Research Thesis

Exploring Psychological Processes Associated with Mental Health Outcomes in People Living with Diabetes

Submitted in partial fulfilment of the degree of Doctorate in Clinical Psychology at the Division of Clinical Psychology, Department of Primary Care and Mental Health, University of Liverpool

Kate Cotton

Supervisors:
Dr Gemma Cherry & Dr Peter Fisher

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Introductory Chapter: Thesis Overview

This thesis aims to explore factors associated with mental health outcomes for people living with diabetes.

Diabetes

The number of people living with diabetes in the UK is predicted to rise to 5.3 million by 2025 (Diabetes UK, 2019). There are seven types of diabetes; 90% of those with diabetes have Type 2 Diabetes Mellitus (T2DM), 8% have Type 1 Diabetes Mellitus (T1DM) and 2% have other types (Diabetes UK, 2022). An estimated 28,000 individuals under 24 years old have T1DM in the UK (National Paediatric Diabetes Audit & Royal College of Paediatrics and Child Health, 2020). More children under 18 have T1DM than T2DM. However, the incidence of T2DM in childhood in the UK is rising, especially in those who are female and of Black or Asian ethnicity (Candler et al., 2018).

T1DM is a chronic, genetic metabolic condition characterised by defects in insulin (the hormone that allows glucose/sugar to be used from carbohydrates for energy) secretion which means glucose cannot move into cells and builds up in the blood stream. Therefore, individuals with T1DM are not able to control their blood glucose (BG) levels which leads to this being higher than optimum which cannot be lowered without administering insulin. When BG levels are high, this is called *hyper*glycaemia and can be fatal if undiagnosed and untreated (National Institute for Health and Care Excellence [NICE], 2022a). T2DM is a metabolic disorder whereby persistent hyperglycaemia is observed due to resistance to the action, not production, of insulin. However, it is not a genetic condition and is predominantly associated with demographic and lifestyle factors.

Persistent and recurrent hyperglycaemia can negatively impact quality and longevity of life and can lead to renal failure, damage to eyesight (Nordwall et al., 2009) and complications such as foot ulceration and potential limb loss (Boulton et al., 2005). Individual BG readings

in individuals with diabetes vary moment by moment dependent on food intake, exercise and insulin delivery. Glycated haemoglobin (HbA1c) is a measure which reflects the average BG over a period of eight to twelve weeks (Nathan & Regan, 2007), giving an accurate overview of general diabetes management over the last few months. For children and adults with T1DM, and adults with T2DM that is managed by lifestyle and diet, the target is to achieve an HbA1c level of 48 mmol/mol (6.5%) or lower to minimise long-term health complications (NICE, 2015; 2022b; 2023). For adults with T2DM that is managed by insulin, the target HbA1c level is 53 mmol/mol (7.0%; NICE, 2022c).

Maintaining glycaemic control involves consistent monitoring of BG levels, diet (calculating carbohydrate), accurate insulin delivery and/or medication adherence and attending diabetes clinic appointments. The factors that impact on glycaemic control in childhood are varied and go beyond those associated with medical presentation and treatment. Longer diabetes duration, more time spent watching television/using computers (Galler et al., 2011) and lower socioeconomic status (Deladoey, Henderson & Geoffroy, 2013; Galler et al., 2011) are associated with poorer glycaemic control. Additionally, socioeconomic deprivation, lower household education and household unemployment are linked to increased hospital admissions for poor diabetes control in children with T1DM (Apperley & Ng, 2017). These risk factors continue into adulthood such that lower socioeconomic status (Bains & Egede, 2011) and poorer health literacy are associated with poorer glycaemic control (Tao et al., 2016). There are also parental influences on children's glycaemic control (Lohan et al., 2017). For instance, the level of agreement between the parent and child on treatment responsibility and diabetes-related conflict are significant predictors of glycaemic control (Lancaster et al., 2015) and diabetes-related conflict between parents can negatively impact on children's glycaemic control (Sood et al., 2012).

Diabetes, Anxiety and Depression

Diabetes is comorbid with depression and anxiety in both children (Akbarizadeh, Naderi & Ghaljaei, 2022; Bernstein et al., 2013; Buchberger et al., 2016) and adults (Collins, Corcoran & Perry, 2009; Roy & Lloyd, 2012; Smith et al., 2013), and both depression and anxiety are also associated with poorer glycaemic control (Anderson et al., 2002; Ducat, Philipson & Anderson, 2014; Indelicato et al., 2017). NICE guidelines (2015; 2022a, 2022b) acknowledge the psychological impact of a diabetes diagnosis in both adults and children and name the importance of healthcare staff remaining vigilant to signs of mental health difficulties and of directing individuals to appropriate psychological and social support.

NICE guidelines (2009) recommend Cognitive Behavioural Therapy (CBT) as a first-line treatment for depression in adults with long-term physical health conditions. There are no specific guidelines for adults with physical health conditions who also experience anxiety. However, for adults who experience Generalised Anxiety Disorder, NICE guidelines recommend CBT for those who do not benefit from lower level interventions such as guided self-help (NICE, 2011). There are no specific guidelines for adolescents with depression and anxiety and chronic health conditions; the guidelines for depression in this population recommend predominantly CBT-based therapies (NICE, 2019) which has limited efficacy for individuals with diabetes (Mather et al., 2022). Considering the utility of CBT in the physical health context, many of the negative automatic thoughts that would be reframed or challenged in CBT (Beck et al., 1979; Beck, 2011) are often rational or realistic. For instance, diabetes distress is often characterised by worries relating to the management of their illness, the long-term implications of having diabetes or feeling angry or frustrated at having the diagnosis (Dennick, Sturt & Speight, 2017; Castensøe-Seidenfaden et al., 2017; Chao et al., 2015). Further investigation of psychological processes underpinning distress in people with diabetes is needed for therapeutic approaches to best meet the needs of this population.

The Thesis

Having a diagnosis of diabetes carries a large cognitive load in terms of consistent management and has implications for the social, psychological and health outcomes of individuals. There is a complex web of biopsychosocial factors which interweave and influence the mental and physical health of those who have diabetes across the lifespan. This thesis broadly aims to advance our understanding of the psychological impact of living with diabetes. It comprises two chapters, a systematic review and empirical research study, separated by a reflective commentary. The systematic review explores psychosocial factors associated with fear of hypoglycaemia in children and young people under 18 years old. The empirical paper investigates anxiety, depression, self-compassion and metacognitive beliefs in adults with diabetes. Both are formatted for submission to Frontiers in Psychology (Appendix I). The reflective commentary focuses on the research process, with critical consideration given to its challenges and the barriers to some groups participating in research.

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Chapter 1: Systematic Review

Psychosocial Predictors and Correlates of Fear of Hypoglycaemia in Children and Young People with Type 1 Diabetes

Abstract

Introduction Type 1 Diabetes Mellitus (T1DM) is a lifelong condition that requires daily monitoring of glucose levels to ensure optimal short- and long-term health outcomes. Fear of hypoglycaemia (FoH) impacts on mental health, quality of life and diabetes management. This systematic review explores demographic, clinical and psychosocial correlates and predictors of FoH in children and young people, aged 18 years and younger, with T1DM. *Methods* MEDLINE, PsycINFO, Psychology Database, Web of Science and CINAHL were systematically searched for quantitative studies that reported bivariate or multivariate associations between demographic, clinical and/or psychosocial variables and FoH. Data were summarised narratively. *Results* Nineteen studies were included. There is tentative evidence that FoH is independent of HbA1c levels, method of insulin delivery and blood glucose monitoring. There is preliminary evidence to indicate that greater hypoglycaemia worry is associated with greater frequency of hypoglycaemia and increased anxiety in children and their parents; hypoglycaemia behaviour is associated with longer duration of diabetes and with greater hypoglycaemia worry; and FoH is associated with reduced quality of life. *Conclusion* While many variables were investigated across studies, few were consistently analysed making conclusions tentative. It is important that clinicians ask patients about FoH, even if they have good hypoglycaemic control. There is no current evidence to support psychological theory underpinning FoH and prospective studies are needed to explore if there are causal psychological mechanisms of FoH to inform psychological therapies for this population.

Introduction

Approximately 40,000 individuals aged under 17 years old live with diabetes in England (Diabetes UK, 2019); most of whom have Type 1 Diabetes Mellitus (T1DM). Consistent management of T1DM is essential to reduce short- and long-term health complications and increase life expectancy (Boulton et al., 2005; Nordwall et al., 2009). Effective control of T1DM has the common side effect of increased risk of *hypo*glycaemia (low blood sugar levels; Frier, 2008). Good glycaemic control results in significantly more severe hypoglycaemic events in adolescents (Diabetes Complications and Controls Trial Research Group, 1997). The incidence of severe hypoglycaemia increased by 29% per year in first 5 years of a 10-year longitudinal study of children and young people (CYP) with T1DM (Bulsara et al., 2004). Symptoms of hypoglycaemia vary between individuals, which leads to difficulties identifying and categorising hypoglycaemic events, and can result in worry and preoccupation with hypoglycaemia (Zammitt et al., 2011). As children move into adolescence, they must adjust to increased independence in managing the condition (Babler & Strickland, 2015). This increased autonomy for their health and T1DM care can be a worrying time for adolescents and their parents (Ersig et al., 2016).

It is more favourable for health outcomes in T1DM to have lower BG and experience and manage mild hypoglycaemic symptoms than it is to have continually higher BG (hyperglycaemia), which has no acute symptoms but increases the risk of long-term health complications associated with T1DM (Lehecka et al., 2012). However, the concept of serious long-term health consequences of asymptomatic *hyper*glycaemia is less tangible and falsely perceived as less of a risk than the immediate and unpleasant experiences of *hypo*glycaemia (Fidler Christensen & Gillard, 2011; Wild et al., 2007).

The adverse physical and social repercussions of the symptoms of hypoglycaemia and worry about future episodes can mean many people with diabetes develop anxiety around

experiencing hypoglycaemia which adversely affects management of diabetes and quality of life (Barendse et al., 2012; Wild et al., 2007). This has been coined *fear of hypoglycaemia* (FoH), a concept which encompasses anxiety associated with hypoglycaemia, and use of maladaptive, over-compensatory coping strategies to avoid hypoglycaemia, such as taking reduced doses of insulin or overeating (Cox et al., 1987; Fidler et al., 2011; Wild et al., 2007). FoH can create a barrier to achieving optimum glycaemic control, with adults with a higher FoH also having poorer diabetic control (Fidler et al., 2011; Rossi et al., 2019).

Whilst CYP with T1DM are at increased risk of mental health difficulties (Baucom *et al.,* 2018; Gonzalez *et al.,* 2008; Majidi, Driscoll & Raymond, 2015), which is linked to poorer glycaemic control (Buchberger et al., 2016; Majidi, Driscoll & Raymond, 2015; Jurgen et al., 2020), there are no current clinical guidelines for CYP with T1DM who experience FoH. Although FoH measures have been validated in children as young as 6 years old (Green, Wysocki & Reineck, 1990), most of the research into FoH focuses on FoH experienced by parents of CYP with T1DM (Barnard et al., 2010; Zhang et al., 2022) and adults (Martyn-Nemeth et al., 2016; Wild et al., 2007). Whilst three narrative literature reviews have explored the negative impact of FoH on the mental and physical wellbeing of CYP with T1DM (Driscoll et al., 2016; Gonder-Frederick et al., 2011; McGill & Levitsky, 2016), no systematic review of FoH in CYP has been conducted.

Understanding demographic, clinical and psychological factors that are linked to, or predict, FoH could inform how best to support CYP to live well with T1DM, and represent an important step towards developing and testing therapeutic approaches most suited to the needs this population. However, no systematic review has examined potential risk factors for the development and maintenance of FoH in CYP. This systematic review seeks to explore demographic, clinical and psychosocial factors associated with, or predictive of, FoH in CYP with T1DM aged under 18 years.

Method

The review was registered on PROSPERO (registration number: CRD42022360703) prior to commencing the searches.

MEDLINE, PsycINFO, Psychology Database, Web of Science and CINAHL were searched using the following search terms: ((fear OR anxi* OR stress OR distress OR worry) and (hypoglycem* OR hypoglycaem*)) and (child* OR adolescen* OR teen* OR youth OR paediatric OR pediatric OR "young person"). Searches were conducted in August 2022 and repeated in May 2023 to identify any new papers that met the inclusion criteria.

Eligibility Criteria

Studies were included if they were 1) peer-reviewed quantitative observation studies which 2) evaluated relationship between any psychosocial, clinical and/or demographic variable and FoH; 3) used either a prospective or cross-sectional design; 4) used published and validated self-reported questionnaires to assess FoH; 5) reported data in people aged 18 years old and under with T1DM; and 6) were published in English.

Screening and Selection

As Figure 1 shows, once duplicated studies had been removed, the titles and abstracts of identified studies were screened against the inclusion criteria and any studies that did not meet these criteria were excluded. The full texts of identified papers were then examined for relevance. All records that could not be accessed were requested from the University of Liverpool Library Service or requests made directly to authors. Screening was conducted by KC; a second reviewer (BC) independently reviewed the titles, abstracts, and full text of identified papers. Any disagreements were discussed, and final agreement reached with the research team (MGC & PF).

Data Extraction and Analysis

Participant and study characteristics, statistical analyses, measures, variables, and results were extracted by KC and cross-checked by an independent reviewer (BC), with discrepancies discussed together, and final decisions reviewed with the wider research team (MGC & PF). Data was extracted on: author, year of publication, study design, clinical and treatment characteristics of participants (duration of diabetes, mean HbA1c and insulin administration method), demographic characteristics of participants (age, gender, ethnicity), measures used and main findings, including psychosocial, clinical and/or demographic correlates/predictors of FoH.

Data were organised, tabulated, and analysed narratively due to the heterogeneity of dependent and outcome variables, study objectives, design and statistical analysis. Synthesis without meta-analysis (SWiM) guidelines were used to synthesize extracted descriptive data (Campbell et al., 2019). The mean and range of participants across the 19 studies was calculated as well as the overall percentage of male and female participants. Mean values of age, duration of diabetes and HbA1c were extracted from the studies that reported this data and overall means were calculated. Effect sizes were interpreted as 0.2, 0.5 and 0.8 indicating 'small', 'medium' and 'large', respectively (Cohen, 1998).

