) • (random$ adj2 allocat$).tw. (26671)	• Distress.mp • Diabetes distress.mp • (diabet* adj2 distress*).mp • (diabet* adj3 (specific or related) adj3 distress).tw. • Problem areas in diabetes.mp • Diabetes distress scale.mp
Web of Science • ALL=diabetes mellitus • ALL= diabetes • ALL= type 2 diabetes • ALL= type 1 diabetes • ALL= non-insulin dependent diabetes mellitus • ALL= insulin dependent diabetes mellitus • Diabetes mellitus type 2 • Diabetes mellitus type 1 • ALL=T2DM • ALL=T1DM	**Web of Science** • ALL=Cognitive behav* therap* • ALL=cognitive therap* • ALL=behav* therap* • ALL=mindfulness • ALL=mindfulness-based cognitive therap* • ALL= psychotherap* • ALL=CBT • ALL=acceptance and commitment therap* • ALL=(acceptance AND commitment) ALL=MBCT • ALL=ACT	**Web of Science** • ALL=(“randomi$ed controlled trial*”) • TS= (intervention NEAR/2 stud*) • ALL=RCT • ALL=intervention* • TS=“random* allocate*” • TS=(randomi$ation OR randomi$ed) • TS=clinical trial • TS=(placebo* or random* or clinical trial* or double blind* or single blind* or rct)	**Web of Science** • ALL=diabetes distress • TS=(diabetes NEAR/2 distress) • ALL= diabetes distress scale • ALL= problem areas in diabetes

CINHL • (MH “diabetes mellitus”) • TX “diabetes mellitus” • TX “diabetes” • (MH”Diabetes mellitus, Type 2”) • (MH”diabetes mellitus, Type 1”) • TX type 2 diabetes • TX type 1 diabetes • TX T1dm • TX T2dm	**CINHL** • (MH”cognitive therapy”) • (MH “behavior therapy”) • cognitive behav* therap* • TXCBT • (MH”psychotherapy”) • (MH”acceptance and commitment therapy”) • TX “acceptance and commitment therapy”or act • (MH “Mindfulness”) • TX mindfulness • TX MBCT or mindfulness based cognitive therapy	**CINHL** **From SIGN** • TX allocate* random* • TX random* allocat* • MH “random assignment” • TX Randomi* control* trial* • TX clinic* n1 trial* • PT Clinical trial • (MH "Clinical Trials")	**CINHL** • TX distress • Tx diabetes distress • TX diabetes-related distress • TX diabet* N3 (specific OR related) N3 stress) • Tx “problem areas in diabetes” • TX diabetes distress scale

Abbreviations: ACT= Acceptance and Commitment Therapy; Cognitive Behavioral Therapy; CENTRAL= Cochrane Central Register of Controlled Trials; CINAHL=Cumulative Index to Nursing and Allied Health literature; MBCT= Mindfulness-based Cognitive Therapy; RCT= Randomised Controlled Trial; SIGN=Scottish Intercollegiate Guidelines Network; T1DM= Type 1 Diabetes Mellitus; T2DM= Type 2 Diabetes Mellitus

Table S2: Characteristics of studies included in the systematic review.

Reference, year, country, reference number	Design	Participants		Control group	Diabetes type	Age: mean (SD); Gender: n (% female)		Inclusion criteria Elevated distress; Elevated HbA1c	Distress scale (primary [P] or secondary outcome in the paper [S])	Post intervention measurement (weeks post intervention)[1]
		Int n	Ctrl n			Int	Ctrl			
CBT studies										
Amsberg et al., 2009, Sweden,58	RCT	36	38	TAU	T1D	41.1 (11.7); 16 (44.4%)	41.4 (12.9); 22 (57.9%)	No Yes (HbA1c >58 mmol/mol; 7.5%)	PAID (S)	40
Chew et al., 2018, Malaysia,45	Cluster RCT	53	71	Placebo control	T2D	55.6 (10.8); 32 (60%)	55.8 (8.8); 44 (62%)	Yes (DDS-17 ≥3) Yes (HbA1c ≥ 64 mmol/mol; 8%, or BP ≥ 140/90 mmHg or LDL level ≥ 2.6 mmol/l)	DDS-17 (P)	0
Clarke et al., 2019, Australia,51	RCT	368	355	Placebo control	T2D	57.7 (10.6); 229 (62%)	57.7 (10.0); 236 (66%)	Yes (PHQ-2 ≥2) No	DDS-17 (S)	4
de Groot et al., 2019, USA,52	RCT	CBT: 36 CBT + exercise: 34[2]	36	TAU	T2D	CBT: 57.9 (10.9); 26 (72%) CBT + exercise: 57.1 (10.7); 28 (82.4%)	54.2 (10.4); 27 (75.0%)	Yes (SCID-IV MDD >2wks) No	DDS-17 (S)	1

Fisher et al., 2013, USA,53	RCT	146[2]	96	Placebo control	T2D	55.82 (9.36); 82 (56.2%)	55.23 (10.88); 57 (59.4%)	Yes (DDS-2 ≥1.5) No	DDS-17 (P)	16
Hermanns at al., 2015, Germany,60	RCT	106	108	Placebo control	T1D and T2D	43.2 (14.9); 60 (56.6%)	43.3 (13.8); 61 (56.5%)	Yes (CES-D ≥16) No	DDS-17 (S) PAID	0
Ismail et al., 2018, UK,46	Cluster RCT	164	170	TAU	T2D	59.0 (11.1); 82 (50.0%)	58.9 (11.4); 89 (52.4%)	No Yes (HbA1c ≥69 mmol/mol; 8.5% on two occasions)	DDS-17 (S)	26
Karlsen, 2004, Norway,47	Quasi RCT	31	32	Waitlist	T1D and T2D	49.2 (14.7); 15 (48%)	48.6 (10.3); 15 (47%)	No No	PAID (P)	4
Lamers et al., 2011, Netherlands,50	RCT	105	103	TAU	T2D	70.7 (6.6); 54 (51.4%)	69.7 (6.6); 52 (50.5%)	Yes (mild to moderate depression according to MINI and HDRS <18) No	PAID (P)	1
Newby et al., 2017, Australia,61	RCT	41	49	Waitlist	T1D and T2D	43.5 (13.3); 33 (81%)	49.3 (11.5); 31 (63%)	Yes (MDD according to MINI) No	PAID (P)	1
Nobis et al., 2015, Germany,61	RCT	129	127	TAU	T1D and T2D	50 (12.0); 82 (64%)	51 (12.0); 80 (63%)	Yes (CES-D ≥23) No	PAID (S)	0
Pibernik-Okanovic et al., 2015, Croatia,56	RCT	74[2]	69	TAU	T2D	57.7 (6.2); 40 (54%)	58.2 (5.6); 36 (52.1%)	Yes (at least one depressive symptom over the last month determined by SCID-I) No	PAID (S)	2

Tunsuchart et al., 2020, Thailand,57	Quasi RCT	28	28	TAU	T2D	58.18 (8.83); 16 (57.10%)	53.89 (7.34); 17 (60.7%)	Yes (DDS-17 ≥2) Yes (HbA1c >53 mmol/mol; 7%)	DDS-17 (P)	0
Van Bastelaar et al., 2011, Netherlands,64	RCT	125	130	Waitlist	T1D or T2D	48 (12.0); 82 (66%)	51 (12.0); 73 (56%)	Yes (CES-D ≥16) No	PAID (S)	0
van der Ven et al., 2005, Netherlands,49	RCT	45	43	Active control (BGAT)	T1D	37.8 (10.6); 52 (59.1%)[3]	NR	No Yes (HbA1c ≥64 mmol/mol; 8% on two occasions prior to the study)	PAID (P)	12
Vaughan et al., 2021, USA, 48	RCT	136	89	TAU	T1D and T2D	Total: 61.9 (8.3)[3] 15 (11%)	8 (9%)	Yes (PHQ-9 ≥10) Yes (HbA1c ≥ 58mmol/mol; 7.5%)	PAID (P)	0
Weinger et al., 2011, USA,66	RCT	74	Placebo control: 75 TAU: 73	Placebo control TAU	T1D and T2D	51.8 (23.7 – 74.2) [4]; 34 (46%)	AC: 54.7(25.0-75.1) [4]; 36 (48%) IC: 56.2 (21.6-74.8); 42 (58%)	No Yes (HbA1c > 58 mmol/mol; 7.5%)	PAID (S)	12
Third wave CBT interventions										
Friis et al., 2016, New Zealand,59	RCT	32	31	Waitlist	T1D and T2D	42.16 (14.70); 20 (62.50%)	46.64 (16.44); 23 (74.19%)	No No	DDS-17 (P)	0

Maghsoudi et al., 2019, Iran,54	RCT	40	40	TAU	T2D	62.95 (3.86); 17 (42.5%)	63.18 (3.57); 21 (52.5%)	Unclear No	DDS-17 (P)	0
Pearson et al., 2018, Australia,55	RCT	38	36	TAU	T2D	57.5 (12.9); 19 (61.3%)	61.1 (11.8); 12 (33.3%)	No Yes (not meeting glycaemic control target)	PAID (P)	0
van Son et al., 2013, Netherlands,65	RCT	70	69	TAU	T1D and T2D	56 (13); 37 (54%)	57 (13); 32 (56%)	Yes (BDI-II ≥13) No	PAID (P)	0
CBT and third wave CBT interventions										
Tovoke et al., 2014, Netherlands,63	RCT	CBT: 32 MBCT: 31	31	Waitlist	T1D and T2D	MBCT: 49.8 (13.3); 14 (45%) CBT: 54.6 (11.3); 16 (50%)	54.7 (10.5); 16 (52%)	Yes (WHO-5 wellbeing index <13) No	PAID (S)	0

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[1] Where there is both a basic and a maintenance intervention, figures are presented as the time since the basic intervention. [2] The original paper has additional treatment arms that are not included in the analysis and therefore aer not reported here. [3] Figures for intervention and control are not reported separately. [4] Median (range)Abbreviations: AC: attentional control; BDI -II: Beck Depression Inventory; BGAT: Blood Glucose Awareness Training; BP: Blood Pressure; CBT: Cognitive Behavioural Therapy; CES-D: Center for Epidemiological Studies Depression Scale; Ctrl: Control arm; DDS: Diabetes Distress Scale; HbA1c: glycated haemoglobin; HDRS: The Hamilton Depression Rating Scale; IC: individual control; Int: Intervention arm LDL: Low density lipoprotein; MBCT: Mindfulness Based Cognitive Therapy; MDD: Major Depressive Disorder; MINI: Mini-International Neuropsychiatric Interview; PAID: Problem Areas in Diabetes Scale; PHQ: Patient Health Questionnaire; RCT: Randomised Controlled Trial; SCID-IV: the Structured Clinical Interview for DSM-IV; TAU: Treatment as usual; T1D: Type 1 Diabetes; T2D: Type 2 Diabetes; WHO= World Health Organisation.

Table S3: TIDieR table of Cognitive Behavioural Therapy intervention content.

Study reference	Who provided? (Level of training)	Mode of delivery (format)	When/how much	Location	Homework recommended (frequency; format)	Individual tailoring (diabetes specific intervention)	Adherence to the intervention assessed?[1] (Strategies to enhance adherence)	Therapist fidelity assessed?[2] (Strategies to assess fidelity)
CBT interventions								
Amsberg et al. 2009,58	1 x diabetes nurse. 1 x psychologist (trained in CBT).	Basic intervention: Face to face (group of 4-6 members) Maintenance intervention: 5 x telephone & 4 x face to face sessions (2 x individual, 2 x group).	Basic intervention: 8 weekly 2-hour sessions over 8 weeks Maintenance intervention: 9 sessions over 38 weeks.	NR	Yes (weekly; individual)	No (Yes)	NR (NR)	NR

Chew et al., 2018,45	2 x nurse and 1 x medical doctor from each clinic (trained in diabetes management and practical coaching skills).	Face to face (group)	4 2hr sessions over 6 weeks (main intervention) followed by a booster session at 3 months post intervention and an evaluation session at 6 months post intervention.	Outpatient health clinics	NR	No (yes)	NR (NR)	NR
Clarke et al. 2019,51	Self-guided	Web-based (individual)	Access to intervention: 8 weeks. Access to the symptom monitoring function: 12 weeks	Online	Yes (weekly; individual)	Yes, based on symptom assessment (No)	Yes (SMS/email reminders)	N/A
de Groot et al. 2019,52	Community mental health professionals (Master's degree and doctoral degree).	Face to face (individual)	10 weekly sessions over 12 weeks.	Community mental health centres and individual private practices	Yes (weekly; individual)	No (Yes)	NR (NR)	NR

Fisher et al., 2013,53	Non-professional interventionists (college graduates trained to deliver the intervention) and self-guided.	1 x Face to face and online (individual)	1 in person session and continual access to the online platform over 3-4 months.	In a convenient location within the community and online	NR	No (Yes)	NR (NR)	NR
Hermanns et al., 2015,60	Certified psychologists (NR).	Face to face (group)	5 90-minute sessions over 5 consecutive days.	Inpatient hospital	Yes (after every session; individual)	No (Yes)	Yes (NR)	NR
Ismail et al., 2018,46	Diabetes nurses (trained in CBT and MI).	Face to face (individual)	12 30-minute sessions over 12 months.	Primary care clinics	NR	Yes (Yes)	Yes (NR)	Yes (audio recorded sessions)
Karlsen et al., 2004,47	Specialist diabetes nurses and people living with diabetes (trained in supportive counselling).	Face to face (group)	9 1.5hr sessions over 12 months.	NR	No formal homework	No (yes)	No (missing more than 2 sessions resulted in exclusion from the study)	NR
Lamers et al., 2011,50	General nurse (no specific mental health expertise trained to deliver the intervention).	Face to face (individual)	4 1hr-sessions on average over approx. 6 weeks.	At home	NR	Yes (No)	NR (NR)	NR
Newby et al., 2017,61	Self-guided and clinician assisted by trained clinical psychologists or psychiatrist registrars (masters or PhD level qualification)	Web-based (individual). Clinician assistance through email and telephone.	6 approx. 20-minute sessions over 10 weeks.	Online	Yes (after every session; individual)	No (No)	Yes (reminder and encouragement emails and minimal clinician assistance)	NR

Nobis et al., 2015,62	Self-guided and clinician assistance by graduate students and psychologists (NR)	Web based (individual). Minimal guidance and feedback from clinicians through messaging	6 approx. 45-minute core sessions and 2 additional sessions, over 6-8 weeks.	Online	Yes (NR; individual)	No (Yes)	Yes (optional daily text messages to support with goal attainment, and adherence facilitating text messages and telephone calls if necessary)	NR
Pibernik-Okanovic et al., 2011,56	1 x psychologist (experienced in CBT based psychoeducation)	Face to face (group)	6 weekly 90-minute sessions over 6 weeks.	Outpatient clinics	Yes (weekly; individual)	No (No)	NR (NR)	No
Tovote et al., 2014,63	Trained therapists (experienced at delivering CBT and trained by a CBT therapist).	Face to face (individually)	8 weekly 45–60-minute sessions over 8 weeks.	Outpatient clinics	Yes (weekly; individual)	No (No)	No (asked to report homework practices on weekly evaluation forms)	Yes (treatment sessions were videotaped)
Tunsuchart et al., 2020,57	Therapist (brief training in CBT).	Face to face (group)	6 weekly 60–90-minute sessions over 6 weeks.	NR	NR	No (No)	NR (NR)	No (Researchers randomly observed therapists during one or more session)
van Bastelaar., 2011,64	Self-guided but feedback and monitoring was provided by a certified health psychologist (NR).	Web-based (individually). Clinician assistance through email	8 weekly sessions over 8 weeks.	Online	Yes (weekly; individual)	No (Yes)	No (reminder emails and homework feedback from clinicians)	NR

van der Ven et al., 2005,49	1 x psychologist and 1 x diabetes specialist nurse (NR).	Face to face (group)	6 weekly 2hr sessions over 6 weeks.	NR	Yes (weekly; individual)	No (Yes)	NR (NR)	No (all sessions were observed through a one-way screen by the researcher)
Vaughan et al 2021,48	16 x psychologists. 5 x nurses. 2 x pharmacists. 1 x social worker (received training in tele-coaching)	Telephone (individual)	Biweekly, approx. 40-min sessions during months 1-3. Monthly 15-min sessions during months 4-6. Bimonthly 15-min maintenance sessions during months 7-12.	Telephone-based	Yes (after every session between sessions 1-6; individual)	No (yes)	NR (NR)	NR (NR)
Weinger et al., 2011,66	Nurses and dieticians currently working as certified diabetes educators (brief training in CBT techniques).	Face to face (group)	5 2hr sessions over 6 weeks.	Outpatient clinics	Yes (after every session; NR)	No (yes)	NR (NR)	No (Written curriculum and investigator observation of the treatment groups)

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[1] where authors have reported adherence figures in text “Adherence to the intervention assessed?” has been answered ‘yes’, where no adherence figures have been reported the question has been answered ‘no’.

[2] where authors have reported ratings of fidelity in text “Therapist fidelity assessed?” has been answered ‘yes’. Where this has not been reported the answer is ‘no’.

CBT= Cognitive Behavioural Therapy; hr= hour; MI= Motivational Interviewing; NR= Not reported

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Table S4: Key therapeutic techniques in the Cognitive Behavioural Therapy interventions

	Action planning	Behavioural activation	Behavioural experiment	Cognitive and/or behavioural self-monitoring	Cognitive restructuring	Exposure	Goal setting	Guided discovery	Problem solving	Psychoeducation	Record keeping of cognitions and/or behaviours and/or feelings	Relaxation	Relapse prevention
CBT interventions													
Amsberg et al., 2009	✓					✓	✓		✓	✓	✓	✓	✓
Chew et al., 2018							✓			✓		✓	
Clarke et al., 2019				✓					✓				
Degroot et al., 2019					✓		✓		✓	✓	✓		✓
Fisher et al., 2013	✓	✓					✓		✓				
Hermanns et al., 2015					✓		✓		✓	✓		✓	✓
Ismail et al., 2018		✓	✓		✓		✓	✓	✓				
Karlsen et al., 2004				✓	✓		✓	✓	✓	✓			✓
Lamers et al., 2011	✓				✓		✓		✓		✓		
Newby et al., 2017		✓		✓	✓				✓	✓			✓
Nobis et al., 2015	✓	✓		✓			✓			✓			
Pibernik-Okanovic et al., 2015		✓							✓	✓	✓		✓
Tovote et al., 2014		✓			✓					✓	✓		✓
Tunsuchart e al., 2020					✓		✓						
Van Bastelaar et al., 2011		✓			✓					✓		✓	✓
Van der Ven et al., 2005					✓		✓						
Vaughan et al., 2021	✓	✓		✓			✓	✓		✓		✓	
Weinger et al., 2011					✓		✓		✓	✓	✓		

Table S5: TIDieR table of third-wave Cognitive Behavioural Therapy intervention content.

Study reference	Intervention type	Who provided? (Level of training)	Mode of delivery (format)	When/how much	Location	Homework recommended (frequency; format)	Individual tailoring (diabetes specific intervention)	Adherence to the intervention assessed?[1] (strategies to enhance adherence)	Therapist fidelity assessed?[2] (strategies to assess fidelity)
Third wave CBT interventions									
Friis et al., 2016,59	Mindfulness self-compassion (MSC) intervention	1 x health psychologist (trained in mindfulness)	Face to face (group)	8 weekly 2.5hr sessions.	Community hall and the waiting room of an outpatient medical centre	No formal homework but encouraged to practice the previous weeks teaching (NA)	No (No)	No ($20 voucher for each MSC session attended	NR
Maghsoudi et al., 2019,54	Acceptance and commitment therapy (ACT)	1 x clinical psychologist. 1 x nurse (NR)	Face to face (group)	8 weekly 90-minute sessions.	Outpatient research and therapy centre	NR	No (No)	No (if participants missed >2 sessions they were excluded from the study)	NR
Pearson et al., 2018,55	Mindfulness	Self-guided (Audio CB developed by a trained mindfulness practitioner)	N/A (individual)	30-minute daily sessions over 8 weeks	At home	N/A	No (No)	NR (NR)	N/A
Tovote et al., 2014,63	Mindfulness Based Cognitive Therapy (MBCT)	Trained therapists (certified and experienced in delivering mindfulness)	Face to face (individual)	8 weekly 45–60-minute sessions over 8 weeks.	Outpatient clinics	Yes (weekly; individual)	No (No)	Yes (treatment sessions were videotaped and participants were asked to report homework practices on weekly evaluation forms)	Yes (treatment sessions were videotaped)
Van Son et al., 2013,65	Mindfulness Based Cognitive Therapy (MBCT)	Certified psychologists (Trained in delivering mindfulness and personal experience	Face to face (group)	8 weekly 2hr sessions over 8 weeks.	Outpatient clinics	Yes (weekly; individual)	No (No)	NR	NR

of mindfulness practice)

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[1] where authors have reported adherence figures in text “Adherence to the intervention assessed?” has been answered ‘yes’, where no adherence figures have been reported the question has been answered ‘no’.

[2] where authors have reported ratings of fidelity in text “Therapist fidelity assessed?” has been answered ‘yes’. Where this has not been reported the answer is ‘no’.

ACT= Acceptance and commitment therapy; CB= Cognitive Behavioural CBT= Cognitive Behavioural Therapy; hr= hour; MBCT= Mindfulness-based Cognitive Therapy; MSC= Mindfulness self-compassion; NR= Not reported

Table S6: Key therapeutic techniques in the third-wave Cognitive Behavioural Therapy interventions.

	Psychoeducation	Mindful meditation and cultivating mindfulness	Identifying core values	Identifying cognitions	Cultivating acceptance	Cognitive defusion	Behavioural Activation	Relapse prevention
Third-wave CBT interventions								
Friis et al., 2016	✓	✓	✓		✓			
Maghsoudi., 2019	✓		✓		✓	✓		
Pearson et al., 2018		✓						
Tovote et al., 2014	✓	✓		✓			✓	✓
Van son., 2013		✓		✓	✓		✓	

*CBT= Cognitive Behavioural Therapy

Figure S7: Funnel plot to assess publication bias for studies investigating the effect of Cognitive Behavioural Therapy interventions on diabetes-related distress. A scatterplot of treatment effect against a measure of study precision, to visually inspect the studies for publication bias and systematic heterogeneity.

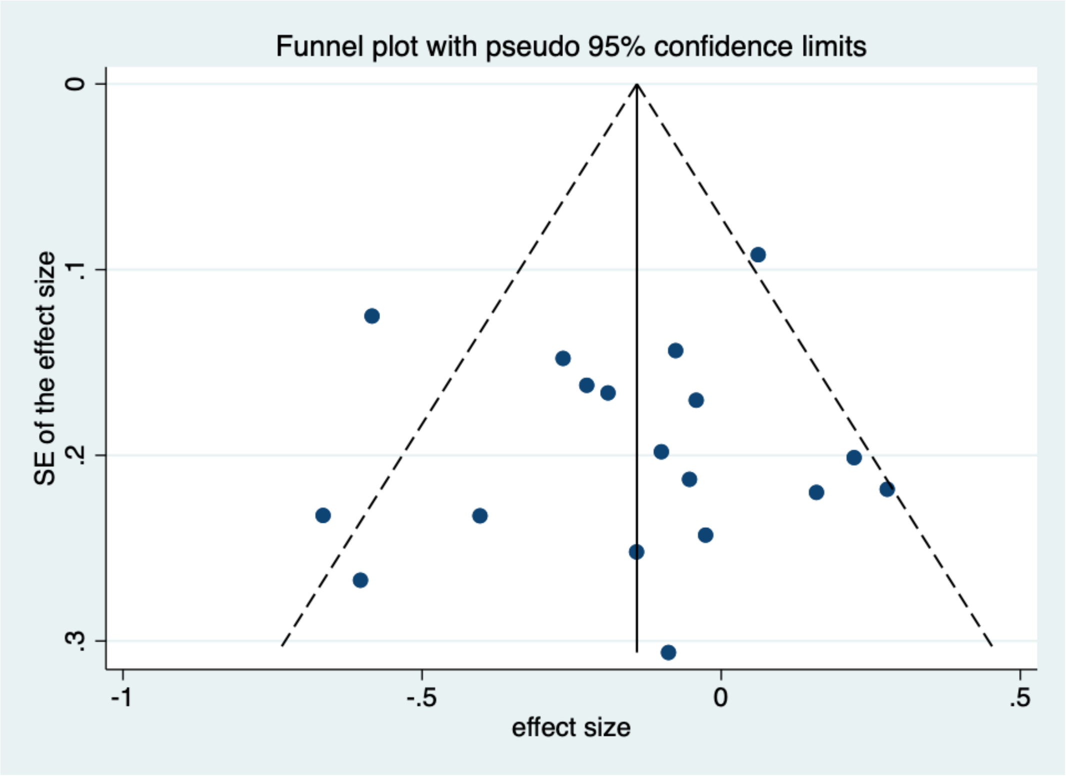


Figure S8: Funnel plot to assess publication bias for studies investigating the effect of Cognitive Behavioural Therapy interventions on diabetes related distress in studies where diabetes related distress was the primary outcome. A scatterplot of treatment effect against a measure of study precision, to visually inspect the studies for publication bias and systematic heterogeneity.

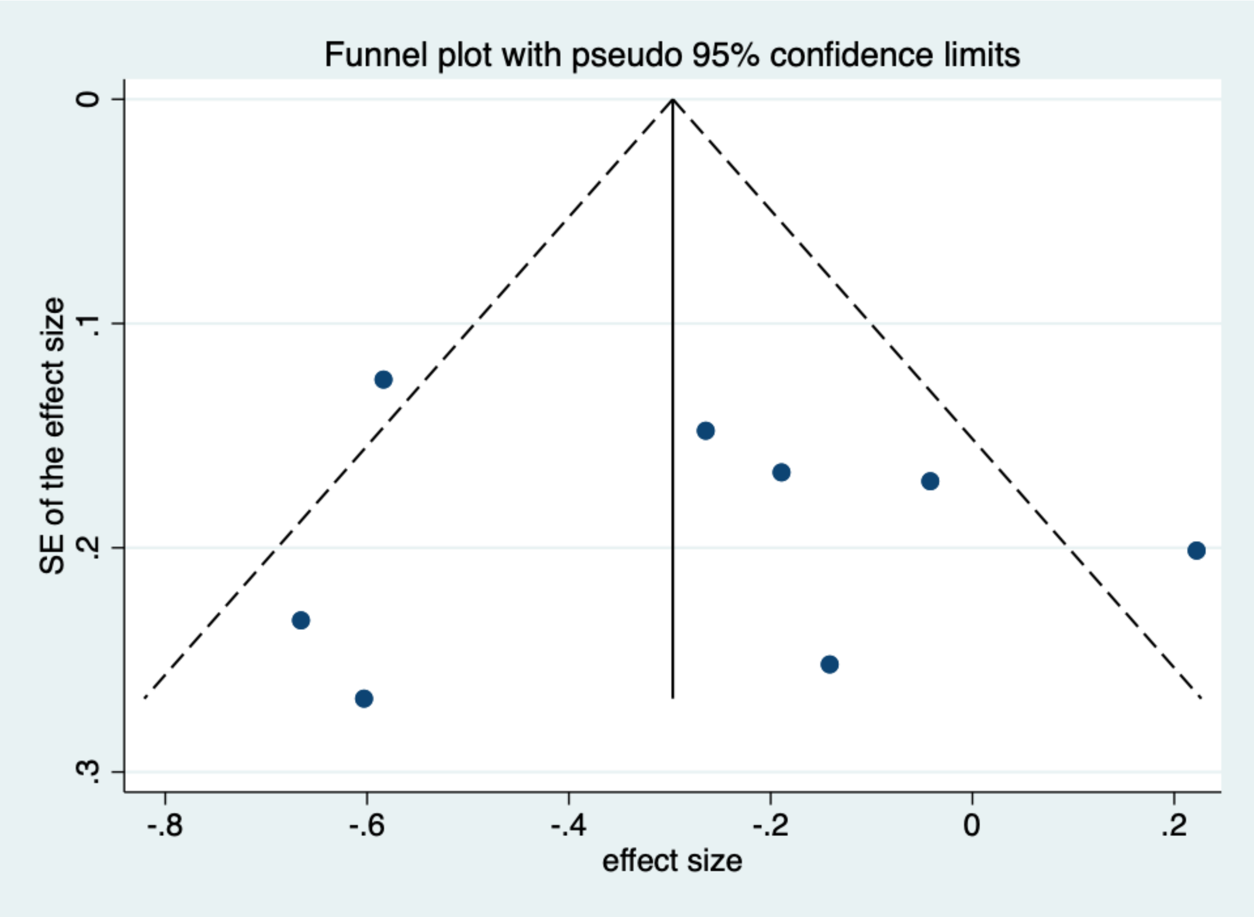


Figure S9: Funnel plot to assess publication bias for studies investigating the effect of Cognitive Behavioural Therapy interventions that aim to target diabetes-related distress on depression. A scatterplot of treatment effect against a measure of study precision, to visually inspect the studies for publication bias and systematic heterogeneity.