Risk of Bias

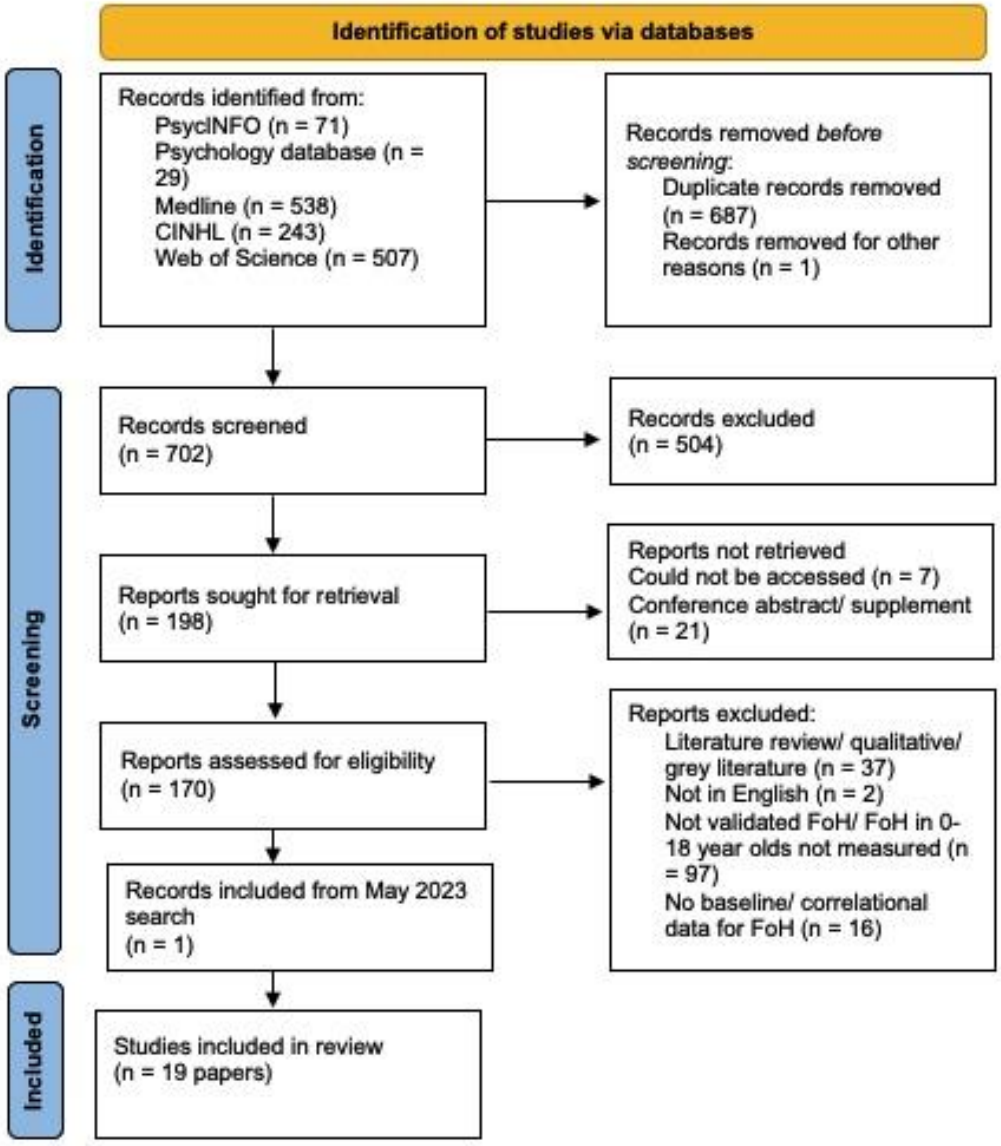
Risk of bias was determined by KC using an adapted version of the Agency for Healthcare Research and Quality tool for assessing the quality of observational studies (Taylor et al., 2014). The tool rates whether studies meet, partially meet, or does not meet key methodological criteria (Appendix II). Risk of bias results were cross-checked by an

independent reviewer (BC), with discrepancies resolved through consensus or discussion with the wider team (MGC & PF).

Results

After removing duplicates, the search strategy identified 702 potential papers, of which the full-text of 170 records were examined for relevance. Nineteen papers were included in the review (see Figure 1).

Figure 1



Study Characteristics

Table 1 summarises the main characteristics of the included studies. Across the 19 studies, the sample size varied from 28 to 1,129 with a total of 4,058 participants recruited. Participants' mean age was 13.08 years (range of 6.8 to 15.9 years) and the average duration of diabetes was 5.86 years. Sixteen studies reported average HbA1c and the mean was 8.4% (range, 7.5% to 9.5%), which is higher than the recommended target of <7.5% for children with T1DM (NICE, 2023; Rewers et al., 2014). Half of participants (50.04%) were male. Eight studies reported data on ethnicity and most participants were Caucasian (Amiri et al., 2015; Coolen et al., 2021; Di Battista et al., 2009; Jurgen et al., 2020; Kamps & Varela, 2010; Kamps et al., 2005; O'Donnell et al., 2021; Reid et al., 2013; Roberts et al., 2020).

Most studies used a cross-sectional design (Amiri et al., 2015; Coolen et al., 2021; Di Battista et al., 2009; Glocker et al., 2022; Gonder-Frederick et al., 2006; Al Hayek et al., 2015; Jabbour & Bragazzi, 2021; Johnson et al., 2013; Jurgen et al., 2020; Kaya & Toklu, 2022; O'Donnell et al., 2021; Reid et al., 2023; Roberts et al., 2020; Shepard et al., 2014; Tumini et al., 2021; Viaene et al., 2017). The remaining three studies used a longitudinal design (Kamps & Varela, 2010; Kamps et al., 2005; Markowitz et al., 2012).

As characterised by the World Bank (Hamadeh et al., 2022), seventeen studies were conducted in high-income countries (Al Hayek et al., 2015; Di Battista et al., 2009; Gonder-Frederick et al., 2006; Glocker et al., 2022; Jabbour & Bragazzi, 2021; Jurgen et al., 2020; Kamps & Varela 2010; Kamps et al., 2005; Markowitz et al., 2012; O'Donnell et al., 2021; Reid et al., 2023; Roberts et al.,2020; Shepard et al., 2014; Tumini et al., 2021; Viaene et al., 2017). One reported data collected from a middle-income country (Kaya & Toklu, 2022), and one from a low-income country (Amiri et al., 2015).

Table 1

Study and Participant Characteristics

Author (year), country	Design	N	Mean age, years (SD)	Gender, n (~%)	Ethnicity, n (~%)	Mean Duration of Diabetes, years (SD)	Mean HbA1c (SD)	Insulin Administration
Al Hayek et al. (2015), Saudi Arabia	Cross-sectional	187	15.27 (1.61)	92 M (49.2) 95 F (50.8)	-	7.1 (5.2)	-	19.3% pump; 80.7% MDI
Amiri et al. (2015), Iran	Cross-sectional	61	9.2 (2.0)	35 M (57) 26 F (43)	Iranian 61 (100%)	3.2 (2.0)	9.4 (1.8)	82% < 3 injections/day; 18% >4 injections/day
Coolen et al. (2021), The Netherlands	Cross-sectional	96	15.2 (1.6)	46 M (48) 50 F (52)	91 (95) Dutch; 1 (1) Non-Dutch	7.0 (4.3)	7.5 (.9)	81% pump; 19% MDI
Di Battista et al. (2009), USA and Canada	Cross-sectional	76	15.91 (1.44)	33 M (43) 43 F (57)	African American/Canadian (11.8); White (84.2); Other (4)	6.42 (3.63)	8.9 (1.86)	-

Author (year), country	Design	N	Mean age, years (SD)	Gender, n (~%)	Ethnicity, n (~%)	Mean Duration of Diabetes, years (SD)	Mean HbA1c (SD)	Insulin Administration
Glocker et al. (2022), Switzerland	Cross-sectional	59	15.1 (3.0)	29 M (49) 30 F (51)	-	7.6 (4.1)	7.6 (1.1)	28% pump; 72% MDI
Gonder-Frederick et al. (2006), USA	Cross-sectional	39	15.36 (1.53)	22 M (56.4) 17 F (43.6)	-	7.03 (4)	7.85 (1.09)	38.9% pump
Jabbour & Bragazzi (2021), Canada	Cross-sectional	61	Insulin injections = 11.9 (1.8); Insulin pump= 12.4 (2.2); CGM = 13.8 (3.1); BGM = 14.6 (1.2)*	-	-	-	Insulin injections = 7.7 (3.1); Insulin pump= 6.8 (1.4); CGM = 7.3 (2.2) BGM = 7.8 (1.4)*	63.9% MDI; 36.1% pump
Johnson et al. (2013), Australia	Cross-sectional	325	11.83 (3.7)	171 M (47) 154 F (53)	-	4.79 (3.5)	8.0 (0.9)	35% pump use
Jurgen et al. (2020), USA	Cross-sectional	83	13.87 (3.21)	41 M (49) 42 F (51)	30 (36) African American; 53 (64) European American	-	9.5 (1.8)	31.3% 2 daily injections; 24.1% MDI; 44.6% pump

Author (year), country	Design	N	Mean age, years (SD)	Gender, n (~%)	Ethnicity, n (~%)	Mean Duration of Diabetes, years (SD)	Mean HbA1c (SD)	Insulin Administration
Kamps & Varela (2010), USA	Longitudinal	Pre-hurricane group: 100; Hurricane interrupted group: 58	Pre-hurricane group: 12.7 (2.6); Hurricane interrupted group: 13 (2.7)	Pre-hurricane group: M 49 (49); 51 F (51) Hurricane interrupted group: 34 M (41); 24 F (59)	Pre-hurricane group: Caucasian (67); African American (26); Hispanic (5); Other (2) Hurricane interrupted group: Caucasian (77.6); African American (19); Hispanic (3.4)	Pre-hurricane group T1: 4.87 (3.19); Pre-hurricane group T2: 5.15 (3.19); Hurricane interrupted group T1: 5.18 (3.64); Hurricane interrupted group T2: 5.87 (3.64)	Pre-hurricane group T1: 8.42 (1.51); Pre-hurricane group T2: 8.44 (1.44); Hurricane interrupted group T1: 8.24 (1.44); Hurricane interrupted group T2: 8.48 (1.61)	-
Kamps et al (2005), USA	Longitudinal	109 (57 T2)	11.9 (2.3)	42 M (39) 67 F (61)	95 Caucasian	-	-	-
Kaya & Toklu (2022), Turkey	Cross-sectional	116	11.42 (2.94)	56 M (48.2) 60 F (51.7)	-	5.30 (2.90)	9.08 (1.72)	-

Author (year), country	Design	N	Mean age, years (SD)	Gender, n (~%)	Ethnicity, n (~%)	Mean Duration of Diabetes, years (SD)	Mean HbA1c (SD)	Insulin Administration
Markowitz et al (2012), USA	Longitudinal	28 (BGM = 12; CMG = 16)	13.4 (3.2)	M (61) F (39)	-	7.2 (3.7)	7.6 (0.6)	86% insulin pump
O'Donnell et al (2021), USA	Cross-sectional	1,035	13.9 (2.3)	543 M (52.5) 492 F (47.5)	768 Caucasian (82.7%), 44 Black (12.8%), 117 Hispanic or Latino (12.8%) Multiracial (4.4%)	5.4 (3.9)	9.0 (2.1)	59% insulin pump
Reid et al. (2023), USA	Cross-sectional	568	15.1 (2.1)	F (50.2) M (49.8)	White (71.1%), Black (11.8%) Hispanic (13.4%) Other (3.7%)	9.73 (3.1)	-	75% pump
Roberts et al. (2020), USA	Cross-sectional	1,129	14.4 (2.2)	F (51.6) M (48.4)	Non-Hispanic white (75.5%), Non-Hispanic Black (9.7%, Hispanic (12.5), other (2%)	7.5 (1.8)	9.2 (1.7)	63.7% insulin pump
Shepard et al (2014), USA	Cross-sectional	259	10.56 (3.31)	M (52) F (48)	Parent only reported	5.24 (3.28)	8.01 (0.97)	60% MDI; 40% insulin pump
Tumini et al. (2021), Italy	Cross-sectional	174	13.6 (3.3)	96 M (55) 78 F (45)	-	5.9 (4.1)	7.6 (1.1)	14% pump; 86% > 4 injections a day

Author (year), country	Design	N	Mean age, years (SD)	Gender, n (~%)	Ethnicity, n (~%)	Mean Duration of Diabetes, years (SD)	Mean HbA1c (SD)	Insulin Administration
Viaene et al. (2017), Belgium	Cross-sectional	63	12.36 (3.90)	35 M (56) 28 F (44)	-	4.07 (2.61)	8.28 (1.07)	-

Note: F = Female; M = male; MDI = Multiple Daily Injections; *data are not from distinct groups

FoH Questionnaires

FoH was assessed using two different questionnaires (details shown in Table 2). The Children's Hypoglycaemia Fear Survey (CHFS; Green, Wysocki & Reineck, 1990; Gonder-Frederick et al., 2006) was used in 15 studies. The remaining 4 studies used the Children's Hypoglycaemia Index (CHI; Kamps et al., 2005).

The CHFS is derived from the Hypoglycaemia Fear Survey (HFS), which was developed and validated in adults with T1DM (Cox et al., 1987) and later adapted and validated for use in 6- to 18-year olds (Green, Wysocki & Reineck, 1990). It has 25 items, rated using a 5-point Likert scale, with 15-items relating to worry about hypoglycaemia (the 'Worry' subscale) and 10-items looking at engagement in behaviours designed to avoid hypoglycaemia (the 'Behaviour' subscale). Each item is scored on a Likert scale from 'Never' to 'Always'. Further analysis has indicated there are two subscales within the Worry subscale: 'Helplessness' and 'Social Consequences'; and two within the Behaviour subscale: 'Maintain High Blood Glucose' and 'Avoidance' (Shepard et al., 2014). Included studies used different scoring methods for the CHFS. Approximately half (47.4%) used a scale that ranged from 0 to 4 (Coolen, 2001b; Glocker et al., 2022; Jabbour & Braggazi, 2021; Kaya & Toklu, 2022; O'Donnell et al., 2021; Reid et al, 2023; Roberts et al., 2020; Shepard et al., 2014; Tumini et al., 2021), four (21.1%) used a scale ranging from 1 to 5 (Amiri et al., 2015; Al Hayek et al., 2015; Gonder-Frederick et al., 2006; Viaene et al., 2017) and the remaining papers did not report the Likert range used (Johnson et al., 2013; Markowitz et al., 2012; Di Battista et al., 2009). Reasons why different Likert scales were used were not reported. Total scores across the included studies therefore ranged from 0-60 or 15-75 for Worry; 0-40 or 10-50 for Behaviour; and 0-100 or 25-125 for the total score; with higher scores indicating greater FoH.

The Children's Hypoglycaemia Index (CHI; Kamps et al., 2005) is an alternative measure of FoH in children and adolescents. The first version had 25-items but was later

amended to have 24 (CHI-II; Kamps & Varela, 2010). The questionnaire has three subscales: 'General Worry' (children's fear relating to a hypoglycaemic episode), 'Situation Worry' (fear relating to having hypoglycaemia in certain settings) and 'Behaviour' (adapting behaviour to avoid hypoglycaemia). Each item is rated on a Likert scale ranging from 'Not Afraid' to 'Extremely Afraid' or 'Never' to 'All the Time'. Scores range from 1 to 120 with higher scores indicating greater FoH. Of the three studies which used a version of the CHI, one used the original version (Kamps et al., 2005) and two used the CHI-II (Jurgen et al., 2020; Kamps & Varela, 2010).