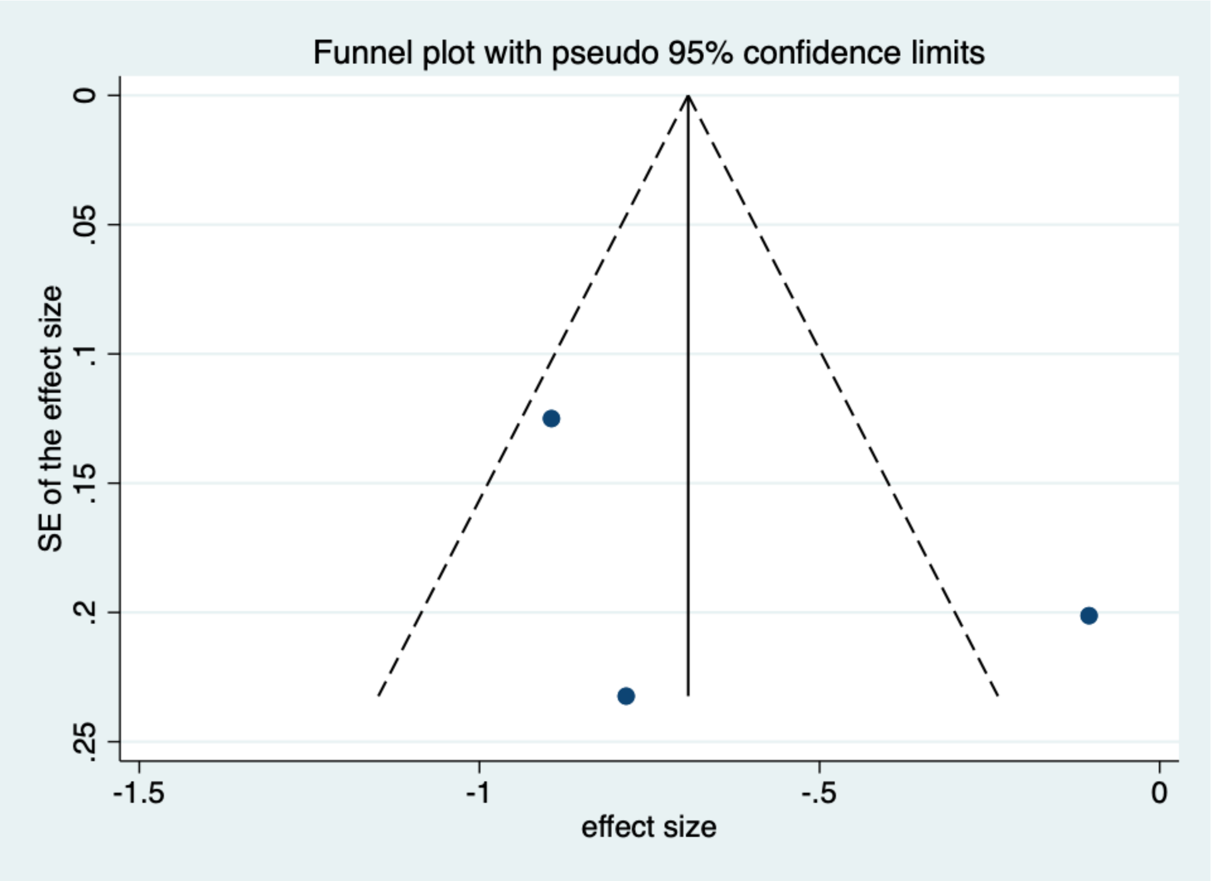


Figure 10. Funnel plot to assess publication bias for studies investigating the effect of Cognitive Behavioural Therapy interventions that aim to target diabetes-related distress on HbA1c levels. A scatterplot of treatment effect against a measure of study precision, to visually inspect the studies for publication bias and systematic heterogeneity.

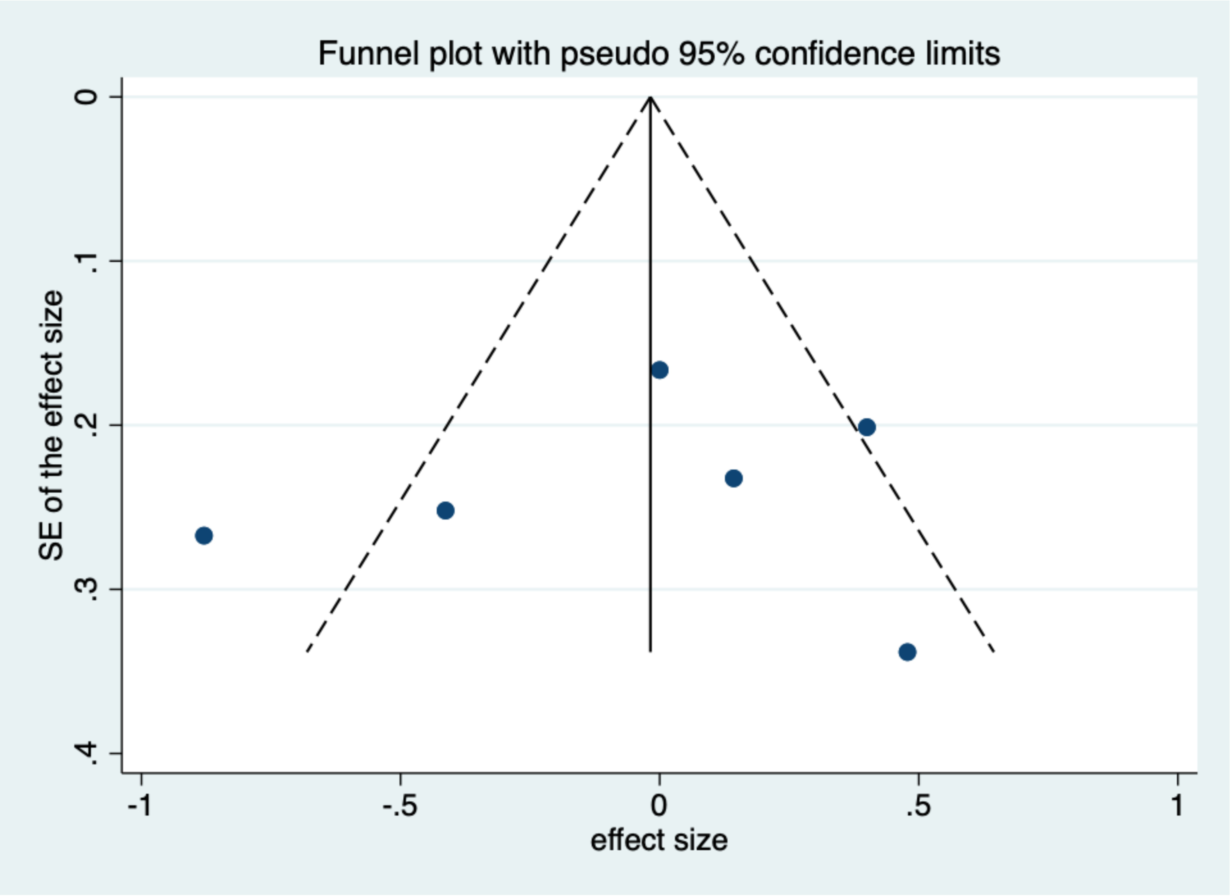


Figure S11. Funnel plot to assess publication bias for studies investigating the effect of third-wave Cognitive Behavioural Therapy interventions on diabetes-related distress. A scatterplot of treatment effect against a measure of study precision, to visually inspect the studies for publication bias and systematic heterogeneity.

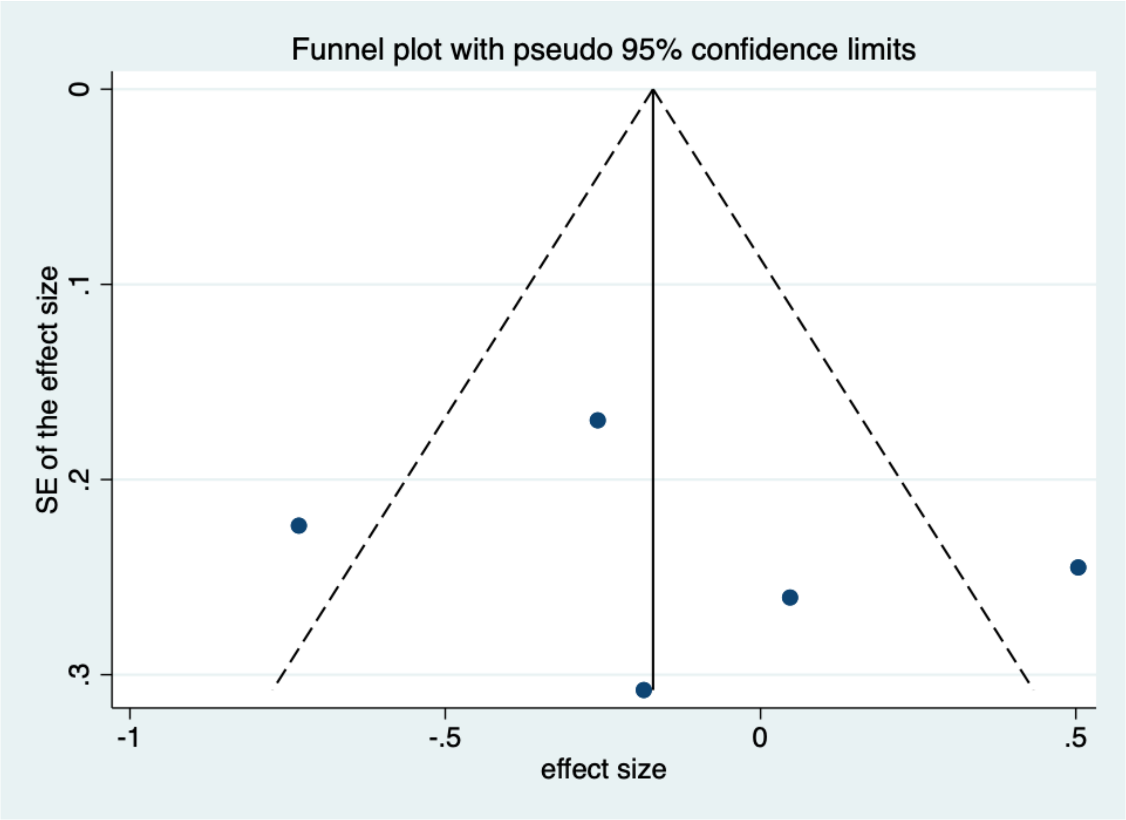


Figure S12. Funnel plot to assess publication bias for studies investigating the effect of third-wave Cognitive Behavioural Therapy interventions on diabetes-related distress where diabetes-related distress was the primary outcome. A scatterplot of treatment effect against a measure of study precision, to visually inspect the studies for publication bias and systematic heterogeneity.

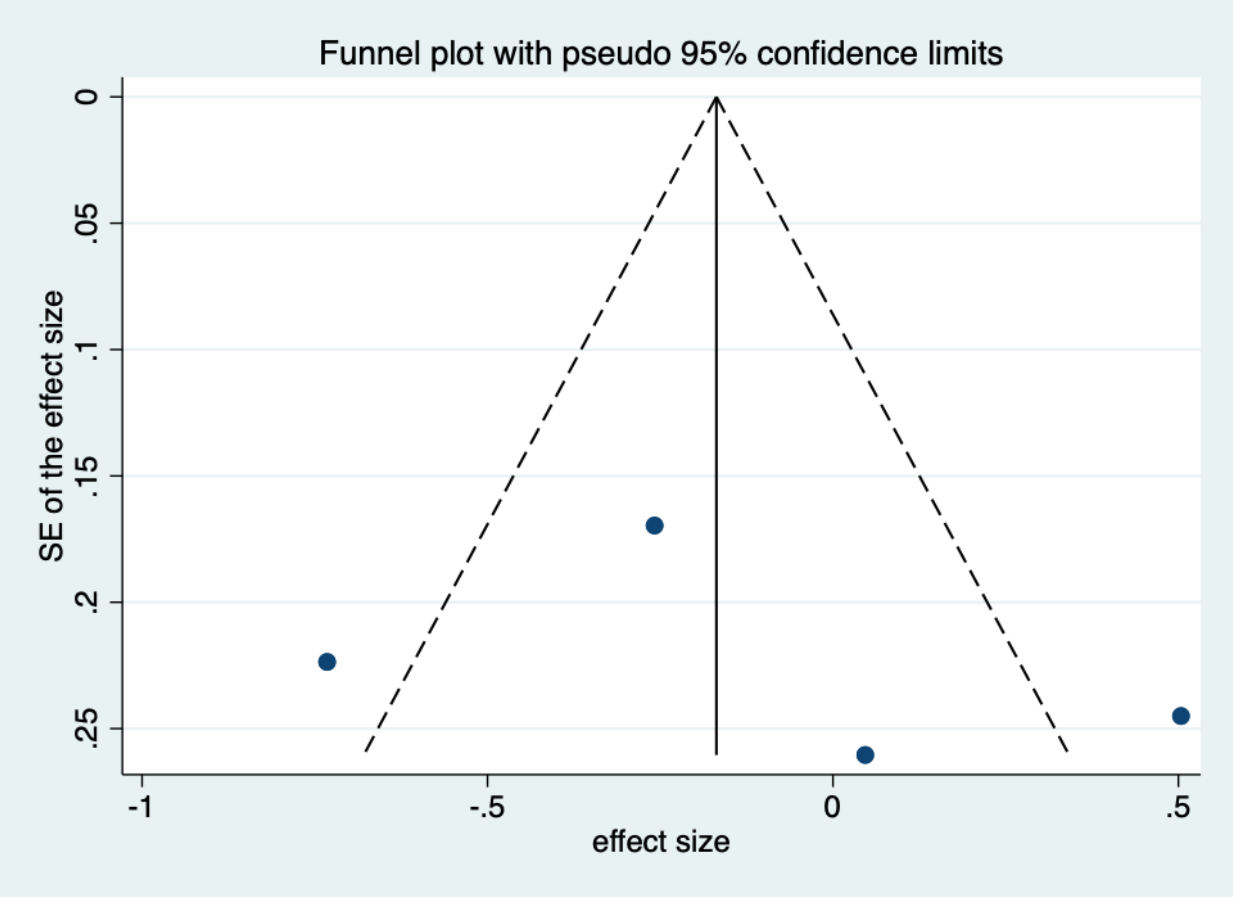


Figure S13. Funnel plot to assess publication bias for studies investigating the effect of third-wave Cognitive Behavioural Therapy interventions that aim to target diabetes-related distress primarily on depression. A scatterplot of treatment effect against a measure of study precision, to visually inspect the studies for publication bias and systematic heterogeneity.