As the included studies used different measures of FoH and not all reported mean scores (missing scores indicated in Table 2) and used different scoring methods, it was not possible to calculate an overall FoH score for the sample. However, generally the sample had low to moderate levels of FoH. Table 2 outlines the scores and scales used.

Table 2

Participant Scores on Fear of Hypoglycaemia Questionnaires

	Hypoglycaemia Fear Survey Revised for Children		
Author	**Hypoglycaemia worry subscale, mean (SD)**	**Hypoglycaemia behaviour subscale, mean (SD)**	**Total score, mean (SD)**
Al Hayek et al. (2015)[b]	-	-	-
Amiri et al. (2015)[b]	Aged < 9 years old = 31.1 (14.7), > 10 years old = 16.9 (11.4)	Aged < 9 years old = 24.8 (7.7), >10 = 21.4 (7.5)	Aged <9 years old = 55.9 (17.9), >10 = 38.2 (16.4);
Coolen et al (2001b)[a]	12.6 (8.3)	-	-
Di Battista et al (2009)	-	-	-
Glocker et al. (2022)[a]	13.73 (8.9)	18.51 (5.7)	32.2 (11.9)
Gonder-Frederick et al. (2006)[b]	33.87 (11.61)	31.36 (4.57)	65.24 (13.24)
Jabbour & Bragazzi (2021)[a]	Insulin injections = 1.98 (41); insulin pump = 2.01 (.33); CMG = 2.01 (.11); BGM = 2.46 (.53)	Insulin injections = 2.08 (.35); insulin pump = 2.1 (.76); CMG = 1.03 (.05); BGM = 2.6 (.63)	Insulin injections = 1.88 (.31); insulin pump = 1.94 (.41); CMG = 1.09 (.43); BGM = 2.94 (.22)

	Hypoglycaemia Fear Survey Revised for Children		
Author	**Hypoglycaemia worry subscale, mean (SD)**	**Hypoglycaemia behaviour subscale, mean (SD)**	**Total score, mean (SD)**
Johnson et al. (2013)	-	-	-
Kaya & Toklu (2022)[a]	13.13 (6.63)	19.18 (7.26)	32.07 (10.72)
Markowitz et al (2012)	BGM = 15.8 (12.2); CGM = 17.9 (14.1)	-	-
O'Donnell et al (2021)[a]	Helplessness/worry about low BG = 7.7 (5.9), Worry about negative social consequences = 3.7 (3.4)	Maintain high BG = 3.6 (2.8),	
Reid et al. (2023)[a]	1.3 (0.7)	1.8 (0.6)	1.6 (0.6)
Roberts et al. (2020)[a]	0.7 (not reported)	1.8 (not reported)	1.2 (not reported)
Shepard et al (2014)	-	-	-
Tumini et al. (2021)[a]	1.09 (0.72)	1.76 (0.74)	1.3 (0.62)
Viaene et al. (2017)[b]	-	-	1.41 (0.71)

	Children's Hypoglycaemia Index			
Author	**Hypoglycaemia General Worry subscale, mean (SD)**	**Hypoglycaemia Situation Worry subscale, mean (SD)**	**Hypoglycaemia Behaviour subscale, mean (SD)**	**Total score, mean (SD)**
Jurgen et al. (2020)	-	-	-	46.95 (13.09)
Kamps & Varela (2010)	22.43 (7.71)	14.6 (5.76)	15.06 (5.25)	51.73 (15.37)
Kamps et al (2005)	19.94 (6.1)	13.28 (4.6)	18.61 (4.7)	51.74 (13.2)

Note, BG = Blood Glucose; BGM = Blood Glucose Meters; CGM = Continuous Glucose Monitoring; Hypoglycaemia Fear Survey Revised for Children (Green et al., 1990); Children's Hypoglycaemia Index (Kamps et al., 2005). [a]scores represent average of all items in subscale or total, range 0-4. [b] scores represent average of all items in subscale or total, range 1-5.

Correlates and Predictors of FoH

As shown in Table 3, 8 studies analysed demographic variables (Al Hayek et al., 2005; Amiri et al., 2015; Glocker et al., 2002; Kamps & Varela, 2010; Jurgen et al., 2020; O'Donnell et al., 2021; Roberts et al., 2020; Shepard et al., 2014); 15 analysed clinical variables (Al Hayek et al., 2005; Coolen et al., 2001b; Di Battista et al., 2009; Glocker et al., 2022; Gonder-Frederick et al., 2006; Jabbour & Bragazzi, 2021; Johnson et al., 2013; Jurgen et al., 2020; Kamps & Varela, 2010; Kaya & Toklu, 2022; Markowitz et al., 2021; O'Donnell et al., 2021; Reid et al., 2023; Roberts et al., 2020; Shepard et al., 2014); and 12 studies analysed psychosocial variables (Al Hayek et al., 2015; Amiri et al., 2015; Di Battista et al., 2009; Glocker et al., 2022; Gonder-Frederick et al., 2006; Kamps et al., 2005; Johnson et al., 2013; Jurgen et al., 2020; Kamps & Varela, 2010; Shepard et al., 2014; Tumini et al., 2021; Vianene et al., 2017).

Table 3

Demographic, Clinical and Psychosocial Factors Analysed within Included Studies

Variable	Studies
Demographic (n = 8)	
Age	Al Hayek et al. (2005); Amiri et al. (2015); Glocker et al. (2002); O'Donnell et al. (2021); Roberts et al. (2020); Shepard et al. (2014).
Gender	Al Hayek et al. (2005); Jurgen et al. (2020); O'Donnell et al. (2021); Roberts et al. (2020); Shepard et al. (2014)
Ethnicity	Jurgen et al. (2021)
Education	Al Hayek et al. (2005)
Socioeconomic status/ family income	Kamps & Varela (2010); Jurgen et al. (2020); Reid et al. (2023)
Clinical (n = 15)	
Time since diagnosis	Al Hayek et al. (2005)
HbA1c	Johnson et al. (2013); Glocker et al. (2022); Al Hayek et al. (2015); Jurgen et al. (2020); Kamps & Varela (2010); Kaya & Toklu (2022); Roberts et al. (2020); Shepard et al. (2014)
Treatment type	Al Hayek et al. (2005); Jabbour & Bragazzi, (2021); Jurgen et al. (2020); Shepard et al. (2014)
Adherence to Insulin	Di Battista et al. (2009); Jurgen et al. (2020); O'Donnell et al. (2021)
Amount and level of exercise	Al Hayek et al. (2005); Di Battista et al. (2009); Jabbour & Bragazzi, (2021); Kaya & Toklu, (2022); Roberts et al. (2020)
BG testing	Di Battista et al. (2009); O'Donnell et al. (2021)

Factors relating to diet adherence	Di Battista et al. (2009); Kaya & Toklu (2022)
Method of BG testing (manual or automated device)	Jabbour & Bragazzi (2021); Markowitz et al. (2021); O'Donnell et al. (2021); Reid et al. (2023)
BG levels	Kamps & Varela (2010); O'Donnell et al. (2021); Shepard et al. (2014)
Frequency/ number of hypoglycaemic episodes	Al Hayek et al. (2005); Coolen et al. (2001b); Gonder-Frederick et al. (2006); Jabbour & Bragazzi (2021); Johnson et al. (2013); Kaya & Toklu (2022); Shepard et al. (2014)
Experiences related to hypoglycaemia	Al Hayek et al. (2005)
Psychosocial (n = 12)	
Child's symptoms of anxiety/ social anxiety	Al Hayek et al. (2015); Di Battista et al. (2009); Gonder-Frederick et al. (2006); Kamps et al. (2005); Kamps & Varela (2010); Shepard et al. (2014)
Child's symptoms of depression	Jurgen et al. (2020)
Child quality of life	Johnson et al. (2013); Tumini et al. (2021)
Child's self-efficacy for diabetes	Amiri et al. (2015)
Parent/ caregiver FoH	Glocker et al. (2022); Tumini et al. (2021); Vianene et al. (2017)
Parent/ caregiver anxiety	Gonder-Frederick et al. (2006); Shepard et al. (2014)
Parenting stress	Viaene et al. (2017)
Parent/ caregiver depression	Shepard et al. (2014)

BG = blood glucose; FoH = fear of hypoglycaemia.

Assessment of Risk of Bias

Table 4 outlines the assessment of risk of bias. Over half of the studies (11; 57.9%) were at low risk of bias (Amiri et al., 2015; Coolen et al., 2001b; Di Battista et al., 2009; Glocker et al., 2022; Gonder-Frederick et al., 2006; Jurgen et al., 2020; Kamps & Varela, 2010; Kaya & Toklu, 2022; Reid et al., 2023; Roberts et al., 2020; Shepard et al., 2014), a fifth (n = 4; 21.1%) were at moderate risk of bias (Al Hayek et al., 2015; Jabbour & Braggazzi, 2021; Markowitz et al., 2021; Tumini et al., 2021) and the remainder were deemed at risk of bias (Johnson et al., 2013; Kamps et al., 2005; O'Donnell et al., 2021; Viaene et al., 2017).

The areas that were of most concern included that only around a third (n = 7; 36.8%) of studies provided adequate data regarding FoH (e.g. information about measures to allow replication and reporting of total and subscale means; Amiri et al., 2015; Glocker et al., 2022; Gonder-Frederick et al., 2006; Jabbour & Braggazi, 2021; Kamps & Varela, 2010; Kamps et al., 2005; Kaya & Toklu, 2022). A power calculation to inform sample size was only reported in 2 studies (10.5%; Kaya & Toklu, 2022; Markowitz et al., 2012) and only half (n = 9; 47.4%) of the studies provided an adequate description of the sample (Al Hayek et al., 2015; Amiri et al., 2015; Coolen et al., 2021; Di Battista et al., 2009; Jurgen et al., 2013; Kamps & Varela, 2010; O'Donnell, 2021; Roberts et al., 2020; Shepard et al., 2014).

Table 4

Assessment of Risk of Bias

Author	Unbiased selection of cohort?	Sample size calculated?	Adequate description of the cohort?	Adequate information dependent variable?	Validated method for outcome variables?	Adequate follow-up period? (longitudinal studies only)	Missing data minimal?	Analysis controls for confounding?	Analytic methods appropriate?
Al Hayek et al. (2015)	Y	N	Y	N	Y	n/a	U	Y	Y
Amiri et al. (2015)	Y	N	Y	Y	Y	n/a	U	n/a	Y
Coolen et al. (2021)	Y	N	Y	U	Y	n/a	Y	Y	Y
Di Battista et al. (2009)	Y	N	Y	N	Y	n/a	Y	Y	Y
Glocker et al. (2022)	Y	N	U	Y	Y	n/a	Y	n/a	Y
Gonder-Frederick et al. (2006)	Y	N	U	Y	Y	n/a	Y	Y	Y

Author	Unbiased selection of cohort?	Sample size calculated?	Adequate description of the cohort?	Adequate information dependent variable?	Validated method for outcome variables?	Adequate follow-up period? (longitudinal studies only)	Missing data minimal?	Analysis controls for confounding?	Analytic methods appropriate?
Jabbour & Bragazzi (2021)	Y	N	U	Y	Y	n/a	U	Y	Y
Johnson et al. (2013)	Y	N	U	N	Y	n/a	U	n/a	Y
Jurgen et al. (2020)	Y	N	Y	U	Y	n/a	Y	Y	Y
Kamps & Varela (2010)	Y	N	Y	N	Y	Y	N	Y	Y
Kamps et al (2005)	Y	N	N	N	Y	N	U	N	Y
Kaya & Toklu (2022)	Y	Y	U	Y	Y	n/a	Y	n/a	Y
Markowitz et al (2012)	Y	Y (not adequately powered)	U	N	Y	Y	U	n/a	Y
O'Donnell et al (2021)	U	N	Y	U	Y	n/a	U	n/a	Y

Author	Unbiased selection of cohort?	Sample size calculated?	Adequate description of the cohort?	Adequate information dependent variable?	Validated method for outcome variables?	Adequate follow-up period? (longitudinal studies only)	Missing data minimal?	Analysis controls for confounding?	Analytic methods appropriate?
Reid et al. (2023)	Y	N	Y	Y	Y	n/a	Y	Y	Y
Roberts et al. (2020)	Y	U	Y	U	Y	n/a	U	Y	Y
Shepard et al (2014)	Y	N	Y	N	Y	n/a	Y	n/a	Y
Tumini et al. (2021)	Y	N	U	N	Y	n/a	Y	n/a	Y
Viaene et al. (2017)	Y	N	U	U	Y	n/a	U	Y	Y

Y = Yes; U = Unclear/ Partially; N = No; N/a = Not applicable.

Hypoglycaemia Worry

As shown in Table 5, 15 studies examined the relationship between hypoglycaemia worry (assessed using the Worry subscale of either the CHI (Kamps & Varela; Kamps et al., 2010) or the CHFS (Green et al., 1990)) and a range of demographic, clinical, and psychosocial variables.

Demographic Variables

Age. Four studies explored the association between age and hypoglycaemia worry, two of which found no relationship (O'Donnell et al., 2021; Roberts et al., 2020,). The remaining two studies reported significant but conflicting findings. Al Hayek et al. (2015) found that 16-18-year olds had greater hypoglycaemia worry than those who were 13-15 years old (2.16 (1.08) vs 2.49 (.7)). In contrast, Amiri et al. (2015) found that children aged 9 years and younger had higher hypoglycaemia worry than those who were 10 and older (31.1 vs 16.9). In multivariate analysis, older age accounted for a significant amount of the variance over and above variables relating to staying well with diabetes, treatment type, HbA1c and experiences relating to hypoglycaemia (Al Hayek et al., 2015, $\beta = .691$).

Socioeconomic Status. Three studies (Al Hayek et al., 2015; Kamps & Varela, 2010; Reid et al., 2023) explored variables related to socioeconomic status (SES) such as family income, food insecurity, parents' education and children's education; child's education was the only factor found to be positively associated with hypoglycaemia worry (Al Hayek et al., 2015, $\beta = -.766$).

Gender. Two of the three studies that examined the relationship between hypoglycaemia worry and gender reported significant findings. Girls had greater worry about hypoglycaemia than boys (Al Hayek et al., 2015, 1.99 (1.02) vs 2.65 (.68); O'Donnell et al., 2021, r_{pb}=-.12 to -.15), but gender did was not an independent predictor of hypoglycaemia

when anxiety and frequency of severe hypoglycaemia were controlled for (Gonder-Frederick et al., 2006). The two studies that found a significant result had higher risk of bias than the study with the non-significant finding. However, the significant result reported by O'Donnell et al., was only a small effect size and might be explained by the large sample size of this study.

Clinical Variables

HbA1c. Five studies analysed the relationship between HbA1c and hypoglycaemia worry; one reported a significant and positive, but small effect size, but, again, the large number of participants for this study should be noted when interpreting this significant result (Roberts et al., 2020; r = .07) and the other four found no relationship (Al Hayek et al., 2015; Kamps & Varela, 2010; Kaya & Toklu, 2022; O'Donnell et al, 2021).