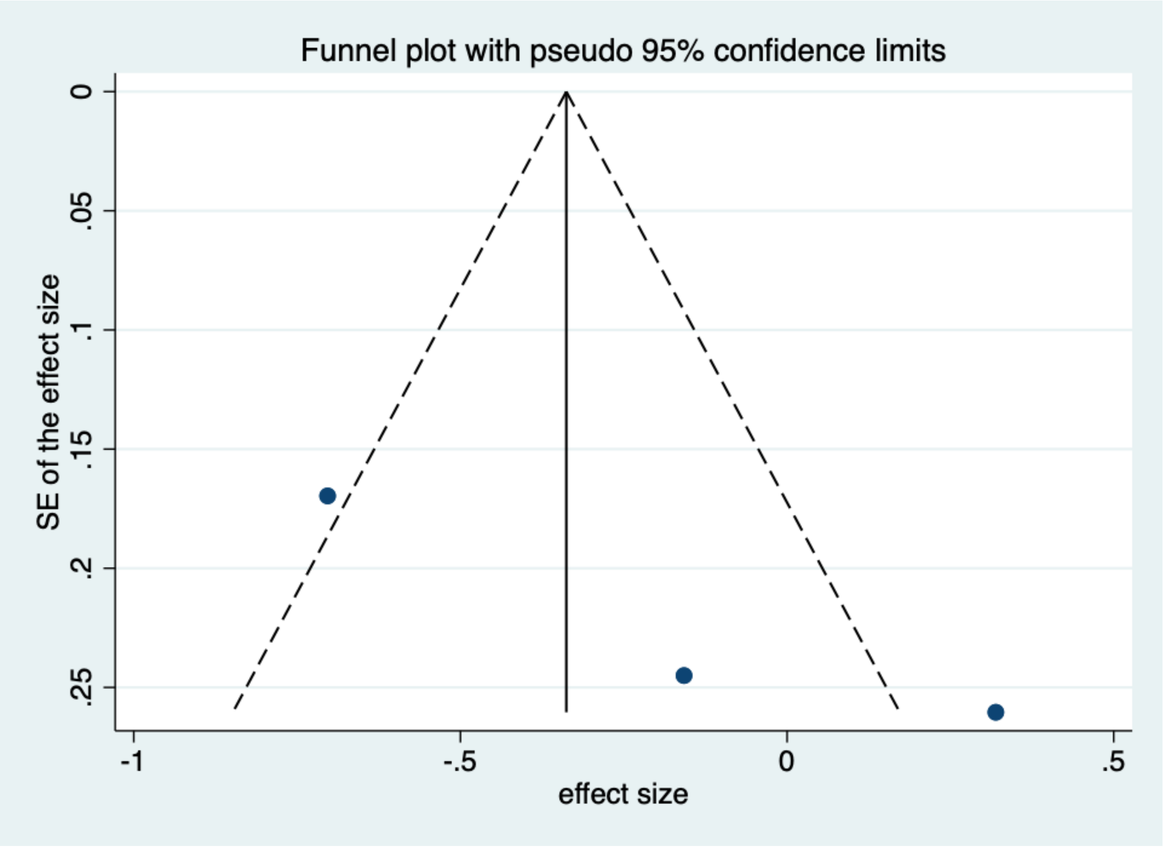


Figure S14. Funnel plot to assess publication bias for studies investigating the effect of third-wave Cognitive Behavioural Therapy interventions that aim to target diabetes-related distress primarily on anxiety. A scatterplot of treatment effect against a measure of study precision, to visually inspect the studies for publication bias and systematic heterogeneity.

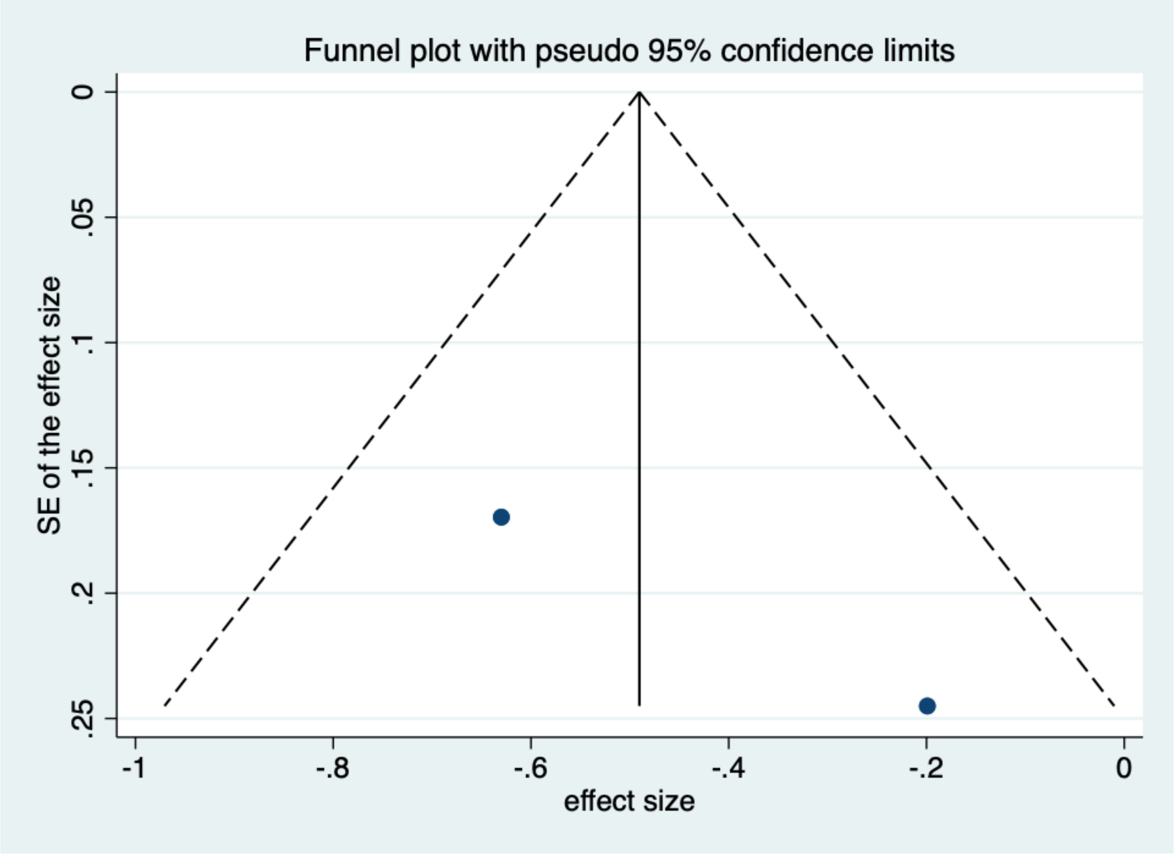
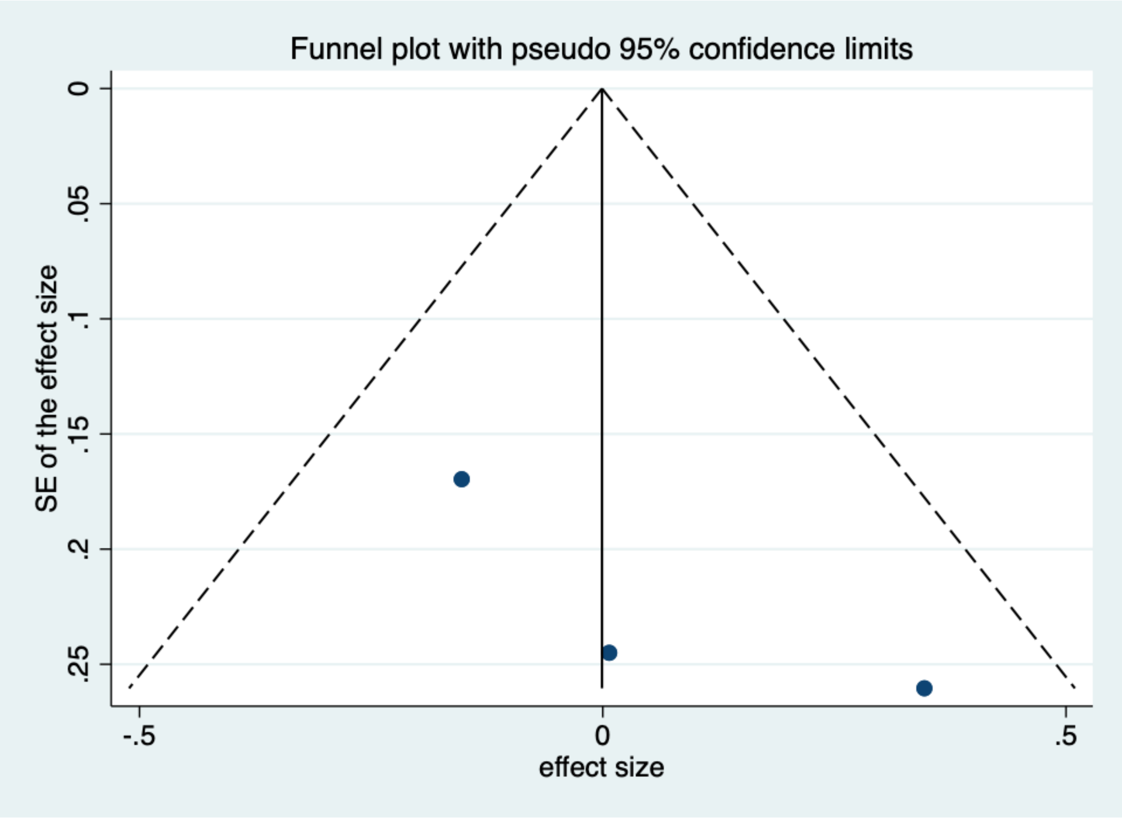


Figure S15. Funnel plot to assess publication bias for studies investigating the effect of third-wave Cognitive Behavioural Therapy interventions that aim to target diabetes-related distress primarily on HbA1c levels. A scatterplot of treatment effect against a measure of study precision, to visually inspect the studies for publication bias and systematic heterogeneity.



Appendix B: Mixed methods implementation study

B1) Per-protocol analyses for Effectiveness outcome. Preliminary analyses exploring pre-post treatment effects of COMPASS on self-reported outcomes.

Self-reported outcome	Group	*n*	Estimated pre-post difference	se	95% lower limit	95% upper limit	Cohens D
Depression (PHQ-9)	**All patients**	8	-1.13	0.74	-2.88	0.63	0.36
	Talking Therapies	4	0	0.71	-2.25	2.25	0.20
	Diabetes service	4	-2.25	1.11	-5.78	1.27	0.77
Anxiety (GAD-7)	**All patients**	8	-0.88	1.54	-4.51	2.77	0.04
	Talking Therapies	4	0.5	0.29	-.42	1.42	-0.18
	Diabetes service	4	-2.25	3.12	-12.17	7.68	0.43
General psychological distress (PHQ-ADS)	**All patients**	8	-2.00	2.17	-7.13	3.13	0.18
	Talking Therapies	4	0.5	0.65	-1.55	2.55	-0.02
	Diabetes service	4	-4.5	4.17	-17.78	8.78	0.58
Diabetes distress (DDS-17)	**All patients**	8	-0.13	0.30	-0.84	0.59	0.27
	Talking Therapies	4	-0.16	0.22	-.86	0.53	0.39
	Diabetes service	4	-0.09	.61	-2.04	1.86	0.08
Functioning (WSAS)	**All patients**	8	1.63	2.82	-5.03	8.28	0.08
	Talking Therapies	4	6.00	3.74	-5.91	17.91	-0.35
	Diabetes service	4	-2.75	3.20	-12.92	7.43	0.76
Health Related Quality of Life (EQ-5D)	**All patients**	8	0.38	0.38	-.51	1.26	-0.22
	Talking Therapies	4	0.25	0.48	-1.27	1.77	0.04
	Diabetes service	4	0.5	0.65	-1.55	2.55	-0.52
Loneliness (UCLA-R)	**All patients**	8	-1.5	1.56	-5.19	2.185	0.35
	Talking Therapies	4	-2.5	1.55	-7.45	2.45	0.42
	Diabetes service	4	-0.5	2.87	-9.64	8.64	0.14
Self-reported HbA1c mmol/mol	**All patients**	6	-4.42	4.13	-15.05	6.21	0.22
	Talking Therapies	2	-2.75	2.75	-37.70	32.19	0.04
	Diabetes service	4	-5.25	6.39	-25.57	15.07	0.31

B2) Per-protocol analyses for Implementation outcomes.

Online sessions completed	Mean	se	95% lower limit	95% upper limit	Median	IQR
Total sample n=8	3.50	0.80	1.60	4.00	3.00	2-4.5
Talking Therapies n=4	3.50	1.70	-1.80	8.80	2.50	1-6
Diabetes service n=4	3.50	0.50	1.91	5.10	3.00	3-5
Therapist sessions attended						
Total sample n=8	2.50	0.71	0.83	4.17	3.00	0.5-4
Talking Therapies n=4	2.25	1.03	-1.03	5.53	2.50	0.5-4
Diabetes service n=4	2.75	1.11	-0.80	6.30	3.00	1-4.5
Therapist support time (minutes)						
Total sample n=8	90.5	29.44	20.90	160.12	72.50	30-144
Talking Therapies n=4	51.30	18.10	-6.30	108.80	60	30-72.50
Diabetes service n=4	129.75	51.90	-35.35	294.85	144	47.50-212

B3) Patient participant information sheet

Investigating the care that people with diabetes receive for their emotional wellbeing.