Method of Insulin Delivery. Of the four studies that explored whether there was a relationship between method of insulin delivery and hypoglycaemia worry, one paper reported that those who used multiple daily injections had significantly higher hypoglycaemia worry than those who used a pump (Al Hayek et al., 2015; 2.11 (1.0) vs 2.42 (.83)). The others found no relationship (Jabbour & Braggazi, 2021; O'Donnell et al., 2021; Reid et al., 2023).

Method of Blood Glucose Monitoring. None of the four papers which looked at methods of BG monitoring found a relationship with hypoglycaemia worry (Jabbour & Bragazzi; Markowitz et al., 2012; O'Donnell et al., 202; Reid et al., 2023).

Diabetes Management. Two of four studies reported significant findings regarding hypoglycaemia worry and factors relating to diabetes management. One study found that those who had higher hypoglycaemia worry also reported measuring BG levels more during exercise (Kaya & Toklu, 2022, 13.77 (6.62) vs 10.69 (6.36)) and another reported a significant negative correlation (a medium effect size), with adherence to insulin injections in girls (r = -.50), but not boys (Di Battista et al., 2009). There was no significant association between hypoglycaemia

worry and adherence to exercise, diet and BG testing (Al Hayek et al., 2015; Di Battista et al., 2009; Kaya & Toklu, 2022; O'Donnell et al., 2021).

Hypoglycaemia Behaviour. Two studies examined the relationship between worry about hypoglycaemia and CYPs' behaviours associated with hypoglycaemia (using the behaviour subscale of CHFS) and both found significant positive correlations, with small effect sizes (Kaya & Toklu, 2022, r=.21; O'Donnell et al., 2021, r=.26). The large sample size of O'Donnell et al's study might partially account for this significant but small effect.

Frequency and Severity of Hypoglycaemia. Frequency of hypoglycaemic events was examined in three studies, all of which found significant results. One found it to be positively correlated with hypoglycaemia worry with a medium effect size (Coolen et al., 2001b, r=.52); the others found that frequency of severe hypoglycaemic events accounted for a significant amount of the variance in hypoglycaemia worry when controlling for gender, mild hypoglycaemia and experiences relating to hypoglycaemia (Gonder-Frederick et al., 2006, R^2=.40) and frequency of severe hypoglycaemia since diagnosis accounted for more of the variance in hypoglycaemia worry than frequency over the last year (Kamps et al., 2005, β=.45 and β = .40).

Psychosocial Variables

Anxiety. All six studies that examined the relationship between CYP's symptoms of anxiety and hypoglycaemia worry found significant results with small to medium effect sizes (Al Hayek et al., 2015, *r* = .240 to 466; Di Battista et al., 2009, *r* = .32 and .52; Gonder-Frederick et al., 2006, *r* = .53; Kamps & Varela, 2010, *r* = .30; Kamps et al., 2005, *r* = .27; Shepard et al., 2014, *r* = .33 and .42). Multivariate analysis and found anxiety accounted for a significant proportion of variance in hypoglycaemia worry when controlling for gender and

experiences and frequency of mild and severe hypoglycaemia (Gonder-Frederick et al., 2006, R^2= .28).

Quality of Life. One study analysed the relationship between worry about hypoglycaemia and CYP's quality of life and diabetes-specific quality of life, finding a significant negative correlation for quality of life, with a medium effect size, and significant negative correlation, with a small effect size, for diabetes-specific quality of life (Tumini et al., 2021, *r* = -.49 and -.17 respectively).

Self-Efficacy for Diabetes. Children's confidence in managing their diabetes was explored in one study and was significantly moderately negatively correlated with worry with a small effect size (Amiri et al., 2015, *r* =-.30).

Parents' FoH. Of the two studies that explored parents' FoH, one reported a positive correlation, with a small effect size, with CYPs' hypoglycaemia worry (Gonder-Frederick et al., 2006, *r* = .32); the other found no association (Tumini et al., 2021).

Parents' Mental Health. Two studies that explored parents' symptoms of anxiety and CYPs' hypoglycaemia worry found significant positive correlations with small effect sizes (Gonder-Frederick et al., 2006, *r* = .33; Shepard et al., 2014, *r* = .16 to .24). One study looked at parents' symptoms of depression, reporting a positive, but small, association with CYPs' hypoglycaemia worry (Shepard et al., 2014, *r* = .16 to .24).

Table 5

Main findings for Hypoglycaemia Worry (n =15)

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	**Demographic**	**Clinical**	
Bivariate associations					
Al Hayek et al. (2015)	Correlational, t-test	CYP anxiety (symptoms of panic, general anxiety, separation anxiety, social anxiety and school avoidance)	Age, gender, education,	Pump vs MDI, HbA1c, duration of T1DM, exercise, viewing hypoglycaemia as problematic, passed out due to hypoglycaemia, hypoglycaemia while awake, hypoglycaemia while asleep, hypoglycaemia in front of others, hypoglycaemia at school	*Demographic variables* Higher in female: 1.99 (1.02) vs 2.65 (.68)* Higher 16-18 years vs 13-15 years: 2.16 (1.08) vs 2.49 (.7)* *Clinical variables* Higher for MDI vs pump: 2.11 (1.10) vs 2.42 (.83)* Higher >7 years vs <7 years duration: 2.7 (.3) vs 2.2 (1)* Higher for those who have experienced hypoglycaemia awake vs had not: 2.6 (.71) vs 1.74 (1.05)* Higher for those who experience hypoglycaemia asleep vs had not: 2.4 (.88) vs 1.95 (1.03)*

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	Demographic	Clinical	
					Higher for those who had experienced hypoglycaemia in front others vs had not: 2.42 (.84) vs 1.8 (1.16) *Psychosocial variables* Symptoms of: panic: *r* = .466* general anxiety: *r* = .426* separation anxiety: *r* = .414* social anxiety: *r* = .240* school avoidance: *r* = .351*

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	**Demographic**	**Clinical**	
Amiri et al. (2015)	Correlational, t-test	Confidence in managing their diabetes	Age		*Demographic variables* <9 years higher than >10 years: 31.1 vs 16.9*** *Psychosocial variables* *r* = -.30*
Coolen et al. (2001b)	Correlational			Frequency of severe; frequency of self-treated hypoglycaemia	*Clinical variables:* Frequency of severe hypoglycaemia *r* = .32**
Di Battista et al. (2009)	Correlational	Social Anxiety		Diabetes self-care activities (adherence to insulin injection, glucose testing, diet and exercise)	*Clinical variables* Insulin injection girls: *r* = -.50** *Psychosocial variables* Social anxiety boys: *r* = .52*; girls: *r* = .32*;

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	**Demographic**	**Clinical**	
Gonder-Frederick et al. (2006)	Correlational	CYP anxiety; parent anxiety; parent FoH			*Psychosocial variables* CYP anxiety: *r* = .53*** Parent anxiety: *r* = .33* Parent FoH (worry): *r* = .32*
Jabbour & Bragazzi (2021)	Correlational, t-test			CGM vs BGM; pump vs MDI	*Clinical variables* None
Kamps & Varela (2010)	Correlational	CYP anxiety	Family income; Parents Education	HbA1c; % BG < 70; % BG >300	*Demographic variables* None *Clinical variables* None *Psychosocial variables* CYP anxiety: CHI-S *r* = .30*; CHI-G *r* = .30*
Kamps et al (2005)	Correlations, regression	CYP symptoms of anxiety			*Psychosocial variables* CYP anxiety: *r* = .27*

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	Demographic	Clinical	
Kaya & Toklu (2022)	t-test, correlational			Hypoglycaemia episode, HbA1c, dietary compliance, exercise, keeping BG in safe range before exercise, getting BG measure before exercise, getting BG during exercise, consuming food regardless of BG before exercise, keeping carbohydrate containing food near during exercise, reducing insulin regardless of re-exercise BG, CHFS-B	*Clinical variables* Getting BG measure during exercise (yes vs no): 13.77 (6.62) vs 10.69 (6.36)* CHI-B: r =.213*
Markowitz et al. (2012)	t-test			Method of BG monitoring (CGM vs BGM)	*Clinical variables* None

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	Demographic	Clinical	
O'Donnell et al. (2021)	Correlational, t-test		Age, sex, ethnicity, commercial insurance,	HbA1C, pump use, BG, BG checks a day, CMG use, boluses/ day, CHFS-B	*Demographic variables* Sex: male[a]: *r* = -.15***; male[b]: *r* = -.12***; Ethnicity (white)[a]: *r* = -.07; Commercial insurance[b]: *r* = -.12** *Clinical variables* CHFS-B: *r* = .26***
Roberts et al. (2020)	Correlational, t-test		Age	HbA1C	*Demographic* None *Clinical variables* *r* = .07*
Shepard et al. (2014)	t-test, correlational	Parent trait anxiety and depression; CYP anxiety			*Psychological variables* Parent anxiety: *r* = .16*[a] and *r* = .24**[b]; parent depression: r = .24**[a] and *r* = .23**[b] child anxiety: r = .33**[a] and *r* = .42**[b]

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	**Demographic**	**Clinical**	
Tumini et al. (2021)	Correlations	Quality of life; Diabetes specific quality of life; Parent FoH			*Psychosocial variables* Diabetes specific quality of life: r = -.49. Quality of life: r = -.17*
Multivariate associations					
Al Hayek et al. (2015)	Multivariate linear regression		Age, gender, education	Exercise, treatment type, duration, HbA1C, frequency of hypoglycaemia, viewing hypoglycaemia as problematic, passed out due to hypoglycaemia, hypoglycaemia while awake, hypoglycaemia while asleep, hypoglycaemia in front of others, hypoglycaemia at school	*Demographic variables* Age: β= .691*** Gender: β = .444** Education: β= -.766*** *Clinical variables* Duration: β = .304* Frequency of hypoglycaemic events: β = -.355*** Hypoglycaemia while asleep: β= -.508** Hypoglycaemia while awake: β = -.602***

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	**Demographic**	**Clinical**	
Gonder-Frederick et al. (2006)	Multivariate linear regression	CYP symptoms of anxiety	Gender	Frequency of severe hypoglycaemia, mild hypoglycaemia and experiencing hypoglycaemia alone, experiences relating to hypoglycaemia	*Demographic variables* None *Clinical variables* Frequency of Severe Hypoglycaemia: R^2=.20** *Psychosocial variables* CYP anxiety: R^2 = .28**
Kamps et al. (2005)	Multivariate linear regression			Frequency of severe hypoglycaemia in last year, frequency of severe hypoglycaemia since diagnosis, experience of mild hypoglycaemia	*Clinical variables* Severe Hypoglycaemia experiences since diagnosis: CHI-S: β = .40*; CHI-G: β=.45**
Reid et al. (2023)	Multivariate linear regression		Food insecurity, Parent education, household education, health insurance,	Diabetes medication regimen, CGM.	*Demographic variables* None *Clinical variables* None

Note. BG = Blood Glucose; CHFS-B = behaviour subscale of Children's Fear of Hypoglycaemia Scale; [a]Helplessness subscale of CHFS-worry subscale; [b]Social consequences subscale of CHFS-worry subscale; *p<.05**p<.01; ***p<.001.

Hypoglycaemia Behaviour

As shown in Table 6, 13 studies examined the relationship between hypoglycaemia behaviour (assessed using the Behaviour subscales of the CHI (Kamps & Varela; Kamps et al., 2010) and the CHFS) and a range of demographic, clinical and psychosocial variables.

Demographic Variables

Age. Two of four studies found significant association between age and hypoglycaemia behaviour. One paper found 16-18-year olds engaged in more hypoglycaemia behaviour than 13-15-year olds (Al Hayek et al., 2015, 2.55 (.63) vs 1.96 (.73)) and another found a positive, correlation with age but reported a small effect size (O'Donnell et al., 2021, r = .08). However, the influence of the large sample size of this study should be considered in relation to the significant result, given the near negligible effect size. Multivariate analysis found that age accounted for a significant amount of the variance in hypoglycaemia behaviour, more so than education, exercise levels, treatment type and HbA1c (Al Hayek et al., 2015; β = .563). The remaining studies found no relationship (Amiri et al., 2015; Roberts et al., 2020). However, the studies that reported significant findings were at a higher risk of bias than those that did not find significant results.

Gender. One of three studies that examined the relationship between gender and hypoglycaemia behaviour found a significant association. Higher hypoglycaemia behaviour was reported in girls than boys (Al Hayek et al., 2015, 2.48 (.66) vs 2.01 (.75), $p<.05$), which remained significant in multivariate analysis (β = .304). The remainder found no association (O'Donnell et al., 2021; Gonder-Frederick et al., 2006).

Socioeconomic Status. Variables relating to SES such as family income, food insecurity, health insurance, child's education and parent's education were explored in four studies. One found a significant negative relationship, with a small effect size, between

hypoglycaemia behaviour and family income but no relationship to parent's education (Kamps & Varela, 2010, r = -.21). No relationship was reported across three papers with health insurance, food insecurity and parent's, child's and the collective household's education (Al Hayek et a., 2015; O'Donnell et al.2021; Reid et al., 2023).

Clinical Variables

HbA1c. None of the five studies that investigated whether there was a relationship between HbA1c and hypoglycaemia behaviour found a significant relationship (Al Hayek et al., 2015; Kamps & Varela, 2010; Kaya & Toklu, 2005; O'Donnell et al., 2021; Roberts et al., 2020).

Duration of Diabetes. The two studies that explored duration of diabetes reported a significant relationship with hypoglycaemia behaviour. One found that those who had T1DM for over 7 years reported greater hypoglycaemia behaviour that those that had had T1DM for less than 7 years (Al Hayek et al., 2015, 2.17 (.74) vs 2.5 (.7)), with duration of diabetes accounting for significant variance in hypoglycaemia behaviour when controlling for other key variables (Al Hayek et al., 2015). Another found a positive correlation, but with a small (near negligible) effect size (Shepard et al., 2014, r = .08).

Method of Blood Glucose Monitoring. One of three studies found that those who used continuous glucose monitoring had lower hypoglycaemia behaviour compared to those using blood glucose monitors (Jabbour & Bragazzi, 2021, 1.03 (.05) vs 2.6 (.63)). The other two found no significant results (O'Donnell et al., 2021; Reid et al., 2023).

Method of Insulin Delivery. Of the two studies that examined method of insulin delivery, one found no significant relationship with hypoglycaemia behaviour (Shepard et al., 2014) whilst the other reported a negative relationship between hypoglycaemia behaviour and pump use, with an extremely small effect size (O'Donnell et al., 2021, r = -.07). Again, the

large sample size of this study should be noted, considering the significance of such a small effect size.

Frequency and Severity of Hypoglycaemia. Of the eight studies that looked at a relationship between frequency of hypoglycaemic events and hypoglycaemia behaviour, two found negative correlations between number of hypoglycaemic events and hypoglycaemia behaviour, with effect sizes ranging from small to large (Jabbour & Bragazzi, 2021, r =-.74 to -.94; Shepard et al., 2014; r = -.17). However, multivariate analysis found that frequency of hypoglycaemia did not account for significant variance relating to hypoglycaemia behaviour when controlling for other variables (Gonder-Frederick et al., 2006; Kamps et al., 2005).

Experiences Relating to Hypoglycaemia. One study looked at different experiences relating to hypoglycaemia and, in multivariate analysis, found that viewing hypoglycaemia as problematic, having passed out due to hypoglycaemia, experiencing hypoglycaemia while awake and having hypoglycaemia while at school all accounted for significant amount of variance in hypoglycaemia behaviour, more so than: exercise, HbA1c, treatment type, hypoglycaemia when asleep or in front of others (Al Hayek et al., 2015).

Blood Glucose Levels. Of the three studies that looked at BG levels in relation to hypoglycaemia behaviour, two found significant associations. One paper reported positive correlations, with a small effect size, with high BG levels (O'Donnell et al., 2021, r = .08 and .13) and a negative correlation, with a small effect size, with having BG levels in range (r = -.12). Again, this paper had a large sample size which might explain the significant results with small effect sizes. However, another found those with highest levels of hypoglycaemia behaviour (maintain high subscale) had a greater percentage of BG readings that were higher (Shepard et al., 2014, F=5.09 to 5.40). The third paper found no relationship (Kamps & Varela, 2010).

Diabetes Management. Variables relating to diabetes treatment adherence and self-care (adherence to medication, diet and exercise) were explored in four studies; one found that those who kept their BG within a safe range before exercise had greater levels of hypoglycaemia behaviours (22.61 (6.11) vs 17.44 (7.21)) but no relationship with nutrition habits or dietary compliance was found (Kaya & Toklu, 2022). One found that the number of boluses administered and the amount of time spent on the BG sensor were negatively correlated, with small effect sizes, with hypoglycaemia behaviour (O'Donnell et al., 2021, *r* = -.13 and -.16). The others found no relationship (Al Hayek et al., 2015; Di Battista et al., 2009). The large sample size O'Donnell et al.'s paper may account for the significant result with small effect size compared to the papers that found no significant results.

Psychosocial Variables

Anxiety. Of the six studies looking at CYP symptoms of anxiety, only two papers reported positive associations with hypoglycaemia behaviour with small effect sizes (Al Hayek et al., 2015, *r* = .219 to .274; Kamps & Varela, 2010, r= .03); the rest found no significant results (Di Battista et al., 2009; Gonder-Frederick et al., 2006; Kamps et al., 2005; Shepard et al., 2014). Multivariate analysis found CYPs' symptoms of anxiety was not associated with hypoglycaemia behaviour when controlling for gender and frequency of hypoglycaemia (Gonder-Frederick et al., 2006).

Quality of Life. One study reported on quality of life and found that diabetes-specific quality of life was negatively associated with hypoglycaemia behaviour but not general quality of life, with a small effect size (Tumini et al., 2021, *r* = -.29).

Self-Efficacy for Diabetes. One study explored children's confidence managing their diabetes and found no relationship with hypoglycaemia behaviour (Amiri et al., 2015).

Parents' FoH. Of the two studies that reported parents' FoH, one found positive correlations, with small effect sizes, between parent's hypoglycaemia behaviour scores and total FoH scores and children's hypoglycaemia behaviour (Tumini et al., 2021, r = .30 and r =.23) but the other found no relationship (Gonder-Frederick et al., 2006). The difference in sample size between these two studies should be noted considering the small effect size with the significant results with Tumini et al. having a sample size five times bigger than Gonder-Frederick et al.

Table 6

Main Findings for Hypoglycaemia Behaviour (n = 13)

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	Demographic	Clinical	
Bivariate associations					
Al Hayek et al. (2015)	Correlational, t-test	CYP anxiety (symptoms of: panic, separation anxiety, social anxiety, school avoidance)	Age, gender,	HbA1c, duration T1DM, hypoglycaemia at school, hypoglycaemia in front of others, hypoglycaemia while awake, frequency of hypoglycaemia, viewing hypoglycaemia as problematic, passed out due to hypoglycaemia, hypoglycaemia while asleep	*Psychosocial variables* Symptoms of: panic: *r* = .274* separation anxiety: *r* = .269* social anxiety: *r* = .297* school avoidance: *r* = .219* *Demographic variables* Higher in female: 2.48 (.66) vs 2.01(.75)* Higher 16-18 yrs vs 13-15 yrs: 2.55 (.63) vs 1.96 (.73)* *Clinical variables* T1DM duration: >7 years vs < 7 years: 2.5 (.7) vs 2.17 (.74)* Experiencing hypoglycaemia in

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	Demographic	Clinical	
					school vs had not: 2.36 (.76) vs 1.81 (.49) Experiencing hypoglycaemia in front of others vs had not: 2.32 (.72) vs 1.9 (.8) Experiencing hypoglycaemia while awake vs had not: 2.42 (.73) vs 2.23 (.92)
Amiri et al. (2015)	Correlational, t-test	CYP confidence in managing diabetes	Age		None
Di Battista et al. (2009)	Correlational	Social Anxiety		Diabetes self-care activities (adherence to insulin injection, glucose testing, diet and exercise)	None
Gonder-Frederick et al. (2006)	Correlational	CYP anxiety; parent anxiety; parent FoH			None

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	Demographic	Clinical	
Jabbour & Bragazzi (2021)	Correlational, t-test			CGM vs BGM; frequency of hypoglycaemia over last 12 months	*Clinical variables* CGM vs BGM: 1.03 (.05) vs 2.6 (.63)** Frequency of episodes hypoglycaemia and those using: MDI: *r* = -.82* Insulin pump: *r* = -.82* CGM: *r* = -.94* BGM: *r* = -.74*
Kamps & Varela (2010)	Correlational	CYP anxiety	Family income; Parents' education	HbA1c; % BG < 70; % BG >300	*Psychosocial variables* CYP anxiety: *r*= .03*. *Demographic variables* Family income: *r* = -.21* *Clinical variables* None
Kamps et al (2005)	Correlational	CYP symptoms of anxiety			None

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	Demographic	Clinical	
Kaya & Toklu (2022)	t-test, correlational	CHFS-W		Hypoglycaemia episode, HbA1c, dietary compliance, exercise, keeping BG in safe range before exercise, getting BG measure before exercise, getting BG during exercise, consuming food regardless of BG before exercise, keeping carbohydrate containing food near during exercise, reducing insulin regardless of re-exercise BG, CHFS-B	*Psychosocial variables* *r* = .213* *Clinical variables* Keeping BG within safe range before exercise (yes vs no) = 22.61 (6.11) vs 17.44 (7.21)***

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	Demographic	Clinical	
O'Donnell et al. (2021)	Correlational, t-test	CHFS-W	Age, sex, commercial insurance,	HbA1C, insulin pump use, mean BG, BG checks a day, CMG use, boluses/ day, % BG readings in range, % BG readings high, % time on sensor, % high (on CMG)	*Psychosocial variables* Worry subscale: r = .26*** *Demographic variables* Age *r* = .08* *Clinical variables* Insulin pump use *r* = -.07*; mean BG *r* = .09*; boluses/ day: *r* = - .13**; % BG readings in-range: *r* = -.12**; % BG readings high: *r* = .08*; % time on sensor *r* = -.16*; % high (on CGM): *r* = .13*
Roberts et al. (2020)	Correlational, t-test		Age	HbA1C	None

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	Demographic	Clinical	
Shepard et al (2014)	One-way ANOVA, correlational	Parent trait anxiety and depression; CYP anxiety		Number of severe hypoglycaemic episodes, number of times medical attention needed for hypoglycaemia, HbA1c, insulin regimen, BG, % of reading <70, % of reading 70-180; % of reading > 180, duration of diabetes,	*Psychological variables* None *Clinical variables* Number of times medical attention needed due to hypoglycaemia: *r* = -.17*[a]; duration of diabetes: *r* = .15*[a] highest tertile[b] had more severe hypoglycaemic episodes: F = 5.22*, higher mean BG: F =5.09*, greater % BG readings >180: F = 5.37* and greater % BG readings >240: F= 5.40*.
Tumini et al. (2021)	Correlations	Quality of life; Diabetes specific quality of life; Parent FoH			*Psychosocial variables* Diabetes specific quality of life: *r*= -.29***; Parent FoH: behaviour subscale =.30***; total score *r*=.23**

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	Demographic	Clinical	
Multivariate associations					
Al Hayek et al. (2015)	Multivariate linear regression		Age, gender, education	HbA1c, exercise, treatment type, duration T1DM, hypoglycaemia at school, hypoglycaemia in front of others, hypoglycaemia while awake, frequency of hypoglycaemia, viewing hypoglycaemia as problematic, passed out due to hypoglycaemia, hypoglycaemia while asleep	*Demographic variables* Age: β = .563*** Gender: β = .304* Duration: β = .316* *Clinical Variables* hypoglycaemia viewed as problematic: β= -.262* Passed out due to hypoglycaemia: β = .502*** Hypoglycaemia while awake: β = -.3* Hypoglycaemia at school: β-.312*
Gonder-Frederick et al. (2006)	Multivariate linear regression	CYP symptoms of anxiety	Gender,	Frequency of severe hypoglycaemia, mild hypoglycaemia and experiencing hypoglycaemia alone, experiences relating to hypoglycaemia, anxiety	None

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	Demographic	Clinical	
Kamps et al (2005)	Multivariate linear regression			Frequency of severe hypoglycaemia in last year, frequency of severe hypoglycaemia since diagnosis, experiencing mild hypoglycaemia	None
Reid et al. (2023)	Multivariate linear regression		Food insecurity, Parent education, household education, health insurance	Diabetes medication regimen, CGM.	None

Note. [a]avoidance subscale of CHFS-behaviour subscale; [b]maintain high blood glucose subscale of CHFS-behaviour subscale; BG = Blood Glucose; BGM = Blood Glucose monitoring; CGM = Continuous Glucose Monitoring; CHFS-W = worry subscale of Children's Fear of Hypoglycaemia Scale;

Total FoH

Table 7 summarises results relating to the total FoH (combined worry and behaviour subscale scores), which were reported in 12 studies (three of which used the CHI to assess FoH (Jurgen et al., 2020; Kamps & Varela; Kamps et al., 2010), and the rest used the CHFS).

Demographic Variables

Age. One of four studies that examined the relationship between CYP age and their total FoH found a significant association, reporting that CYP younger than 9 years had higher total scores than those 10 years and older (Amiri et al., 2015, 55.9 vs 38.2). The others, which were deemed to be at less risk of bias, found no relationship (Glocker et al., 2022; Jurgen et al., 2020; Roberts et al., 2020).

Gender. One study looked at the relationship between total FoH and gender, and reported a positive association between female gender and higher total FoH, with a small effect size (Jurgen et al., 2020, r_{pb} =.22, p<.05).

Ethnicity. One paper looked at ethnicity and found no significant association with total FOH (Jurgen et al., 2020).

Socioeconomic Status. One paper explored SES and found a negative correlation with total FoH, with a small effect size (Jurgen et al., 2020, r = -.27).

Clinical Variables

HbA1c. None of the four studies looked at the relationship between total FoH and HbA1c levels found a significant relationship (Glocker et al., 2022; Jurgen et al., 2020; Kaya et al., 2022; Roberts et al., 2020).

Method of Insulin Delivery. Two studies looked at treatment type and total FoH and found no significant results (Jabbour & Braggazi et al., 2021; Jurgen et al., 2020).

Method of BG Monitoring. One paper looked at BG monitoring and total FoH and found a significant result. Those who used blood glucose monitoring had higher total FoH than those who used continuous glucose monitoring (2.94 (.22) vs 1.09 (43); Jabbour & Braggazi et al., 2021).

Diabetes Management. Three studies looked at diabetes self-care and adherence to treatment and lifestyle factors associated with staying well with T1DM. One found a negative correlation between adhering to MDI as prescribed and total FoH, but only for boys, with a small effect size (Di Battista et al., 2009, r = -.38). Another found that those who missed meals, exercised and reduced insulin regardless of BG levels prior to exercising had higher total FoH scores but no other factors relating diabetes care around diet and exercise were significant (Kaya & Toklu, 2022). One paper found no association with adherence or type of insulin delivery (Jurgen et al., 2020).

Frequency and Severity of Hypoglycaemia. Two of three studies that examined the relationship between total FoH and frequency of hypoglycaemic episodes found a significant relationship. One paper found a positive association, with a small effect size (Kaya & Toklu, 2022, r = .25) and multivariate analysis found frequency of severe hypoglycaemia accounted for significant amounts of variance for total FoH, more so than experiences relating to hypoglycaemia (Gonder-Frederick et al., 2006, R^2= .22). One study found no significant correlation (Johnson et al., 2013).

Psychosocial Variables

Anxiety. All three of the studies that examined the relationship between CYPs' symptoms of anxiety and their total FoH found significant relationships, with small effect sizes (Di Battista et al., 2009, r = .30 and .45; Gonder-Frederick et al., 2006, r = .48; Kamps et al., 2005, r = .25). Multivariate analysis found that CYPs' anxiety accounted for a significant

proportion of the variance, more so than gender or experiences relating to hypoglycaemia (Gonder-Frederick et al., 2006, R^2= .23).

Depression. Only one study looked at CYPs' symptoms of depression, reporting a positive correlation with FoH, with a small effect size (Jurgen et al., 2020, *r* = .29).

Self-efficacy for Diabetes. CYPs' confidence in managing their diabetes was examined in one study and was negatively, significantly correlated with total FoH, with a small effect size (Amiri et al., 2015, *r* = -.30).

Quality of Life. Two studies that explored the association between total FoH and quality of life found significant results, with a small effect size (Johnson et al., 2013, quality of life 22% lower in those highest FoH quartile; Tumini et al., 2021, *r* = -.17). FoH was also significantly negatively correlated with diabetes-specific quality of life, with a medium effect size (Tumini et al., 2021, *r* = -.50).

Parental Psychosocial Factors. One of the three studies looking at parental psychosocial factors reported a positive correlation between parents' hypoglycaemia behaviour and CYPs' total FoH , with a small effect size (Tumini et al., 2021, *r* = .17) the other two found no relationship (Gonder-Frederick et al., 2006; Viaene et al., 2017). Mediation analysis found no relationship between parenting stress, parents' FoH and CYPs' total FoH (Viaene et al., 2017). It is important to note that Tumini et al. had a sample size more than double the size of the other two papers which found no significant findings, which is an important consideration given the small effect size.