We are inviting you to take part in a research study called "Emotional Wellbeing in Diabetes".

- Please read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide whether or not you wish to take part.
- You are free to decide whether to take part in this research study. If you choose not to take part, this will not affect the care you get from your healthcare service in any way.
- You can stop taking part in the study at any time, without giving a reason.
- This study forms part of a PhD project.
- Thank you for reading this information. If you decide to take part you will be given a copy of this information sheet and asked to sign a consent form via an online platform called Qualtrics. All the information will be included in this email.
- Ask us if there is anything that is not clear or if you would like more information.

Important things that you need to know

- We want to explore the treatment that people with both type 1 (T1D) and type 2 diabetes (T2D) receive for their emotional wellbeing.
- We are looking at the different treatments used in [INSERT NAME OF SERVICE] for people with diabetes who need emotional support. The treatment you receive for your emotional wellbeing will be decided by your care team.
- For this study we will ask you to complete some questionnaires and you may be asked to take part in an interview to give your feedback on the study and on any treatment you receive.

Contents

How to contact us

This study forms part of a PhD project. Therefore if you have any questions about this study, please talk to the research team:

Miss Emma Jenkinson, PhD student and primary research co-ordinator. Health Psychology Section, King's College London.

emma.jenkinson@kcl.ac.uk

Dr. Joanna Hudson. Health Psychology Section, King's College London.

joanna.hudson@kcl.ac.ukDr. Ruth Hackett. Health Psychology Section, King's College London.

ruth.hackett@kcl.ac.uk

1 Why are we doing this study?

This study is for people who want support to manage their emotional wellbeing alongside their diabetes. We will explore the treatments that people with T1D and T2D receive for their emotional wellbeing within [insert name of service]. This will hopefully help us to understand more about the care people with diabetes are receiving for their emotional wellbeing and how people with diabetes feel about this care.

Why might people with diabetes need support for their emotional wellbeing?

We know from research that people with diabetes can experience extra challenges because of their health condition, e.g., coming to terms with their diagnosis, managing changes to their lifestyle and managing their blood glucose levels. These challenges mean that people with diabetes are more likely to experience symptoms of emotional distress. This means that it is important for us to understand the treatment people are receiving for their emotional wellbeing alongside their diabetes so that we can make sure that these treatments are helpful for people with diabetes.

What are we trying to find out?

We want to find out the best way of treating feelings of emotional distress in people who have diabetes. Therefore, we want to explore the treatment that people receive for this within [INSERT SERVICE] for their emotional wellbeing and how people with diabetes feel about their treatment.

2 Why are we asking you to take part?

We have asked you to take part because you have either T1D or T2D, and you have recently spoken to a healthcare professional at [INSERT NAME OF SERVICE] and discussed that support to manage your emotional wellbeing may be useful to you.

3 What do you need to know about the treatments in this study?

The treatment you receive for your emotional wellbeing will be decided by you and your healthcare team depending on your individual needs and what treatment [INSERT NAME OF SERVICE] can provide. This may include face to face, group, or digital treatment.

By taking part in this study, you may receive a new digital treatment from [INSERT NAME OF SERVICE]. The new treatment called COMPASS, is specifically tailored to help people with long term conditions (LTCs) like diabetes. This treatment is based on a form of treatment known as cognitive behavioural therapy (CBT). This research study wants to find out if COMPASS is helpful for people with diabetes. It also would like to ask people about their views of digital therapy generally (e.g. is it an acceptable form of treatment and what may help or hinder people using digital therapy).

What will you need to do if you take part?

If you and your health care professional have decided COMPASS is a good treatment option for you to try, we will ask you to:

Complete a consent form and some brief questionnaires before accessing COMPASS. You will be asked to complete the consent form online. The questionnaires will also be administered online.

1) Complete questionnaires 12 weeks after the first set of questionnaires online.
2) Complete a 6-month follow up questionnaire online.

You may also be invited to take part in a brief interview with our research team about your experience of the care you received at [INSERT NAME OF SERVICE] but you do not have to do this if you don't want to.

We provide more information on points 1-4 at the end of this leaflet.

For people who decide not to use COMPASS as a treatment we would like to understand more about how and why some people choose not to use COMPASS. We will ask you to take part in a brief interview about your views of digital therapies. This will help us to better understand if there is anything we can do to help improve the way digital treatments like COMPASS are provided (e.g. providing more technical support/group based support). You will not be asked to complete any questionnaires if you are not using COMPASS.

We provide more information about what the brief interview will involve at the end of this leaflet.

What will happen to you during the study?

If you decide to take part in the study, for those who are using the COMPASS treatment, we will ask you to complete some questionnaires before starting your treatment. You will then start your treatment with [INSERT SERVICE] and continue this for as long as they recommend it.

If you choose to take part in the study and are not using COMPASS as a treatment option, you will then start your treatment with [INSERT SERVICE] and continue this for as long as they recommend it. We will contact you to complete a brief interview to explore your views on digital therapies.

What checks and tests will be done?

[IAPT]As part of your usual care, you will have taken part in an assessment phone call with a healthcare professional, and you will have consented to be contacted about research projects. Following this our research team will contact you to explain this study and answer any questions you may have about the study.

[GSTT] As part of your usual care you will have attended a routine appointment with your healthcare team, and you will have consented to be contacted about research projects. Following this our research team will contact you to explain this study and answer any questions you may have about the study.

5 What are the possible benefits of taking part in this study?

We hope that you will be helped by your treatment, but this cannot be guaranteed.

By taking part you will help us to get a better understanding of the types of treatments used by people with diabetes for their emotional wellbeing and improve the care of others moving forward and the research field.

6 What are the risks and benefits of taking part?

The risk of taking part is minimal. The treatment you will receive throughout the study period is what would be recommended as part of routine care and these treatments meet healthcare service standards.

If at any time you feel distressed, the research team and healthcare service will provide support with their protocols and procedures. As with any study involving psychological treatment, some of the topics and questionnaires may be distressing, especially if they require discussing your diabetes and mental wellbeing in detail. Please contact a member of the research team if you feel you need more support.

The nature of the interview that you will be invited to take part in is unlikely to be sensitive. However, if you do find some questions distressing you are free not to answer or take a break.

More information about taking part

Do you have to take part in the study?

No, it is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form.

If you decide not to take part in this study, you will receive the standard treatment, which is provided by your healthcare service. A decision not to take part at any time will not affect the standard of care you receive.

Will you get back any travel costs?

Taking part in this study will not require any travel. You can access all the questionnaires online. The interviews will also be conducted via the Microsoft Teams software.

Can you stop taking part after you've joined the study?

You can stop taking part in all of this study, or in any part of it, at any time and without giving a reason. But please talk to one of the research team first. They can advise you about any concerns you may have.

A decision to stop taking part at any time will not affect the standard of care you receive.

What will happen to information collected about you during the study?

We will keep all of your personal information confidential. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

We will record the interview using Microsoft Teams software. The recording will be password protected, and the interview will be typed up. Some of the interviews may be typed up by typists/transcription company called 'ClearVoice' who are contracted externally by King's College London. The typists/transcription company will have to adhere to King's College London data processing procedures.

The recording will be deleted, and any personal details or identifiable information will be removed.

We will store your contact details separately on password protected secure server through King's College London. Only the researchers will have access to the data. The information will be destroyed seven years after the research has finished. If you withdraw or are no longer able to participate in the study, we will continue to hold the information collected up until this point.

If any risk to you or others is disclosed, such as self-harm or suicide, we will need to break confidentiality. Your safety is very important. If you disclose this to us, we will therefore contact your GP to ensure you remain safe. You will be made aware of the breach of confidentiality.

If you consent to take part in the research study, any of the information collected about you may be inspected by the study sponsor (including representatives of the sponsor). Your records may also be looked at by the regulatory authorities or ethics committees.

These inspections are to check that the study is being carried out correctly and is following all the correct confidentiality and security procedures.

We may use information collected about you to support other research and advances in healthcare in the future. This information will only ever be shared anonymously using the study identification number. We will NEVER share information that could identify you personally or provide others with personal contact details. We will ask if you consent to this in the consent form but this is optional.

How will we use the information about you?

We will need to use information from you and your records at [INSERT NAME OF SERVICE] for this research project.

This information will include your name, contact details, clinical characteristics and details of your socio-demographic background. We will use this information to do the research or to check your records to make sure the research is being done properly.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep the information about you that we already have.

We also need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information at

1. www.hra.nhs.uk/information-about-patients/
2. Our leaflet available at:

   www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research (KCL)

   or

   https://www.slam.nhs.uk/about-us/privacy-and-gdpr (SLaM)
3. By asking one of the research team
4. by sending an email to the Data Protection Officer:

   info-compliance@kcl.ac.uk (KCL)

   or

InformationGovernance@slam.nhs.uk (SLaM)

What will happen to the results of the study?

We may publish the results of the study in scientific journals so that other healthcare professionals can see them. The study results may also be presented at conferences.

Importantly, you will not be identified in any report; your identity and any personal details will be kept confidential. Where data or quotes are used, they will be completely anonymous, and you will not be identifiable in any way. A summary of the study results study will also be sent to you in a newsletter via email from the research team once results have been analysed.

Who is organising and funding the study?

This study is organised by a research team in the Health Psychology Section at King's College London, which has run research studies for many years. The study coordination, data collection and analysis, and administration will be provided by the research team. The study is also funded by King's College London. You can contact the research team by using the contact details at the end of this information sheet.

Your healthcare service is not receiving any money or other payment for asking you to be part of the study.

King's College London has overall responsibility for the conduct of the study. We are responsible for ensuring the study is carried out ethically and in the best interests of the study participants.

Who has reviewed the study?

The study has been authorised by the Health Research Authority (HRA) as well as by [insert name of NHS research ethics committee] and the hospital's Research and Development Office.

What if new information becomes available during the course of the study?

Sometimes during a study, new information becomes available about the treatments that are being studied. If this happens, the therapist will tell you about it and discuss with you whether you want to continue the study. If you decide to stop taking part in the study, your therapist will arrange for your care to continue outside of the study.

Your therapist might also suggest that it is in your best interests to stop taking part in the study. They will explain the reasons and arrange for your care to continue outside the study.

What happens if the study stops early?

Very occasionally a study is stopped early. If this happens, the reasons will be explained to you. Your healthcare service will arrange for your care to continue outside of the study.

What if something goes wrong for you?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [Miss Emma Jenkinson, +44 7530001779 and emma.jenkinson@kcl.ac.uk]. If you remain unhappy and wish to complain formally, you can do this through the SLaM Patient Advice and Liaison Service (PALS) on 0800 731 2864, pals@slam.nhs.uk.

In the event that something does go wrong, and you are harmed during the research, you may have grounds for legal action for compensation against King's College London and/or SLaM NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

8 Contact details for further information

If you want further information about this study, contact the research team using the details below.

Research team contact details:

Miss Emma Jenkinson (PhD student and primary research coordinator): emma.jenkinson@kcl.ac.uk

Dr. Joanna Hudson: joanna.hudson@kcl.ac.uk

Dr. Ruth Hackett: ruth.hackett@kcl.ac.uk

Thank you for taking the time to consider taking part in this study.

What happens next?

If you are happy to take part, we ask that you sign the consent form that will be sent to you in an email as a website link.

Further information about what taking part will involve: If you and your healthcare professional have decided COMPASS is a good option for you, you will need to follow steps 1-4. If you do not use COMPASS go to step 5 below.

1. Complete the consent form and some brief questionnaires before accessing COMPASS

If you decide to take part, we will first ask you to sign a consent form and complete some brief questionnaires online before accessing COMPASS. You can complete the consent form online through a secure platform called Qualtrics. This will be emailed to you. We will send you the link to the online questionnaires in an email. We think that it will take you about 30 minutes to complete the questionnaires.

2. Complete a questionnaire pack 12 weeks after the first set of questionnaires

The research team will contact you after 12-weeks to complete another questionnaire. We expect this to take you around 25 minutes to complete. The questionnaires can be completed online. At 12-weeks we will email you with a link to the online questionnaire.

3. Complete a questionnaire pack after 6-months

The research team will contact you 6-months after your first questionnaire to complete a follow up questionnaire. We expect this to take you around 25 minutes to complete. The questionnaires can be completed online. At 6-months we will email you with a link to the online questionnaire.

All of the questionnaires in this study will be completed online. All the questionnaires will be completed online using a well-known, secure platform called Qualtrics. We will email you the link to all of the questionnaires when it is time for you to complete them. All the instructions on how to access the questionnaires will be sent to you via email and we will be able to provide support with accessing the questionnaires if you need this.

Here is a link to the privacy statements of the secure questionnaire platform.

Qualtrics:
https://www.qualtrics.com/privacy-statement/

4. Taking part in a brief interview with our research team about your experience of the care you received.

At 12 weeks, we will also ask if you would like to speak with one of our research team to do a short interview about how you found the care you received. This will last approximately 40-60 minutes and can be done over the phone. You do not have to do this if you do not want to.

5. Taking part in a brief interview with our research team for those who do not use COMPASS.

For people who decide not to use COMPASS, after 12-weeks we will ask if you would like to speak with one of our research team about your views of digital therapies. This will help us to better understand if there is anything we can do to help improve the way digital treatments like COMPASS are provided. We would also like to understand more about how and why some people choose not to use COMPASS. You will not be asked to complete any questionnaires (step 1-3) if you are not using COMPASS.

6. Giving the research team permission to access essential information from your records that are held at [INSERT NAME OF SERVICE]

As part of your routine care at [INSERT NAME OF SERVICE] they will collect information on the following areas:

1) The service records information about how many appointments you attend, how long these appointments last, the mode in which you spoke with your therapist and whether you need any extra treatment or support when you have completed your treatment programme. This helps the service to understand how good they are at providing people with access to the treatments they need. This information is also <u>very</u> important for this research study. This means we need your permission to access this information.

Your name **<u>will never</u>** appear next to the information that is noted down from your records. Instead, a unique number identification code will be used. This means the data will be anonymous.

B4) Patient participant consent form (administered online via Qualtrics)

CONSENT FORM (for those who uptake COMPASS)

Investigating the care that people with diabetes receive for their emotional wellbeing.