Table 7

Main findings for Total score of Fear of Hypoglycaemia (n =12)

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	Demographic	Clinical	
Bivariate associations					
Amiri et al. (2015)	Correlational, t-test	Confidence in managing diabetes	Age		*Demographic variables* Age <9 years higher than >10 years: 55.9 vs 38.2*** *Psychosocial variables* Confidence in managing diabetes: *r* = -.30*
Di Battista et al. (2009)	Correlational	Social Anxiety		Diabetes self-care activities (adherence to insulin injection, glucose testing, diet and exercise)	*Clinical variables* Insulin injection; boys: *r* = -.38* *Psychosocial variables* Social anxiety; boys: *r* = .45** girls: *r* = .30*
Glocker et al. (2022)	Correlational, t-test		Age	HbA1c, real time vs intermittent CGM	None

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	Demographic	Clinical	
Gonder-Frederick et al. (2006)	Correlational	CYP anxiety; parent anxiety; parent FoH			*Psychosocial variables* CYP anxiety: r = .48***
Jabbour & Bragazzi (2021)	Correlational, t-test			CGM vs BGM; pump vs MDI	*Clinical variables* CGM vs BGM: 1.09 ± 43 vs 2.94 ± .22**
Johnson et al. (2013)	Correlational	Quality of life		Frequency of severe hypoglycaemia	*Clinical variables* None *Psychosocial variables* 22% lower quality of life in those in the highest FoH quartile compared to lowest (no effect sizes reported)

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	Demographic	Clinical	
Jurgen et al. (2020)	Correlational	CYP symptoms of depression	SES, race, age, Gender	HbA1c, adherence, treatment type	*Clinical variables* None *Demographic Variables* SES: *r*= -.27* Gender: *r* = .22* *Psychosocial variables* *r*= .29**
Kamps et al (2005)	Correlational	CYP symptoms of anxiety			*Psychosocial variables* *r* = .25*

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	Demographic	Clinical	
Kaya & Toklu (2022)	t-test, Correlational			Hypoglycaemia episode, HbA1c, dietary compliance, exercise, keeping BG in safe range before exercise, getting BG measure before exercise, getting BG during exercise, consuming food regardless of BG before exercise, keeping carbohydrate containing food near during exercise, reducing insulin regardless of re-exercise BG, CHFS-B	*Clinical variables* Missing meal (yes vs no): 33.87 (10.68) vs (30.01 (10.48)* Exercise (yes vs no): 33.93 (11.77) vs 29.94 (9)* Reduce bolus regardless of pre-exercise BG level (yes vs no): 35.64 (12.80) vs (31.09 (9.93)* Number of hypoglycaemic episodes: *r*=.25**
Roberts et al. (2020)	Correlational, t-test		Age	HbA1C	None

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	Demographic	Clinical	
Tumini et al. (2021)	Correlations	Quality of life; Diabetes specific quality of life; Parent FoH			*Psychosocial variables* Diabetes specific quality of life: r = -.50*** Quality of life: r = -.17*; Parent FoH (behaviour subscale): r=.17*
Viaene et al. (2017)	Correlational	Parent FoH; Parenting stress			None
Multivariate analysis					
Gonder-Frederick et al. (2006)	Multivariate linear regression	Anxiety	Gender	Frequency of severe hypoglycaemia, mild hypoglycaemia and experiencing hypoglycaemia alone, experiences relating to hypoglycaemia.	*Clinical variables* Frequency of Severe Hypoglycaemia: R^2=.22** *Psychosocial variables* CYP anxiety R^2 = .23**
Jurgen et al. (2020)	Mediation analysis		SES, race, age, gender	HbA1c, Adherence	*Clinical variables* Indirect effect of FoH on HbA1c through adherence: B= -.09, SE = .04*

Author (year)	Analysis	Independent Variables			Main Findings
		Psychosocial	Demographic	Clinical	
Reid et al. (2023)	Multivariate linear regression		Food insecurity parent education, household education, health insurance	diabetes medication regimen, CGM.	None
Viaene et al. (2017)	MANCOVA, Mediation analysis	Parent FoH; Parenting stress	Gender, parent gender, age, time since diagnosis	Time since diagnosis	None

Note. CGM = continuous glucose monitoring; SES = socioeconomic status

Discussion

This systematic review narratively synthesised the findings of 19 studies reporting demographic, clinical, and psychosocial correlates or predictors of FoH in CYP with T1DM. While a large range of variables were examined across individual studies, few factors were consistently analysed, meaning that conclusions are tentative. However, there were some variables that were more consistently measured across studies and for which more firm conclusions can be drawn regarding their association with FoH. These include HbA1c levels, diabetes duration, frequency of hypoglycaemia, method of insulin delivery, method of blood glucose monitoring, hypoglycaemia worry and behaviour, CYPs' symptoms of anxiety and parents' mental health difficulties.

Of the seven studies which looked at HbA1c and FoH, only one found an association with hypoglycaemia worry, with a near negligible effect size (Roberts et al., 2020). This paper had a much larger sample size compared to the papers which did not find significant results. Large sample sizes can lead to marginal effect sizes being identified as statistically significant which can lead to results being wrongly interpreted as clinically significant (Andrade, 2020). Therefore, taken together the results suggest that HbA1c levels and FoH are largely independent. This is in line with the adult literature which reports little evidence of a relationship between HbA1c and FoH (Schmidt et al., 2020). Across the six studies that looked at associations between method of insulin delivery and FoH (Al Hayek et al., 2015; Jabbour & Bragazzi, 2021; Jurgen et al., 2020; Shepard et al. 2014; O'Donnell et al., 2021; Reid et al., 2023), only two found a relationship, with lower hypoglycaemia worry (Al Hayek et al., 2015) and lower hypoglycaemia behaviour (O'Donnell et al., 2022) each associated with pump use. Again, the larger sample sizes and small effect sizes should be noted in the studies which found significant results and might explain the significant results. Similarly, only one of four studies found an association between hypoglycaemia behaviour and total FoH (Jabbour & Bragzzi,

2021). Collectively, these findings suggest that FoH occurs largely independently method of monitoring or maintaining BG levels. As reviewing HbA1c and associated treatment modalities is a primary focus of medical monitoring, there is need for more research in this area to ascertain the relationship, if any, between treatment type, glucose control and FoH.

Longer duration of diabetes was related to greater hypoglycaemia behaviour in both studies (Al Hayek et al., 2015; Shepard et al., 2014). Longer duration of diabetes is associated with higher HbA1c in CYP (Hanberger et al., 2008) and might lead to greater use of behaviours to avoid hypoglycaemia, However, as only one study looked at this, more evidence is required to substantiate this hypothesis.

Frequency of hypoglycaemia was significantly positively correlated with hypoglycaemia worry in all three studies that examined it (Coolen et al., 2001b; Gonder-Frederick et al., 2006; Kamps et al., 2005). This is in line with adult populations whereby experiencing severe hypoglycaemia is associated with greater worry about hypoglycaemia (Coolen et al 2021a). However, results were less consistent for hypoglycaemia behaviour and total FoH. Two studies found a significant, negative correlation between frequency of hypoglycaemia and hypoglycaemia behaviour (Jabbour & Braggazi et al., 2021; Shepard et al., 2014). However, frequency of hypoglycaemia did not independently predict hypoglycaemic behaviour in both studies that examined this relationship using multivariate statistics (Gonder-Frederick et al., 2006; Kamps et al., 2005). Therefore, it might be assumed those who engage more in behaviours to avoid hypoglycaemia experience less hypoglycaemic episodes. While only one (Kaya & Toklu, 2022) of two papers reported a significant positive association between frequency of hypoglycaemic events and total FoH, multivariate analysis found frequency of severe hypoglycaemia was an independent predictor of total FoH (Gonder-Frederick et al., 2006). This incongruence in results possibly is due to the differing associations with the two subscales, making interpretation of a total score more challenging.

CYPs' symptoms of anxiety were found to be positively correlated with hypoglycaemia worry in all six studies that reported on this (Al Hayek et al., 2015; Di Battista et al., 2009; Gonder-Frederick et al., 2006; Kamps & Varela, 2010; Kamps et al 2005; Shepard et al., 2014) and in all four papers that reported on total FoH (Di Battista; Gonder-Frederick et al., 2006; Kamps et al., 2005; Gonder-Frederick et al., 2006). This is in line with literature suggesting that having T1DM in CYP is associated with greater symptoms of anxiety (Baucom et al., 2018; Gonalez et al., 2008; Maijidi et al., 2015), and fits with broader literature that confirms an association between anxiety and fear of recurrence in young people with cancer (Perri et al., 2022; Yang et al., 2019). In contrast, there was little support for an association between anxiety and hypoglycaemia behaviour. Only two of six papers reported positive, but weak, associations with hypoglycaemia behaviour (Al Hayek et al., 2015; Kamps & Varela, 2010). Behaviours such as avoidance can reduce feelings of anxiety in the short-term (Lovibond et al., 2008) but leads to more chronic anxiety presentations long-term (Arnudova et al., 2017) which might explain these results. More research is warranted to understand these associations and associated implications for clinical practice.

Both papers which investigated the relationship between hypoglycaemia worry and behaviour found a positive association (Kayla & Toklu, 2022; O'Donnell et al., 2021) which tentatively indicates that worry and engagement in more behaviours to avoid low, or maintain high, BG levels are related. This is in line with literature that anxiety impacts negatively on CYPs' diabetes management, coping behaviours and glycaemic control (Anderson et al., 2002; Rechenberg, Whittemore & Grey, 2017). Prospective research on the relationship between anxiety and engagement in maladaptive coping behaviours would be beneficial to understand this relationship and determine antecedence.

Both papers which looked at parents' anxiety and CYPs' hypoglycaemia worry found a positive association (Gonder-Frederick et al., 2006; Shepard et al., 2014). While there is not

conclusive evidence, this is in line with literature that parents' anxiety impacts negatively on their children's diabetes management and mental health (Bassi et al., 2020). Further research is needed to understand the relationship between parents' and CYPs' FoH, including temporal and dyadic relationships and processes.

Similarly, both papers that looked at quality of life found increased FoH was negatively associated with general and diabetes-specific quality of life (Johnson et al, 2013; Tumini et al., 2021). Although this is in line with evidence of the impact of having T1DM in CYP on disease-specific quality of life (Nieuwesteeg et al., 2012), further research is needed before conclusions can be drawn.

There were several factors which were found to be associated with FoH but only tested in one study so while there is weak evidence to indicate a relationship, further research is warranted. These include self-efficacy for diabetes (Amiri et al., 2015), CYPs' symptoms of depression (Jurgen et al., 2020) and parents' symptoms of depression (Shepard et al., 2014).

Limitations

Whilst this is the first review to systematically examine correlates and predictors of FoH in CYP with T1DM, only published papers written in English were included in this review so there may be papers within the grey literature or written in other languages which have been excluded, thus introducing publication or language/cultural bias. The bias for publishing significant results is well documented, meaning that non-significant findings are likely left in the unpublished (grey literature) sphere; which is noted as having implications for conclusions drawn when excluding this literature (Winters & Weir, 2017). Therefore, caution must be taken when drawing conclusions from the findings of this review and future research should include endeavour to include grey literature. Only quantitative studies were included as the aim was to explore associated factors relating to FoH. While this was appropriate in relation to the aim,

including qualitative research may have strengthened the findings and added contextual understanding.

Recommendations for Future Research

Whilst several variables have been investigated in relation to FoH, across 19 studies, few were examined in multiple papers and most examined relationships only cross-sectionally. This means that whilst tentative conclusions can be drawn, further research is required to determine more conclusive relationships between variables, including temporal precedence.

It is of note that the participants included in the studies, on average, had low to moderate levels of FoH which may have impacted on the results. In future research, it would be beneficial to understand factors associated with clinically significant levels of FoH, and to further explore the relationship between hypoglycaemia worry and behaviour, as well as overall FoH. There is a lack of representation in the included studies of participants from marginalised ethnic groups or low-income countries. There is an acknowledged publication bias in research towards more privileged groups (Henrich et al., 2010) and it is important that future research endeavours to explore FoH in marginalised groups, especially given evidence of health inequalities within diabetes (Marmot, 2010). Half of the papers included had moderate to significant risk of bias and it is important that future studies have greater methodological rigour to improve the evidence-base.

No papers investigated FoH in relation to psychological theory that underpins therapeutic models. There is currently limited evidence for underpinning theories to explain distress in CYP with T1DM and consequently, limited evidence for models of therapy for this population (Kanapathy & Bogle, 2017; Sansom-Daly et al., 2012; Winkley et al., 2006). Therefore, further understanding of FoH might help to understand the experience of CYP with T1DM and the association between T1DM, anxiety and depression, and FoH (Bernstein et al.,

2013; Buchberger et al., 2016). Further research would support the evidence-base to inform intervention studies to identify therapies that are most suitable and effective for this population.

Clinical Implications

While firm conclusions cannot be drawn, there is tentative evidence that HbA1c is not associated with FoH and possible evidence that hypoglycaemia worry is associated with psychosocial factors such as increased use of maladaptive behaviours relating to hypoglycaemia (e.g. hypoglycaemia behaviour), symptoms of anxiety both in CYP and their parents, and reduced quality of life. It is therefore important that clinicians explore FoH with patients, particularly worry associated with hypoglycaemia, even if there is evidence of good glycaemic control. There is possible evidence that those who have more episodes of hypoglycaemia may experience greater FoH and further research is needed to ascertain if this could be a clinical indicator of increased FoH. Support from clinical psychology in paediatric care is important at multiple levels: in multidisciplinary meetings, in professional consultation and clinical supervision with medical and nursing staff, and via one to one support with CYP and their families. By working across these levels, clinical psychologists can support teams to recognise when CYP might be experiencing FoH and can educate on the possible implications of this and need to monitor CYPs' mental health, given the evidence of comorbidity of mental health problems in CYP with T1DM and the implications this can have for treatment and management.

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Chapter 2: Bridging Chapter

Journey of the Thesis

Research is seldom a straight-forward process. The finalised and pristine, published journal outcome rarely shows the journey and process of getting to that point. Reflexivity is reflecting on the research process while critically evaluating the researcher's role within this; recognising the researcher's own values and beliefs and how this shapes the research (Green & Thorogood, 2018). This allows researchers to consider how the way they understand the world is influenced by the research they do, and how the research they do impacts on their view of the world (Wilkinson, 1988). While there is emphasis and value placed on reflection and reflexivity in qualitative research, there is little space called for this within quantitative research. Jamieson, Govaart & Pownall (2023) consider that perhaps the power of quantitative research comes from the belief that it is free from bias and research influences due to the perceived objectivity of statistics and figures. Therefore, bringing reflexivity into this arena feels like it weakens what is thought be a robust and gold-standard methodology. Conducting research, especially in sensitive areas, is said to have emotional impacts on researchers which is important to highlight throughout the process (Ryan & Golder, 2006). The way we conduct research from the gaps in the literature we see, the questions we pose, the way me make sense of data to the limitations and conclusions we come to, all have bias behind them (Jamieson *et al.*, 2023).

Research often drives change in policy and practice and these changes often impact on those in society who are most disadvantaged and disempowered. Considering that those who conduct research are predominantly from the most privileged groups, it is important to consider the process and reflect on this within quantitative research (Jamieson *et al.*, 2023). For these reasons, I think it is important for me to use this chapter to reflect on the journey of this research project and my role within this.