Chief Investigator: Dr Joanna Hudson

Email: joanna.hudson@kcl.ac.uk Telephone: 0207 188 1189

Please initial each box:

1.	I confirm that I have read and understood the information sheet [version X_, XX/XX/2020] for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my healthcare or legal rights being affected. I understand that data collected cannot be withdrawn up until the point I choose to no longer take part.	
3.	I agree to the researchers from the sponsor, accessing essential information about my psychological treatment from my medical records that are kept at [INSERT NAME OF SERVICE]	
4.	I agree to take part in this study.	
5.	I agree to potentially being interviewed as part of this study (This is optional – you do not have to agree to this to take part in the study).	
6.	If I take part in an interview, I agree to the interview being audio-recorded and transcribed.	
7.	If I take part in an interview, I agree to quotations from the interview being published anonymously (you will not be able to be identified through this).	
8.	I understand that the information collected about me will be used to support other research in the future and may be shared anonymously (e.g. using my unique patient identifier) with other researchers. (This is optional – you do not have to agree to this to take part in the study).	
9.	I agree to being sent a summary of the study results via an email newsletter, once the findings have been analysed (This is optional – you do not have to agree to this to take part in the study.)	
10.	I agree to be added to a database of participants that will help to inform the next phase of our research after this study. (This is optional – you do not have to agree to this to take part in the study).	

Patient's name	Patient's signature	Date

Please provide your contact details below:

Full name……….

Telephone number…….

Email address…….

Please provide your **GP's** details below:

GP name and surgery name ………………………………………………………………………………………

GP surgery postal address………………………………………………………………………………………

GP surgery telephone number………………………………………………………………………………………

B5) Baseline questionnaire pack

Baseline questionnaires: A research study to investigate the care that people with diabetes receive for their emotional wellbeing.

We will encourage people to complete this questionnaire before accessing COMPASS or treatment sessions with their therapist.

You may have already completed some questionnaires with [service] as part of your usual care. This is a separate research study but some of the questionnaires used are the same. This is to make sure our research remains independent from your usual care. We appreciate this will feel repetitive. Your involvement is really valuable and can help us to understand more about the best way of treating emotional wellbeing in people with diabetes and hopefully improve that care. As this is an online questionnaire all the questions will be asked through your internet browser, once you have finished all the questions we will automatically receive your answers..

The questionnaire takes about 30 minutes to complete. You can take a break if you want, but please complete the questionnaires on the same day. Thank you for your time and participation. We are very happy to answer any questions - just contact us using the details at the bottom of this letter.

Yours sincerely,

The Emotional Wellbeing in Diabetes Study Team

Miss Emma Jenkinson (PhD student and primary research coordinator):
emma.jenkinson@kcl.ac.uk

Please input your participant ID number. You can find this on the email with the link to this questionnaire.

Demographic Questionnaire

Please tick the answer of your choice or provide the information required

Age

What is your age?

___ years' old

Gender

What gender do you identify as?

- Male
- Female
- Other – please describe
- Prefer not to say

Ethnicity

What is your ethnic group?

White

- English, Welsh, Scottish, Northern Irish or British
- Irish
- Gypsy or Irish Traveller
- Any other white background (please specify)

Mixed or multiple ethnic groups

- White and Black Caribbean
- White and Black African
- White and Asian
- Any other mixed or Multiple ethnic background (please specify)

Asian or Asian British

- Indian
- Pakistani
- Bangladeshi

- Chinese
- Any other Asian background (please specify)

Black, African, Caribbean or Black British

- African
- Caribbean
- Any other black, African, or Caribbean background (please specify)

Other ethnic group

- Arab
- Any other ethnic group (please specify)

Home environment

Do you live

- Alone
- With partner
- With child/children
- With partner and child/children
- With other relatives
- With friends/flatmates

What is your postcode of the home you currently live in?

Or

- Prefer not to say

Education

We would like to know your education level. Which category below best describes your education level:

☐ GCSE

☐ A-levels

☐ Undergraduate degree

☐ Postgraduate (excluding PhD and Doctorate)

☐ Doctoral level

Other: please specify

Employment status

Which category below best describes your employment status:

- ☐ Employed
- ☐ Unemployed
- ☐ Unpaid voluntary work
- ☐ Not working and no benefits
- ☐ Retired
- ☐ dent
- ☐ Long-term sick or disabled
- ☐ Home maker/Carer
- ☐ ctively seeking work
- ☐ Rather not say

Diagnosed health conditions

We would like to know what conditions (i.e physical, psychological/psychiatric) you have been medically diagnosed with. Please could you specify any diagnosed conditions that you have? Please include your diabetes diagnosis e.g. type 1 diabetes or type 2 diabetes.

Use of psychotropic medication

We would like to know whether you are taking any psychotropic medication (anti-depressant/anxiety medication)?

- ☐ Prescribed and taking
- ☐ Prescribed but not taking
- ☐ Not prescribed
- ☐ Would rather not say
- ☐ Not sure

Use of diabetes specific medication

We would like to know whether you are currently taking any medication for your diabetes?

☐ Prescribed and taking
☐ Prescribed but not taking
☐ Not prescribed

☐ Would rather not say

☐ Not sure

Please could you specify what medication you are currently taking for your diabetes. This may include insulin treatment or other medications.

☐

Current blood glucose levels

We would like to know your latest HbA1c test result. If you know this, please could you specify it here:

☐

Please specify the date you received this result:

☐

If you do know this, did this information come from

☐ Your medical records

☐ Your memory

Or if you don’t know this information please indicate below

☐ Don’t know

Patient Health Questionnaire (PHQ-9)

Over the last two weeks, how often have you been bothered by any of the following problems? Please circle your answer on the scale provided.

1. Little interest or pleasure in doing things.

0	1	2	3
Not at all	Several days	More than half the days	Nearly every day

2. Feeling down, depressed, or hopeless.

0	1	2	3
Not at all	Several days	More than half the days	Nearly every day

3. Trouble falling or staying asleep, or sleeping too much.

0	1	2	3
Not at all	Several days	More than half the days	Nearly every day

4. Feeling tired or having little energy.

0	1	2	3
Not at all	Several days	More than half the days	Nearly every day

5. Poor appetite or overeating.

0	1	2	3
Not at all	Several days	More than half the days	Nearly every day

6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down.

0	1	2	3
Not at all	Several days	More than half the days	Nearly every day

7. Trouble concentrating on things, such as reading the newspaper or watching television.

0	1	2	3
Not at all	Several days	More than half the days	Nearly every day

8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual.

0	1	2	3
Not at all	Several days	More than half the days	Nearly every day

9. Thoughts that you would be better off dead or hurting yourself in some way.

0 Not at all	1 Several days	2 More than half the days	3 Nearly every day

*** If you answered 1, 2 or 3 for Q9**, please go to Patient Health Questionnaire Part B on the next page.

* If you answered 0 for Q9, please go to page 5 and complete the GAD-7 scale.

Patient Health Questionnaire (PHQ-9) - Part B

You mentioned that you are having thoughts that you would be better off dead or hurting yourself in some way. We would like to ask you to complete some extra questions. We also provide further information below for where you can access further help and support.

1. Are you currently making plans about how you would end your life?

Yes	No

***If you answered Yes, please go to Q2.**

* If you answered No, please got to **Q3**.

2. Are you currently taking any action to carry out these plans?

Yes	No

If yes, please rate how likely you think it is currently, that you will act on these plans to end your life?

0 ------- 1 ------- 2 ------- 3 ------- 4 ------- 5 ------- 6 ------- 7 ------- 8 ------- 9 ------- 10

No current chance

Definitely going to do this soon

3. What do you think stops you acting on these thoughts?

If you are feeling very distressed, or you are having thoughts about harming yourself or taking your own life, it is very important you ask someone for help.

It may feel that the really distressing feelings will never go away, or you cannot be helped – but you are not alone and not beyond help. There are people you can talk to who want to help.

- Is there a family member, friend or neighbour who you could talk to who might be able to help?
- You can call the Samaritans 24 hours a day for support. Telephone number: 116123. Website: www.samaritans.org.

If you feel that you may harm yourself and are unable to keep yourself safe, you should seek help immediately. There are people who want to help:

- go to your local A&E where the healthcare team can help you 24-hours a day.
- call an ambulance on 999

If you or anyone else is in immediate danger:

please call the Police or Ambulance Service on 999.

Generalized Anxiety Disorder scale (GAD-7)

Over the last two weeks, how often have you been bothered by any of the following problems? Please mark your answer on the scale provided.

1. Feeling nervous, anxious, or on edge.

0 Not at all	1 Several days	2 More than half the days	3 Nearly every day

2. Not being able to stop or control worrying.

0 Not at all	1 Several days	2 More than half the days	3 Nearly every day

3. Worrying too much about different things.

0 Not at all	1 Several days	2 More than half the days	3 Nearly every day

4. Trouble relaxing.

0 Not at all	1 Several days	2 More than half the days	3 Nearly every day

5. Being so restless that it's hard to sit still

0 Not at all	1 Several days	2 More than half the days	3 Nearly every day

6. Becoming easily annoyed or irritable.

0 Not at all	1 Several days	2 More than half the days	3 Nearly every day

7. Feeling afraid as if something awful might happen.

0 Not at all	1 Several days	2 More than half the days	3 Nearly every day

DDS-17 Measure of diabetes specific distress

Living with diabetes can be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Consider the degree to which each of the 17 items below may have distressed or bothered you during the past month and circle the appropriate number.

1. Feeling that diabetes is taking up too much of my mental and physical energy every day.

1	2	3	4	5	6
Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem

2. Feeling that may doctor doesn't know enough about diabetes and diabetes care.

1	2	3	4	5	6
Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem

3. Feeling angry, scared and/or depressed when I think about living with diabetes.

1	2	3	4	5	6
Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem

4. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.

1	2	3	4	5	6
Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem

5. Feeling that I am not testing my blood sugars frequently enough.

1	2	3	4	5	6
Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem

6. Feeling that I am often failing with my diabetes routine.

1	2	3	4	5	6
Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem

7. Feeling that my friends or family are not supportive enough or self-care efforts (e.g., planning activities that conflict with my schedule, encouraging me to each the “wrong” foods).

1	2	3	4	5	6
Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem

8. Feeling that diabetes controls my life.

1	2	3	4	5	6
Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem

9. Feeling that my doctor doesn’t take my concerns seriously enough.

1	2	3	4	5	6
Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem

10. Not feeling confident in my day-to-day ability to manage diabetes.

1 Not a Problem	2 A Slight Problem	3 A Moderate Problem	4 Somewhat Serious Problem	5 A Serious Problem	6 A Very Serious Problem

11. Feeling that I will end up with serious long-term complications, no matter what I do.

1 Not a Problem	2 A Slight Problem	3 A Moderate Problem	4 Somewhat Serious Problem	5 A Serious Problem	6 A Very Serious Problem

12. Feeling that I am not sticking closely enough to a good meal plan.

1 Not a Problem	2 A Slight Problem	3 A Moderate Problem	4 Somewhat Serious Problem	5 A Serious Problem	6 A Very Serious Problem

13. Feeling that friends or family don't appreciate how difficult living with diabetes can be.

1 Not a Problem	2 A Slight Problem	3 A Moderate Problem	4 Somewhat Serious Problem	5 A Serious Problem	6 A Very Serious Problem

14. Feeling overwhelmed by the demands of living with diabetes.

1 Not a Problem	2 A Slight Problem	3 A Moderate Problem	4 Somewhat Serious Problem	5 A Serious Problem	6 A Very Serious Problem

15. Feeling that I don’t have a doctor who I can see regularly enough about my diabetes.

1	2	3	4	5	6
Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem

16. Not feeling motivated to keep up my diabetes self-management.

1	2	3	4	5	6
Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem

17. Feeling that friends or family don’t give me the emotional support I would like.

1	2	3	4	5	6
Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem

UCLA-R Loneliness Scale

How often do each of these statements relate to you? Please indicate how often each of the statements below is descriptive of you.

1. I feel in tune with people around me

1 Never	2 Rarely	3 Sometimes	4 Often

2. I lack companionship

1 Never	2 Rarely	3 Sometimes	4 Often

3. There is no one I can turn to

1 Never	2 Rarely	3 Sometimes	4 Often

4. I do not feel alone

1 Never	2 Rarely	3 Sometimes	4 Often

5. I feel part of a group of friends

1 Never	2 Rarely	3 Sometimes	4 Often

6. I have a lot in common with people around me

1 Never	2 Rarely	3 Sometimes	4 Often

7. I am no longer close to anyone

1 Never	2 Rarely	3 Sometimes	4 Often

8. My interests and ideas are not shared by those around me

1 Never	2 Rarely	3 Sometimes	4 Often

9. I am an outgoing person

1 Never	2 Rarely	3 Sometimes	4 Often

10. There are people I feel close to

1	2	3	4
Never	Rarely	Sometimes	Often

11. I feel left out

1	2	3	4
Never	Rarely	Sometimes	Often

12. My social relationships are superficial

1	2	3	4
Never	Rarely	Sometimes	Often

13. No one really knows me well

1	2	3	4
Never	Rarely	Sometimes	Often

14. I feel isolated from others

1	2	3	4
Never	Rarely	Sometimes	Often

15. I can find companionship when I want it

1	2	3	4
Never	Rarely	Sometimes	Often

16. There are people who really understand me

1	2	3	4
Never	Rarely	Sometimes	Often

17. I am unhappy being so withdrawn

1	2	3	4
Never	Rarely	Sometimes	Often

18. People are around me but not with me

1	2	3	4
Never	Rarely	Sometimes	Often

19. There are people I can talk to

1	2	3	4
Never	Rarely	Sometimes	Often

20. There are people I can turn to

1 Never	2 Rarely	3 Sometimes	4 Often

Work and Social Adjustment Scale (WSAS)

People's problems sometimes affect their ability to do certain day-to-day tasks in their lives. To rate your problems, look at each section and determine on the scale provided how much your problems impairs your ability to carry out the activity.