The Original Study

Originally, the empirical design was the same as is outlined in the empirical chapter of this paper but with an adolescent population. For reference, this is an online, cross-sectional design. Due to ethics around parental consent and covid-19 restrictions, recruitment for the study was primarily through letters sent to patients at Alder Hey Children's Hospital who met the inclusion criteria. These letters were addressed to parents if the young person was aged 12-15, and to the young person themselves if they were 16-18. It was not possible at the time of the study to be present at clinics due to covid-19 restrictions, many of which were running virtually to protect this vulnerable population. Online platforms such as Twitter and closed Facebook groups were utilised to attempt to recruit participants. In the four months it was live, there was a 1% uptake of those contacted through Alder Hey hospital. On reflection, many of these forms of recruitment predominantly target parents rather than the young people directly, which may not have been the case had recruiting in person at clinics been possible.

Reflection and Decision to Change

Throughout the development of the original study, I was lucky to have input from young people who were part of the Experts by Experience group, GenerationR at Alder Hey Children's Hospital. They provided support with the original design and also offered a reflective space for me to share the difficulties in recruitment. They shared disappointment that the study had not had more success with recruitment, as they shared their passion that there were more interventions available to young people with chronic health conditions which are co-produced by young people and research based specifically on young people's experiences. Anecdotally, the group shared their reflections on the amount of pressure they felt throughout the pandemic to perform at school while feeling isolated and sadness for experiences they missed out on, which was likely to impact on recruitment. GenerationR offered the advice that

they felt that they struggled to engage with long written information, especially in the new era of tik tok and 30 second videos. They suggested adjusting research in a way that engaged young people, presenting it in a format they were used to, such as short videos.

The decision was made as a research team that given the timeframe of the Doctorate in Clinical Psychology, the project would be amended to recruit from an adult population. This has led me to reflect on the points made by Jamieson *et al.* (2023): that I am not representative of the population I felt pulled to engage in research. Ultimately, I had the goal to add to the evidence base and make meaningful change to the psychological support available to young people with T1DM. I do not have the lived experience of being an adolescent with T1DM and living through the current time. While there are skills and educational attainment which merit me with the credentials to be able to conduct research, I have to consider the limits that this brings in terms of not being representative of the population I seek to recruit and understand. Perhaps in a perfect scenario, I might have pursued this project for longer, found ways to increase involvement of young people in the development of the project and researched ways to increase recruitment. However, it is important to reflect on the real life pressures of the research world. Pressures such as Universities pushing for academic staff to publish increased amounts of papers to increase revenue, which is arguably deemed of more value that the rigor of the research itself and much of research being mandatory as part of fulfilment of academic attainment. As pressure from universities for their staff to publish increases, so does the bias of the research (Fanelli, 2010) and publication pressure increases fabricating, falsifying or plagiarizing in research (Tijdink, Verbeke & Smulders, 2014). Such pressures perhaps do not offer time and resource to encourage the most meaningful, bottom-up research. I acknowledge the added pressure of fulfilling this research in a manageable timeframe and the impact this had on the decision to change to an adult population that was more likely to enable the

completion of this piece of work. As a research team we have endeavoured to keep the voice of young people present by reflecting on the process and the barriers of the original study and by looking at the experience of T1DM across the lifespan in this thesis as a whole, with a systematic review focussing on children and young people.

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Chapter 3: Empirical Study

The Role of Metacognitive Beliefs and Self-Compassion in Anxiety and Depression for Adults who have Diabetes

Abstract

Introduction Diabetes is associated with mental health difficulties such as anxiety and depression which can impact negatively on diabetes-related health outcomes and quality of life. This cross-sectional study examined associations between anxiety, depression, self-compassion, metacognitive beliefs, rumination and worry in adults with diabetes. *Method* Adults (aged 18 years and over) with a self-confirmed diagnosis of diabetes and proficiency in English completed self-report measures assessing anxiety, depression, self-compassion, metacognitive beliefs, rumination and worry. *Results* A total of 257 participants were included. Metacognitive beliefs, worry and rumination explained additional variance in anxiety and depression, after controlling for clinical and demographic variables. Worry and rumination fully mediated the relationship between positive metacognitive beliefs and anxiety and depression and partially mediated the relationship between negative metacognitive beliefs and anxiety and depression. Self-compassion did not explain additional variance in anxiety or depression after accounting for demographic and clinical variables and worry and rumination, respectively. *Conclusion* The metacognitive model may provide an appropriate theoretical framework for understanding distress experienced by adults with diabetes. Longitudinal research is needed to fully test this model.

Introduction

The number of people living with diabetes in the UK is rising; 3.9 million people lived with the condition in 2019, predicted to rise to 5.3 million by 2025 (Diabetes UK, 2019). There are seven types of diabetes; 90% of those with Diabetes have Type 2 diabetes, 8% have Type 1 diabetes and 2% have other types (Diabetes UK, accessed 2022). Adults with a diagnosis of diabetes often experience comorbid depression and anxiety (Collins, Corcoran & Perry, 2009) which can have a negative impact on glycaemic control (Anderson *et al.*, 2002; Ducat, Philipson & Anderson, 2014; Indelicato *et al.*, 2017). Maintaining glycaemic control is essential to avoid long-term negative health outcomes such as diabetic retinopathy and nephropathy (Nordwall et al., 2009).

The National Institute for Health and Care Excellence (NICE) recommends Cognitive Behavioural Therapy (CBT) as a first-line treatment for depression in adults with long-term physical health conditions (NICE, 2009). There are no specific guidelines for adults with physical health conditions who also experience anxiety; however, for adults who experience Generalised Anxiety Disorder, NICE guidelines recommend CBT for those who do not benefit from lower level interventions such as guided self-help (National Institute for Health Care Excellence, 2011). Meta-analysis has shown the limited efficacy of current psychological interventions such as CBT for individuals with diabetes (Mather et al., 2022). Therefore, while it is important there is further research into CBT, it may be that not everyone would benefit from CBT and it is important that there are a variety of models represented in the research literature. Diabetes distress is often characterised by worries relating to the management of the condition, fear of hypoglycaemia, the long-term implications of having diabetes or feeling angry or frustrated at having the diagnosis (Dennick, Sturt & Speight, 2017; Cox et al., 1987; Polonsky et al., 2015). Considering this, two such models which may add to understanding of anxiety and depression in those who have diabetes include the Self-Regulatory Executive

Function (S-REF; Wells & Matthews,1994) model, which underpins Metacognitive Therapy (MCT; Wells, 2009), and the self-compassion model (Neff, 2003a), which informs Compassion Focused Therapy (CFT; Gilbert 2009).

Self-Regulatory Executive Function Model

The S-REF model proposes that the way in which a person thinks about their thoughts is linked to emotional distress (Wells & Mathews, 1994). These beliefs are termed metacognitive beliefs and they determine how a person manages deals with commonly-occurring negative thoughts and feelings and attributes meaning to their thoughts. Of particular importance is a response style called the Cognitive Attentional Syndrome (CAS; Wells & Matthews, 1994). The CAS consists of three elements: rumination or worry, threat monitoring and maladaptive coping strategies (Wells & Matthews, 1994). Maladaptive metacognitive beliefs activate and maintain the CAS and continual activation can lead to emotional distress. Positive metacognitive beliefs about the CAS (e.g. "worrying about my blood glucose levels helps keep me safe") are theorised to indirectly lead to and maintain emotional distress as individuals are more likely to continually respond to thoughts with unhelpful thinking styles, due to the belief they are beneficial. Similarly, negative metacognitive beliefs of the CAS (e.g. "my worrying is uncontrollable") are hypothesized to both directly and indirectly lead to emotional distress due to the distress of perceiving no control of thoughts and/or a reluctance to reduce engagement with negative thoughts due to belief that they cannot be controlled (Wells & Matthews 1994). By contrast to CBT, the associated therapy, MCT, does not focus on challenging and changing negative thoughts, but rather focuses on changing the metacognitive beliefs that guide responses to these thoughts. As such, MCT may form a more applicable model for understanding and treating distress experienced by people with chronic health

conditions where many of the worries are realistic and rational but the meaning attributed to the process of worrying (metacognitive beliefs) might be problematic (McPhillips et al., 2019).

Empirical studies support the utility of the S-REF model in understanding distress; metacognitive beliefs are associated with anxiety and depression in several physical health conditions, including multiple sclerosis (Heffer-Rahn & Fisher, 2018), cancer (Anderson et al., 2019; Cook et al., 2015), epilepsy (Fisher & Noble, 2017), cardiac conditions (Anderson et al., 2019) and diabetes (Purewal & Fisher, 2018; Cherry et al., 2023). Further, a systematic review indicated that metacognitive beliefs are positively associated with anxiety, depression and quality of life in adults with a range of chronic health conditions (Capobianco et al., 2020). A systematic review found medium to large effect sizes in favour of MCT in treating general mental health difficulties in comparison to CBT (Normann & Morina, 2018) but the efficacy of MCT for adults with diabetes is yet to be established.

Self-Compassion

Neff's self-compassion model has three components: self-kindness, common humanity and mindfulness (Neff, 2003a). Self-compassion is an attitude directed towards the self that protects against self-judgement, isolation, and rumination. Feelings of loneliness in adults with diabetes are associated with poorer blood glucose control (Kobos et al., 2020); it could be hypothesized that elements of the self-compassion model such as common humanity (the recognition that flaws or difficulties are shared experience of humanity and not yours alone) are less likely to be part of the experience of individuals who have a chronic health condition who feel more isolated in their experience. Higher levels of self-compassion are associated with greater levels of well-being and ability to self-manage physical illness and injury (Neff, 2011; Terry & Leary, 2011). Adults with chronic health conditions who are more self-compassionate have better and more adaptive coping strategies (Sirois, Molnar & Hirsch,

2015). Self-compassion is negatively associated with anxiety and depression in adults with chronic health conditions, such as: diabetes (Ferrari, Dal Cin & Steel, 2017; Friis et al., 2015), epilepsy (Baker, Caswell & Eccles, 2019) and cancer (Brown et al., 2020; Gillanders et al., 2015; Pinto-Gouveia et al., 2014; Przezdziecki et al., 2013), with worry and excessive rumination mediating relationships between self-compassion and anxiety and depression in adults with cancer (Brown et al., 2020). The associated therapy, CFT (Gilbert, 2009), conceptualises three emotion-regulation systems, named the threat, drive and soothe systems (Gilbert, 2009). The threat system denotes the emotions and behaviours relating to recognising and responding to threats. The drive system relates to the motivation and reward in seeking out goals, and the soothe system encompasses recovery and contentment when the threat and drive systems are not activated. Imbalance in the systems is theorised to be associated with lower self-compassion and higher levels of anxiety and depression. CFT aims to support people to increase their self-compassion which balances out the three systems thereby reducing symptoms of anxiety and depression. A systematic review found therapies which focus on increasing self-compassion in those who have chronic health conditions are effective in increasing self-compassion and reducing anxiety and depression (Ferrari et al., 2019; Kilic et al., 2022). However, as with MCT, the efficacy of CFT for adults with diabetes is not well-established.

Current Study

Both MCT and CFT have the potential to be effective interventions for anxiety and depression in adults with diabetes. Rumination and worry are key components of each model involved in the activation and maintenance of the CAS (S-REF model, Wells & Matthews, 1994) and the threat system (self-compassion model, Gilbert, 2009). Worry generates greater anxiety, and rumination is associated with greater depression (Calmes & Roberts, 2007;

McLaughlin, Borkovec & Sibava, 2007). Therefore, worry and rumination could plausibly mediate relationships between metacognitive beliefs and self-compassion, and depression and anxiety. The mediating role of rumination in the relationship between metacognitive beliefs and depression and anxiety has been observed for people with diabetes (Cherry et al., 2023) and the mediating role of worry and rumination in the relationship between self-compassion and anxiety and depression for those who have cancer (Brown et al., 2020). However, no study has examined and compared these relationships in adults with diabetes. The current study is the first to explore whether metacognitive beliefs and self-compassion each separately contribute to anxiety and depression in people living with diabetes, and the potential mediating role of worry and rumination, respectively, and thus represents an important step in establishing whether one or both models hold utility for adults with diabetes.

Hypotheses

1. Self-compassion will be negatively correlated with worry, rumination, anxiety and depression.
2. Metacognitive beliefs will be positively correlated with worry, rumination, anxiety and depression.
3. Worry and rumination will be positively correlated with anxiety and depression.
4. Self-compassion and metacognitive beliefs will each account for a significant amount of variance in anxiety and depression after controlling for demographic and clinical covariates and worry and rumination, respectively.
5. The relationship between both metacognitive beliefs and self-compassion and anxiety/depression will be mediated by worry/rumination.

Method

Ethical Approval

Ethical approval was sought from the University of Liverpool (Appendix III and IV) prior to the study commencing.

Study Design

A cross-sectional survey design was used. Experts by experience from the Liverpool University Experts by Experience group supported with the materials and procedure by providing feedback on all the materials and trialling the online process of participating.

Participants and Procedure

A self-selecting sample of adults (aged 18 years and over) with a self-confirmed diagnosis of diabetes and proficiency in English were recruited. Participants were ineligible if they did not self-identify as speaking English sufficiently to consent to the study, were under 18, did not self-report a diagnosis of diabetes or self-identified as having gestational diabetes. Participants were recruited via the volunteer research database Research for the Future (https://www.researchforthefuture.org/) who advertised on their social media platforms and sent individual invites to those on their database who met the research criteria (Appendix V). Interested participants were directed to a link to Qualtrics where they could access the Participant Information Sheet and consent forms. All participants were required to read the information sheet (Appendix VI) and complete the consent form (Appendix VII) before they could access the questionnaires. Participants completed seven measures. On completion of the study participants were offered the opportunity to enter a prize draw for one of four £50 One4All vouchers and shown the debriefing sheet (Appendix VIII).

Measures

Self-Compassion

Self-compassion was assessed using the Self-Compassion Scale (SCS; Neff, 2003b; Appendix IX), a 26-item scale containing six subscales. These are self-kindness, common humanity, mindfulness and their respective negative opposite items, self-judgement, isolation and over-identification. Participants were asked to rate each item on a 5-point Likert scale with responses ranging from 1 (almost never) to 5 (Almost always). The subscales of self-kindness and self-judgment have scores ranging from 5 to 25. The remaining four subscales range in scores from 4 to 20. Subscale scores are calculated as means, with higher scores indicating greater self-compassion. Only the three positive subscale scores (self-kindness, mindfulness and common humanity) were used in analyses as the negative self-compassion items assess similar constructs to anxiety, depression, worry and rumination (e.g. 'when I fail at something important to me I become consumed by feelings of inadequacy'), and previous research has indicated that negative subscales are representative of pathology, rather than self-compassion (Muris & Petrocchi, 2017; Muris et al., 2018). The SCS is a reliable and valid scale in adults, the six subscales evidence good internal reliability (Cronbach's α ranging from .75 to .81, Neff, 2003b).