1. **Work –** if you are retired or choose to not have a job for reasons unrelated to your problem, please tick N/A (not applicable)

0 Not at all	1	2 Slightly	3	4 Definitely	5	6 Markedly	7	8 Very severely

NA ☐

2. **Home Management** (e.g. cleaning, tidying, shopping, cooking, looking after home or children, paying bills)

0 Not at all	1	2 Slightly	3	4 Definitely	5	6 Markedly	7	8 Very severely

3. **Social Leisure Activities** with other people, e.g. parties, bars, clubs, outings, visits, dating, home entertaining etc

0 Not at all	1	2 Slightly	3	4 Definitely	5	6 Markedly	7	8 Very severely

4. **Private Leisure Activities** done alone, e.g. reading, gardening, collecting, sewing, walking etc

0	1	2 Slightly	3	4 Definitely	5	6 Markedly	7	8 Very severely

5. **Family and Relationships** – Form and maintain close relationships with others including the people that I live with

0 Not at all	1	2 Slightly	3	4 Definitely	5	6 Markedly	7	8 Very severely

NHS
South London and Maudsley
NHS Foundation Trust

KING'S College LONDON

EQ-5D-3L Measure of Health-related Quality of Life

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

SELF-CARE

I have no problems with self-care ☐

I have some problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

PAIN / DISCOMFORT

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

ANXIETY / DEPRESSION

I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

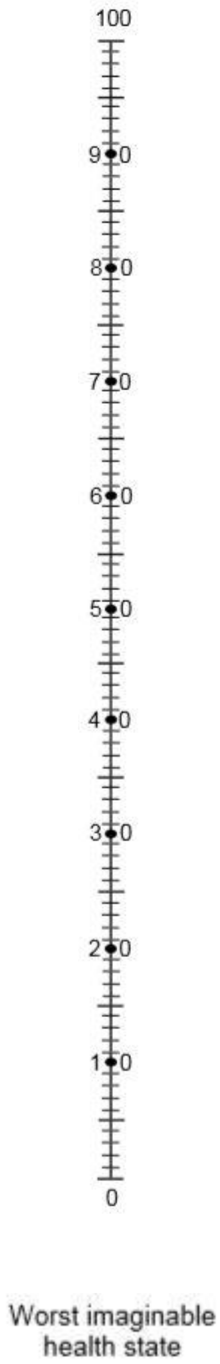
- We would like to know how good or bad your health is TODAY.
- The scale is numbered from 0 to 100.
- 100 means the best health you can imagine.

  0 means the worst health you can imagine

- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below

Best imaginable
health state

YOUR HEALTH TODAY ☐



B6) Patient participant semi-structured interview schedule

Introduction

- You kindly agreed to be contacted to take part in an interview about your experiences of taking part in this study. I am currently contacting people who took part in this study to find out about their experiences of taking part and of receiving treatment for their emotional wellbeing alongside their diabetes.

- Are you still happy to complete the interview?

- I would like to audio record the conversation we have today so I can refer back to it later, it enables me to listen to you better, is that okay?

Before we start there are a few things I'd just like to mention:

- What we talk about will be used as part of the study, but anything said will remain anonymous, we're going to ensure this by not using your real name when we type up the interview. Is that ok?

- If I ask a question that you don't want to answer that is absolutely fine, just say so and I'll ask you a different question. If at any point you would like to have a break or stop participating, then please just tell me and we will stop the interview.

- Do you have any questions before we start? Are you happy to continue?

- Right before I start the interview, I will do a brief introduction, please just ignore me.
- Can I press record?

- This is participant: [xxx]. Today is the Date:

Section A: EVERYONE. First I would like to ask you what made you want to take part in the study?

- Prompts
  - What were your reasons for agreeing to take part?
  - What were your expectations of the study?
  - How did you find the recruitment process? (Prompt: contact with the researcher only over the telephone, the screening process, the online links being sent?)
  - Was there enough information to help you understand what would be involved in taking part?
  - Is there anything we could have changed / any more information we could have provided at this stage that would have been helpful?
  - How have you found completing the questionnaires so far (prompts: time, ease, relevance)

  - How did you find the level of contact with the research team across the study? (Prompt: would you have liked more or less? Would you have preferred the contact to have been through different channels of communication?)

Section B: FOR EVERYONE

- What made you seek treatment for your emotional wellbeing?

FOR GSTT only.

- How did you feel about your healthcare professional suggesting that you should receive support for your emotional wellbeing?
- Tell me about the different treatment options that were described to you? (Prompt: were any other options described to you)

Section B: FOR IAPT ONLY. I'd like to find out about your experience of being referred and assessed by [INSERT NAME OF SERVICE]

- Tell me about your experience of the referral process? (Prompt, how did you learn about IAPT?)
- Tell me about your experience of the assessment process?
- Could anything have been done differently?
- How were the different treatment options explained to you when you had your first assessment?

Confirm their treatment option eg face to face, digital, group.

- What made you decide on your treatment option?
  - If a digital treatment option – what made you choose a digital treatment option (inc COMPASS)? If not digital, why not?
  - If not digital how would you feel about using a digital treatment option?
- Can you describe to me how COMPASS was explained to you at your assessment?

- **[No treatment]** For those who did not engage with the service/commence any treatment – no right or wrong answers but what were the reasons that meant you did not start treatment?

-

Section C: I would now like to find out about your experience of the treatment you received.

FOR THOSE THAT DIDNT RECIEVE COMPASS. Did you find the treatment you received beneficial? If so what was it about the treatment you received that worked for you and your DM?

Can you explain how your DM was talked about during in therapy in the context of your mood?

Was that helpful? Why/why not?

FOR THOSE WHO RECEIVED COMPASS ONLY. I would now like to find out about your experience of using COMPASS

.

ENGAGERS:

- What were your expectations of COMPASS before trying it?
- Were there any barriers to you using a digital treatment? Were there any facilitators?
- What was your first impression of COMPASS?
- How did you find COMPASS treatment after a while of using it?
- How did you use COMPASS? (Prompt: one module a week? Therapist support?)
- What did you like about COMPASS?
- What did you dislike about COMPASS?
- How did you feel that the content covered in COMPASS related to your diabetes and your mood/distress?
- Was the information included relevant to your needs? (Prompt: was the content relevant to T1DM or T2DM?)
- If no: Currently COMPASS is used for a range of LTCs and not specific to DM, is there anything we could do to make it more useful for you?
- Is there anything more you would have liked?
- What technique do you think you are most likely to use in your life from the COMPASS platform?
- How did you find the time commitment? (Prompt: were you able to fit COMPASS into your normal routine? If yes did you have any strategies to do this)
- Even though we are now out of lockdown, do you think that COVID-19 had any influence on your experience of using COMPASS? (eg being at home more etc)
- Was there anything that made you want to come back to COMPASS?
- Would you recommend anything we could do/add to keep people engaged in COMPASS? (Prompt: especially for those who aren't engaged)
- Would you recommend COMPASS to a friend who has T1DM/T2DM and is experiencing distress/anxiety/depression? Why/ why not?
- What do you think about this treatment for managing emotional distress?
- Do you think that you would have benefitted from a treatment for low mood/distress/anxiety that was not focused around your LTC? (Prompt: was this aspect useful or not?)
- Did you feel as though COMPASS was suitable to someone like you in terms of your age, gender, ethnicity, diabetes status?
    - Any aspects in particular?
- What could be done to improve this?
- How does COMPASS compare to other forms of treatment you have accessed for your T1/T2DM and/or distress?

COMPASS NON-ENGAGERS: We've noticed that you registered on the COMPASS platform but did not use COMPASS.

- What reasons were there that meant you did not end up using COMPASS? (e.g. length of modules, content, finding it upsetting/ boring/ frustrating, difficulties finding the time to do it, not finding it helpful/relevant, not understanding the purpose, changes in circumstances/ life events etc)
- Is there anything that could have helped you to continue accessing COMPASS?
- Do you think there is a treatment that you would have been more likely to use that wasn't COMPASS? If so what? Why?

COMPASS DROP OUT: We have noticed that you started using COMPASS but have now stopped/withdrawn from the study/dropped out?

- What were your expectations of COMPASS before trying it?
- What was your first impression of COMPASS?
- How did you find COMPASS treatment after a while of using it?
- How did you use COMPASS?
- What reasons were there that meant you did end up dropping out of compass? (e.g. length of modules, content, finding it upsetting/ boring/ frustrating, difficulties finding the time to do it, not finding it helpful/relevant, not understanding the purpose, changes in circumstances/ life events etc)
- Was there anything you disliked?
- If yes: How could we change this to better meet your needs?
- Was there anything that you liked?
- Was there anything you thought worked well that we could do more of?
- Is there anything that could have helped you to continue accessing COMPASS?
- Would you recommend COMPASS to a friend who has T1D/T2DM and is experiencing distress/anxiety/depression? Why/Why not?
- How did you feel that the content covered in COMPASS related to your DM and your mood/distress?
- Can you explain if you felt the content was relevant to the challenges you face with diabetes? Why/ why not? How might we improve on this?
- Do you think that you would have benefitted from a treatment for low mood/distress/anxiety that was not focused around your LTC? (Prompt: was this aspect useful or not?)
- What do you think about this treatment for managing emotional distress?
- Did you feel as though COMPASS was suitable to someone like you in terms of your age, gender, ethnicity, diabetes status?
    - Any aspects in particular?
- What could be done to improve this?
- How does COMPASS compare to other forms of treatment you have accessed for your DM and/or distress?
- **Drop out**: Now you've dropped out what are you plans in terms of seeking support

COMPASS NON-REGISTERED: We've noticed that you were eligible for COMPASS, but that you did not sign up to access COMPASS platform.

- What reasons were there that meant you did not end up signing up to access COMPASS?
- Is there anything that could have helped you to register and access COMPASS?
- How did you find the digital on-boarding session? Was this helpful

Section D. Now I would like to tell me about the support provided by your guide

- How were you supported using COMPASS? (format, frequency)
- Was there anything you felt the guide offered that the COMPASS online sessions on their own could not offer?
- What was helpful about the guide?
- What was unhelpful?
- How would you like to be supported when using COMPASS?
- Do you think the guide is needed?

- We are considering incorporating different forms of support into COMPASS like peer support or social support. Would you access this support? Would this be useful for you?

EVERYONE: I now want to find more about the link between your DM and your emotional wellbeing and about how your mood has been since the study?

- What is the link between your DM and your distress/?
- Would you experience low mood and/or anxiety if you were not diagnosed with DM?
- What challenges do you face when managing your diabetes?
- How does these challenges impact on your mood?
- Linked to the challenges you described – would it be helpful to include this in COMPASS? Y/N – why?
- How might you like COMPASS to do this? Prompt: Key scenarios that may be helpful for people with diabetes
- And vice versa what challenges do you face when managing your mood?
- How does this impact on your diabetes?
- Linked to the challenges you described – would it be helpful to include this in COMPASS? Y/N – why?
- How might you like COMPASS to do this? Prompt: scienarios that are relevant for you?
- How has your mood/feelings of distress changed since you received COMPASS? (if it has changed, why do you think this is?)
- How do you feel you have been coping with your DM since receiving COMPASS?
- Did you notice any difference in your symptoms, thoughts, feelings, lifestyle, social/relationships?
- Do you think that you would have benefitted from a treatment for low mood/distress/anxiety that was/was not focused around your LTC?

Closing and Ending

- Thank you very much for sharing your thoughts and experiences with me today.

- What you've told me will really help us to understand participants' experiences and hopefully will ultimately help us to improve COMPASS, which will help us develop better treatments for distress in diabetes.
- Now, is there anything else you would like to tell me? Is there anything you would like to ask me?

Appendix C: Cross sectional study

C1) Supplementary materials for manuscript under review

	n(%)/mean (sd)	Non-LTC group	LTC group	Mean diff	95% CI	Statistical test	*p*-value
Total attended assessment:	13,549	10,003 (73.82%)	3546 (26.17%)			$X^{2=}$12.47	p<.001
Demographic variables							
Age (years):	36.74 (12.61)	34.33 (10.70)	43.53 (14.89)	-9.20	-9.66 to -8.74	t=-39.443	p<.001
Gender (% Female)	9,288 (69.30%)	6,802(68.74%)	2,486 (70.87%)			$X^{2=}$0.5.49	p=0.019
Ethnicity:						X^2=97.25	p<.001
Asian or Asian British	978 (7.54%)	716 (7.16%)	262 (7.39%)				
Black or black British	2666 (20.56 %)	1,769 (17.68%)	897 (25.30%)				
Mixed	1,018 (7.85%)	738 (7.38%)	280 (7.90%)				
Other	931 (7.18%)	704 (7.04%)	227 (6.40%)				
White	7,377 (56.88%)	5,610 (56.10%)	1,767 (49.83%)				
Ethnic minority (% Yes) Missing: n= 600	5593 (43.19%)	3927 (39.26%)	1666 (46.98%)			X^2=57.73	p<.001
Deprivation decile:	3.40 (1.68)	3.47 (1.73)	3.17 (1.53)	0.30	0.24 to 0.36	t= 9.13	p<.001
GP referral (% Yes)	1,486 (11.00%)	913 (9.13%)	573 (16.16%)			X^2=134.13	p<.001
Talking Therapies service, A	7,665 (56.57%)	5,825 (58.23%)	1,840 (51.89%)			x^2 = 42.87	p<0.001
Clinical variables							
PHQ-9	13.88 (6.17)	13.36 (6.11)	15.33 (6.20)	-1.97	-2.20 to -1.73	t= -16.35	p<.001
GAD-7	12.51 (5.27)	12.25 (5.27)	13.2 (5.19)	-0.98	-1.18 to -0.78	t =-9.48	p<.001
WSAS	18.05 (9.32)	17.44 (9.06)	19.85 (9.85)	-2.41	-2.79 to -2.03	t= -12.50	p<.001

Supplementary Table 1: The demographic and clinical characteristics of those who attended an assessment.

CI= Confidence Interval; LTC= Long-term Condition.

Supplementary Table 2: The demographic and clinical characteristics of those who engaged with treatment.

	n(%)/mean (sd)	Non-LTC group	LTC group	Mean diff	95% CI	Statistical test	*p*-value
Total Engaged:	4622	3,468 (34.67%)	1,154 (32.54%)			$X^{2=}1.204$	*p=0.022*
Demographic variables							
Age (years):	36.63 (12.04)	34.49 (10.14)	43.06 (14.71)	-8.57	-9.33 to -7.81	t= -22.02	*p*<.001
Gender (% Female)	3222 (70.27%)	2410 (70.10%)	812 (70.79%)			$X^{2=}1.99$	*p*=0.656
Ethnicity:						$X^2(4) = 70.56$	*p*<.001
Asian or Asian British	291 (6.30%)	209 (6.03%)	82 (7.12%)				
Black or black British	850 (18.40%)	550 (15.86%)	300 (26.00%)				
Mixed	337 (7.29%)	245 (7.06%)	92 (7.97%)				
Other	267 (5.78%)	202 (5.82%)	65 (5.63%)				
White	2,758 (59.67%)	2,171 (62.60%)	587 (50.87%)				
Ethnic minority (% Yes):	1,745 (37.75%)	1,206 (34.77%)	539 (46.70%)			$X^2=52.58$	*p*< .001
Deprivation decile:	3.49 (1.75)	3.58 (1.81)	3.21 (1.55)	0.37	0.26 to 0.49	t=6.27	*p*<.001
GP referral: (% Yes):	401 (8.68%)	242 (6.98%)	159 (13.77%)			$X^2=50.59$	*p*<.001
Talking Therapies service, A: (% Yes):	2,682 (58.03%)	2,068 (59.63%)	614 (53.21%)			$x^2 = 14.67$	*p*<0.001
Clinical variables							
PHQ-9	13.62 (5.7)	13.14 (5.6)	15.07(5.75)	-1.93	-2.31 to -1.55	*t*= -10.0	*p*<.001
GAD-7	12.67 (4.88)	12.48 (4.85)	13.23 (4.94)	-0.76	-1.08 to -0.43	*t* =-4.56	*p*<.001
WSAS	17.84 (8.65)	17.27 (8.32)	19.56 (9.40)	-2.29	-2.88 to -1.71	*t*= -7.75	*p*<.001

CI= Confidence Interval; LTC= Long-term Condition

Supplementary table 3: Binary logistic regressions of long-term condition status on assessment attendance, treatment engagement, and receipt of internet-enabled therapies (Model 2)

Model 2	Attended assessment			Engagement			Internet-enabled therapy		
	Odds ratio	P-value	95% CI	Odds ratio	P-value	95% CI	Odds ratio	P-value	95% CI
LTC status	1.12	0.018	1.02 -1.24	0.94	0.141	0.86 -1.02	0.67	<0.001	0.56 - 0.82
Age	1.00	0.456	1.00- 1.00	1.00	0.548	1.00 -1.00	0.98	<0.001	0.97-0.99
Gender	0.97	0.458	0.89-1.05	1.06	0.176	0.97-1.14	0.90	0.199	0.68 – 0.92
Ethnicity	0.76	<0.001	0.71-0.83	0.77	<0.001	0.71-0.83	0.79	0.002	0.59-0.86
Deprivation decile	0.99	0.960	0.98-1.03	1.04	<0.001	1.02-1.07	1.13	<0.001	1.09-1.17

CI= confidence interval; LTC= long-term condition. Variables included in Model 2: LTC status, age, gender, ethnicity, and deprivation decile.

Supplementary table 4: Fully adjusted binary logistic regressions of long-term condition status on assessment attendance, treatment engagement, and receipt of internet-enabled therapies (Model 3)

Model 3	Attended assessment			Engagement			Internet-enabled therapy		
	Odds ratio	P-value	95% CI	Odds ratio	P-value	95% CI	Odds ratio	P-value	95% CI
LTC status	1.16	0.062	0.99 -1.35	0.97	0.563	0.89- 1.07	0.74	0.003	0.60 - 0.90
Age	1.00	0.441	1.00- 1.01	1.00	0.135	1.00 -1.01	0.98	<0.001	0.97 - 0.98
Gender	0.83	0.011	0.72-0.96	1.02	0.602	0.94-1.11	0.92	0.337	0.79 – 1.09
Ethnicity	0.82	0.003	0.70-0.94	0.81	<0.001	0.75-0.87	0.79	0.003	0.68 – 0.92
Deprivation decile	1.02	0.202	0.99-1.06	1.03	0.010	1.01-1.05	1.02	0.457	0.98-1.06
PHQ-9	0.99	0.091	0.97-1.00	0.98	<0.001	0.97-0.99	0.98	0.035	0.97-1.00
GAD-7	1.02	0.021	1.00-1.04	1.03	<0.001	1.02-1.04	1.02	0.096	1.00-1.04
WSAS	0.99	0.040	0.98-1.00	1.00	0.467	0.99-1.00	0.98	0.002	0.97-0.99
GP referral	0.99	0.891	0.81-1.21	0.77	<0.001	0.67-0.88	0.99	0.918	0.76-1.27
Service	4.29	<0.001	3.59-5.14	1.19	<0.001	1.10-1.29	0.16	<0.001	0.13-0.20

CI= confidence interval; LTC= long-term condition. Variables included in model 3: LTC status, age, gender, ethnicity, deprivation decile, baseline PHQ-9 (depression), GAD-7 (anxiety) and WSAS (social functioning) scores, GP referral source and service.

	n(%)/mean (sd)	Non-LTC group	LTC group	Mean diff	95% CI	Statistical test	*p*-value
Total Attended assessment:	13,549	10,003	3,546				
Total received internet-enabled therapy (% yes of those attended assessment):	868 (6.41%)	727 (7.27%)	141 (3.98%)			X^2 =47.30	*p*<.001
Demographic variables							
Age (years):	33.35 (9.80%)	32.82 (9.31)	36.16 (11.42)	-3.34	-5.12 to -1.56	t= -3.69	*p*<.001
Gender (% Female)	620 (71.84%)	520 (71.82%)	100 (71.94%)			$X^{2=}$0.0008	*p*=0.977
Ethnicity:						$X^2(4) = 16.41$	*P* = *0.003*
Asian or Asian British	47 (5.41%)	35 (4.81%)	12 (8.51%)				
Black or black British	143 (16.47%)	108 (14.86%)	35 (24.82%)				
Mixed	49 (5.65%)	38 (5.26%)	11 (7.80%)				
Other	63 (7.26%)	57 (7.84%)	6 (4.48%)				
White	519 (59.79%)	449 (61.76%)	70 (4.26%)				
Ethnic minority (% Yes):	310 (35.71%)	244 (33.56%)	66 (46.81%)			X^2= 8.29	*p*=0.004
Deprivation decile:	3.80 (1.88)	3.83(1.89)	3.60 (1.80)	0.22	-0.12 0.56	t= 1.29	*p*= 0.198
GP referral: (% Yes):	84 (9.68%)	65 (8.94%)	19 (13.48%)			X^2= 2.76	*P* = 0.097
Talking Therapies service A: (% Yes):	775 (89.29%)	662 (91.06%)	113 (80.14%)			x^2 =14.71	*p*<0.001
Clinical variables							
PHQ-9	12.92 (5.79)	12.81 (5.80)	13.51 (5.90)	-0.71	-1.77 to 0.35	*t*= - 1.31	*p*=0.095
GAD-7	12.25 (5.13)	12.15 (5.14)	12.77 (5.08)	-0.62	- 1.56 to 0.32	*t* =-1.29	*p*= 0.098

WSAS	17.84 (8.65)	16.57 (8.05)	18.43 (8.94)	-1.90	-3.40 to -0.36	*t*= -7.75	*p*=0.008

Supplementary Table 5: The demographic and clinical characteristics of those who received internet-enabled therapy.

Supplementary table 6: Binary logistic regressions of binary logistic regressions of receipt internet-enabled therapies on treatment engagement (Model 2)

Model 2	Engagement		
	Odds ratio	P-value	95% CI
Internet enabled therapy	2.78	<0.001	2.40- 3.21
LTC status	0.95	0.310	0.87 -1.04
Age	1.00	0.789	0.99- 1.00
Gender	1.05	0.231	0.97-1.14
Ethnicity	0.78	<0.001	0.72-0.84
Deprivation decile	0.92	<0.001	0.90-1.15

CI= confidence interval; LTC= long-term condition. Variables included in Model 2: LTC status, age, gender, ethnicity, and deprivation decile.

Supplementary table 7: Fully adjusted binary logistic regressions of receipt internet-enabled therapies on treatment engagement (Model 3)

Model 3		Engagement	
	Odds ratio	P-value	95% CI
Internet-enabled therapy	2.68	<0.001	2.30 – 3.10
LTC status	0.99	0.807	0.90 -1.09
Age	1.00	0.021	1.00- 1.01
Gender	1.02	0.681	0.94-1.11
Ethnicity	0.81	<0.001	0.75-0.88
Deprivation decile	1.03	0.013	1.01 -0.05
PHQ-9	0.98	<0.001	0.97-0.99
GAD-7	1.02	<0.001	1.02-1.05
WSAS	0.99	0.737	0.99-1.00
GP referral	0.76	<0.001	0.66-0.88
Service	1.30	<0.001	1.20-1.41

CI= confidence interval; LTC= long-term condition. Variables included in model 3: LTC status, age, gender, ethnicity, deprivation decile, baseline PHQ-9 (depression), GAD-7 (anxiety) and WSAS (social functioning) scores, GP referral source and IAPT service.

Appendix D: Qualitative stakeholder study

D1) Qualitative study stakeholder participant information sheet

Participant information sheet: Healthcare professionals

IRAS reference number: [301444]

Investigating the care that people with diabetes receive for their emotional wellbeing.

We would like to invite you to take part in an interview for a research study conducted by King’s College London. We are inviting you to this very important research study as you are working in a service which is currently providing psychological support to people with diabetes and is currently implementing COMPASS.

COMPASS is an online cognitive behavioural therapy (CBT) platform tailored to treat psychological distress in long term health conditions such as diabetes. This study will investigate your experiences of assessing people with diabetes for psychological support and/or using online CBT treatments such as COMPASS to help support the emotional wellbeing of patients with either type 1 or type 2 diabetes.

Joining the study is entirely up to you, before you decide we will tell you why the research is being done and what it will involve.

Please read through this information sheet. We will contact you in a few days to give you the chance to ask any questions about the study and to decide if you are interested in taking part in the study

What is the purpose of the study?

This study aims to contribute towards improving the quality of care provided to patients experiencing psychological distress alongside their diabetes. The study will explore both patients’ and healthcare professionals’ experiences of the treatment people with type 1 and type 2 diabetes receive for their emotional wellbeing. This study forms part of a PhD project.

We are contacting you because you either i) referred a person with diabetes to access psychological support, ii) assessed a person with diabetes for psychological support or you have supported individuals with diabetes using COMPASS or iiii) Work in or alongside one of the health care services implementing COMPASS. We are interested in the barriers and facilitators of using digital treatment platforms within psychological services. We are interested in your thoughts about the factors that influence the treatment option you recommend to patients. If you supported patients using COMPASS, we will also ask some specific questions relating to your experience of using and supporting patients on COMPASS. We hope to keep improving COMPASS and therefore if you did support a patient using COMPASS we would be delighted to hear your thoughts about online programmes and how easy/difficult they are to use as part of your usual practice.

Why have I been asked to take part?

We have asked you to take part in the study because you are working in or alongside a service which is providing psychological support for individuals with diabetes, and you are working in a service which is currently implementing COMPASS. We are interested in speaking to people who have experience of referring people with diabetes for psychological support, assessing patients with diabetes for psychological treatment and those people who have experience of supporting patients in their use of COMPASS. We are also interested to speak to those who are working alongside psychological services that are implementing new treatments for people living with diabetes eg COMPASS.

Do I have to take part?

No, it is up to you if you would like to join the study – you do not have to. If you would like to take part, then we will contact you in a few days to give you the chance to ask any questions about the study. We will then ask you if you want to take part in our study and arrange an interview. You are free to change your mind and to withdraw at any time.

What will the study involve?

The study will involve you taking part in a short interview about your experiences and opinions of assessing individuals with type 1 or type 2 diabetes for psychological treatment and/or supporting individuals with type 1 or type 2 diabetes using COMPASS. The researcher will also ask some general information about you before the interview starts. The interview will last approximately 30-40 minutes and will be completed via Microsoft Teams.

If you agree to take part, we first ask that you sign the online consent form that is completed through the well-known secure platform Qualtrics. This will be sent to you in an email.

Will my information be kept confidential?

All your personal information will be kept confidential using your unique study identification number. The only time we would break confidentiality is if you were to say something which identified you as being at risk to either yourself or others. Interviews will be conducted on Microsoft Teams and will be audio recorded. Participants will be asked to turn off their cameras if they do not wish to be on the recording. The interview will be saved onto a password protected server and typed up. The recording will be deleted, and any personal details or identifiable information will be removed. Some of the interviews may be typed up by a typist (a transcription company) that are recommended by King's College London called 'ClearVoice'. The typist/transcription company will adhere to King's College London data processing procedures.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your initials, name, contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

1. At www.hra.nhs.uk/information-about-patients/
2. our leaflet available from
www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research (KCL)
or
https://www.slam.nhs.uk/about-us/privacy-and-gdpr (SLaM)
3. by asking one of the research team
4. by sending an email to the Data Protection Officer info-compliance@kcl.ac.uk (KCL) or InformationGovernance@slam.nhs.uk (SLaM)

If you consent to take part in the research, any of the information collected about you may be inspected by the study sponsor (including representatives of the sponsor). Your records may also be looked at by the regulatory authorities or ethics committees. These inspections are to check that the study is being carried out correctly and is following all the correct confidentiality and security procedures.

What are the possible disadvantages / benefits of taking part?

The risk of taking part is minimal. You will only need to take part in an interview once. The nature of the interview is unlikely to be sensitive. You are free to not answer certain questions if you find them distressing.

There will be no direct benefits to you for taking part in this study. However, the results will provide important information on the psychological care of individuals with type 2 diabetes.

What if there is a problem?

If you have a question or concern about any aspect of this study, you can speak to the any of the researchers involved in the study who will do their best to answer. You can contact the research team using the contact details at the bottom of this information sheet

In the event that something does go wrong, and you are harmed during the research, you may have grounds for legal action for compensation from the NHS and/or King's College London but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen to the results of the research study?

The results of this study may be published in scientific journals and at scientific conferences. You will not be identified in any report. Where quotes may be used, they will be completely anonymous. If you are interested in the results, a summary of the results will be sent to you by the research team in an email newsletter once the results have been analysed.

Who has reviewed the study?

The study has been authorised by the Health Research Authority (HRA) as well as by [insert name of NHS research ethics committee] and the hospital's Research and Development Office.

How has the study been funded?

The study has been funded by King's College London.

Any further queries?

This study forms part of a PhD project. Therefore, if you have any questions about this study, please talk to the **research team**:

Miss Emma Jenkinson (PhD student and primary research coordinator): emma.jenkinson9@nhs.net

Dr Joanna Hudson: joanna.hudson@kcl.ac.uk

Dr Ruth Hackett: ruth.hackett@kcl.ac.uk

If you have any further questions or concerns about the study, you may contact the following organisations:

For independent advice on participating in NHS research:

Patient Advice and Liaison Service (PALS) - 0207 188 8803

For independent advice about making a complaint:

South London Independent Complaints Advisory Service (ICAS) – 0300 456 2370