Metacognitive Beliefs

Metacognitive beliefs were assessed using the Metacognition Questionnaire – 30 (MCQ-30; Wells and Cartwright-Hatton, 2004, Appendix X). Items are rated using a 4-point Likert scale from 1 (do not agree) to 4 (agree very much). There are five subscales: positive beliefs about worry (PMCBS), negative beliefs about the uncontrollability and dangerous nature of worry (NMCBS), cognitive confidence (CC), need to control thoughts (NC), and cognitive self-consciousness (CSC). Subscale scores range from 6 to 24, higher subscales

scores indicate greater conviction in metacognitive beliefs. The scale has good-excellent internal consistency (Cronbach's coefficient alpha for subscales ranges from .72 - .93; Wells & Cartwright-Hatton, 2004).

Worry

Worry was assessed using the brief Penn State Worry Questionnaire (PSWQ), a 5-item self-report questionnaire (Topper et al., 2014, Appendix XI) which was developed from the original 16-item questionnaire (Meyer et al., 1990). Worry is assessed using a 5-point Likert-scale with responses ranging from 1 (not at all typical of me) to 5 (very typical of me). Items are summed to provide a total score; higher overall scores indicate greater worry. The shorter scale correlates highly with the full version (r = .91-.94) and has good to excellent internal consistency (Cronbach's coefficient alphas ranging from 0.84-0.91; Topper et al., 2014).

Rumination

Rumination was assessed using the 5-item brief Ruminative Response Scale (RRS; Topper et al., 2014, Appendix XII). Each item assesses rumination using a 4-point Likert-scale with each response ranging from 1 (almost never) to 4 (almost always). Scores are summed, with higher overall scores indicating greater rumination. The brief RRS correlates highly with the full version (r=.88-.91) and has acceptable to good internal consistency (Cronbach's coefficient alphas ranging from 0.78-0.81; Topper et al., 2014).

Depression

Depression was assessed using the Patient Health Questionnaire-9 (PHQ-9; Kroenke, Spitzer & Williams, 2001; Appendix XIII), a short 9-item questionnaire which assesses severity of depression as categorised by the Diagnostic and Statistical Manual of Mental

Disorders-IV (American Psychiatric Association, 1994). Respondents are asked to rate the presence of 9 core symptoms of depression within the last two weeks. Each item is rated on a 4-point Likert scale with response options ranging from 0 (not at all) to 3 (nearly every day). Scores are summed to give a total score which ranges from 0 to 27 (higher score indicating more depressive symptoms). The PHQ-9 has excellent internal consistency (Cronbach's coefficient alpha .89; Kroenke et al., 2001).

Anxiety

Anxiety was assessed using the Generalised Anxiety Disorder 7 scale (GAD-7, Appendix XIV), a short 7-item questionnaire which assesses the severity of symptoms of anxiety (Spitzer, Kroenke & Williams, 2006). Respondents are asked to consider how the bothered they have been by the statements provided over the last 2 weeks using a 4-point Likert scale. Scores can range from 0 to 21 (higher score indicating greater severity of anxiety symptoms) with each item being scored from 0 (not at all) to 3 (nearly every day). The GAD-7 has excellent internal consistency (Cronbach's coefficient alpha .92; Spitzer et al., 2006).

Demographic Questionnaire

Demographic information was assessed using a questionnaire developed for the purposes of this study, which asked participants to self-report their age, gender, diagnosis, time since diagnosis, comorbid diabetes related complications or conditions, socio-economic status (using postcode) mental health difficulties and previous/ current psychology input (Appendix XV).

Statistical Analysis

Variables were first examined for normality, kurtosis and skewness. All the variables met criteria for normality other than the Positive Beliefs subscale of the MCQ-30 which showed skewness (1.115), and the PSWQ which showed kurtosis (-1.347). However, due to the large sample size, parametric tests were deemed appropriate (Piovesana et al., 2018). Data were screened and one participant was removed for stating they were awaiting confirmation of diabetes diagnosis.

To address the first three hypotheses, correlations between variables were examined using Pearson's correlation analyses. The fourth and fifth hypotheses were assessed using a series of hierarchical multiple linear regressions, with depression and anxiety as outcome variables and clinical and demographic covariates controlled for. Power analysis stipulates that 166 participants would be required to adequately power a regression with 14 predictor variables (with power of 90%, alpha of .05 and medium effect size F = 0.15). In Step 1, demographic and clinical variables (age, gender, deprivation index, duration of diabetes, type of diabetes, prior mental health support, employment status and number of diabetes related complications) were entered; step 2 controlled for rumination (depression as outcome variable) or worry (anxiety as outcome variable); and step 3 controlled for MCQ-30 subscales (S-REF model) or SCS subscales (self-compassion model).

Results

In total, 389 participants accessed the online questionnaires. One participant was removed due to not self-reporting having a diagnosis of diabetes and 131 participants were removed as they did not complete any of the questionnaires. The remaining 257 participants were included in analysis, 236 of which completed all questionnaires.

Table 1 illustrates a summary of the demographic and clinical characteristics of the participants who took part in the study. The numbers of participants reflect how many provided the information (e.g. 249 participants provided their age). The mean age of participants was

58.4 years (standard deviation [SD] 14.89) and most participants (89.9%) identified as White British. Approximately half (52.1%) of participants identified as female. Half (54.4%) of those who took part had type 2 diabetes, 44.4% had type 1 diabetes and 1.2% had another type. Mean duration of diabetes was 21.49 years. Majority of participants had mild symptoms of anxiety (68.8%) and minimal symptoms of depression (64.3%). A tenth (9.7%) had severe symptoms of anxiety and 4.6% had severe symptoms of depression. Those who were in employment accounted for 45.5% of participants and 54.9% had achieved degree level of education or above. Only 5.4% of participants reported having support from anyone else for their diabetes. Over two-thirds (71.7%) of participants reported other comorbid medical conditions and 52% reported no diabetes related conditions. Previous support with mental health, defined as either psychological therapy or psychotropic medication, was self-reported by 51.8% of participants.

Table 1

Demographic and clinical characteristics (n = 257)

Demographic and clinical characteristic		n (%) unless otherwise stated
Age (n = 249)	Mean age, years (SD)	58.45 (14.89)
Gender identity (n = 257)	Female (including trans-female)	134 (52.1)
	Male (including trans-male)	118 (45.9)
	Non-binary	3 (1.2)
	Prefer not to say	2 (0.8)
Ethnicity (n = 257)	White British (English, Scottish, Welsh)	231 (89.9)
	White Irish	5 (1.9)
	Asian	6 (2.3)
	Black	3 (1.2)
	Mixed/ multiple ethnicities: White and Black	1 (0.4)
	Mixed/ Multiple ethnicities: White and Asian	3 (1.2)
	Mixed/ Multiple ethnicities: any other	1 (0.4)

	Arab	2 (0.8)
	Other	1 (0.4)
Relationship Status (n = 255)	Single/ never married	70 (27.5)
	Married/ civil partnership (including same sex)	145 (56.9)
	Divorced	22 (8.6)
	Widowed	18 (7.1)
Employment (n = 253)	In employment	115 (45.5)
	Not in employment	138 (55.5)
Educational attainment (n = 253)	Degree level or above	139 (54.9)
	Below degree level	114 (45.1)
Level of deprivation (n = 245)	Deprivation Index, mean (SD)	5.56 (3.07)
Mean duration diabetes (n= 244)	Years, mean (SD)	21.49 (16.37)
Type of diabetes (n = 257)	Type 1	114 (44.4)
	Type 2	140 (54.5)
	Other	3 (1.2)
Support with Diabetes from someone else (n =257)	Yes	14 (5.4)
	No	243 (94.6)
Number of Diabetes related complications (n = 257)	None	134 (52.1)
	1	74 (28.8)
	2	32 (12.5)
	3	11 (4.3)
	4	5 (1.9)
	5	1 (0.4)
Comorbid medical conditions (n = 257)	Yes	182 (71.7)
Previous Mental Health Support (n = 257)	Yes	133 (51.8)
Anxiety symptoms (n = 237)	Minimal	163 (68.8)
	Mild	37 (15.6)
	Moderate	14 (5.9)
	Severe	23 (9.7)
Depression symptoms (n = 238)	Minimal	153 (64.3)
	Mild	40 (16.8)
	Moderate	22 (9.2)
	Moderately severe	12 (5)
	Severe	11 (4.6)

Note. Deprivation Index from Index of Multiple Deprivation, Ministry of Housing, Communities and Local Government (2019), scores range from 1-9 with 1 being most deprived and 9 being least deprived.

Correlations

Table 2 presents means, SDs and bivariate (Pearson) correlations among all independent and dependent variables. In support of hypothesis 1, all three SCS subscales were significantly negatively correlated with anxiety (r = -.239 to -.356, p<.001), depression (r = -.277 to -.372, p<.001), worry (r = -.145, p<.05 to -.307, p<.001) and rumination (r = -.197 to -.317, p<.001).

With regard to the second hypothesis, all the MCQ-30 subscales were significantly, positively correlated with anxiety (r = .288 to .740, p<.001) but only four (CC, CSC, NMCBS and NC) were positively correlated with depression (r = .381 to .645, p<.001); PMCBS were not significantly correlated with depression (r = .106, p =.051). However, all MCQ-30 subscales were positively correlated with rumination (r = .210 to .705, p<.001) and worry (r = .354 to .739, p<.001).

In line with the third prediction, rumination and worry were positively correlated with anxiety and depression (r = .719 and .782, p<.001; r = .749 and .616, p<.001).

Table 2

Descriptive statistics and intercorrelations between independent variables, mediator variables and depression (PHQ-9 scores) and anxiety (GAD-7 scores)

	2	3	4	5	6	7	8	9	10	11	12	M	SD
1.GAD-7	.733**	.749**	.719**	.406**	.288**	.409**	.740**	.498**	-.320**	-.239**	-.356**	13.88	5.98
2.PHQ-9		.616**	.782**	.468**	.106	.381**	.645**	.541**	-.372**	-.277**	-.366**	17.22	6.92
3.PSWQ			.698**	.354**	.369**	.437**	.739**	.456**	-.277**	-.145*	-.307**	14.26	6.62
4.RRS				.437**	.210**	.411**	.705**	.575**	-.305**	-.197**	-317**	10.79	3.90
5.CC					.128*	.195**	.440**	.413**	-.238**	-.122**	-.237**	11.11	4.57
6.PMCBS						.375**	.352**	.358**	.028	.046	.032	10.06	4.29
7.CSC							.546**	.463**	.033	.021	.085	13.28	4.30
8.NMBCS								.638**	-.249**	-.164**	-.273**	11.65	4.87
9.NC									-.193**	-105	-.178**	10.36	3.80
10.SK										.707**	.761**	2.52	.92
11.CH											.702**	2.82	1.04
12.MF												2.92	.92

Note. GAD-7 = Generalised Anxiety Disorder 7 Scale; PHQ-9 = Patient Health Questionnaire 9; PSWQ = Penn State Worry Questionnaire; RRS = Brief Ruminative Response Scale. *MCQ-30 subscales:* CC= Cognitive Confidence; PMBCS = Positive Metacognitive Beliefs; CSC = Cognitive Self-consciousness; NMBCS = Negative Metacognitive Beliefs; NC= Need to Control. *SCS subscales:* SK= Self-Kindness; CH = Common Humanity; MF = Mindfulness; M = mean, SD = standard deviation.
**p<.001, *p<.05

Contribution of Self-Compassion to Anxiety and Depression

Table 3 shows two hierarchical regression models for anxiety and depression while controlling for sociodemographic and clinical variables and rumination and worry, respectively. Sociodemographic and clinical variables were included in Step 1; this step was significant for both anxiety (F = 8.63, df = 218, p<.001), accounting for 19.3% of the variance, and depression (F = 11.24, df = 216, p<.001), accounting for 25.8% of the variance. The independent predictors at this step for anxiety were deprivation index (β = -.161, p<.05), age (β = -.285, p<.05), past mental health support (β =-.243, p<.001). For the depression model, the independent predictors at this step were age (β = -.257, p<.05), number of diabetes related complications (β = .251, p<.001) and past mental health support (β = -.307, p <.001).

Step 2 added worry and rumination to the models, respectively. This step was also significant for both models, accounting for 54.7% of the variance (F = 34.23, df = 218, p<.001) for anxiety, and 60.7% of the variance for depression (F = 43.37, df =216, p<.001). The independent predictors for the anxiety model at this step were number of diabetes related complications (β =.104, p<.05) and worry (β = .730, p<.001); number of diabetes related complications (β = .130, p<.05) was an independent predictor of depression.

The final step added SCS subscale scores and was significant for both anxiety (F = 26.84, df =218, p<.001), accounting for an additional 1.6% of the variance, and for depression (F = 34.06, df = 216, p<.001), accounting for an additional 1.8% of the variance. In the final model, there were one independent predictor for anxiety which was worry (β = .680, p<.001) and one independent predictor for depression, rumination (β =.674, p<.001).

Table 3

Summary of Self-Compassion Hierarchical Regression Predicting Anxiety (GAD-7 Score) and Depression (PHQ-9 Score)

	Anxiety (GAD-7 score)					Depression (PHQ-9 score)				
	Variable	ΔR^2	Sig	Standardised βeta	*T*	Sig.	Variable	ΔR^2	Sig	Standardised βeta	*T*	Sig.
Step 1		**.193**	**<.001**					**.258**	**<.001**			
	Deprivation Index			**-.161**	**-2.554**	**.011**	Deprivation Index			-.107	-1.753	.081
	Age			**-.285**	**-3.162**	**.002**	Age			**-.257**	**-2.965**	**.003**
	Gender			.034	.519	.604	Gender			.078	1.239	.217
	Ethnicity			.045	.727	.468	Ethnicity			.091	1.523	.129
	Type of Diabetes			-.003	-.036	.971	Type of Diabetes			.100	1.243	.215
	Duration of diabetes			-.039	-.480	.632	Duration of diabetes			-.016	-.211	.833
	Number of diabetes related complications			.085	1.305	.193	Number of diabetes related complications			**.251**	**3.997**	**<.001**
	Past Mental Health support			**-.243**	**-3.643**	**<.001**	Past Mental Health support			**-.307**	**-4.774**	**<.001**
	Employment Status			.089	1.167	.244	Employment Status			.137	1.873	.062
Step 2		**.547**	**<.001**					**.607**	**<.001**			
	Deprivation Index			-.039	-.815	.416	Deprivation Index			-.073	-1.635	.104
	Age			.002	.028	.978	Age			.035	.532	.595
	Gender			-.048	-.974	.331	Gender			.006	.129	.898
	Ethnicity			-.009	-.185	.854	Ethnicity			.012	.274	.784
	Type of Diabetes			.010	.153	.878	Type of Diabetes			.049	.834	.405

	Anxiety (GAD-7 score)					Depression (PHQ-9 score)					
	Variable	ΔR^2	Sig	Standardised βeta	*T*	Sig.	Variable	ΔR^2	Sig	Standardised βeta	*T*	Sig.
	Duration of diabetes			-.110	-1.812	.071	Duration of diabetes			-.051	-.907	.366
	Number of diabetes related complications			**.104**	**2.119**	**.035**	Number of diabetes related complications			**.130**	**2.801**	**.006**
	Past Mental Health support			-.023	-.441	.660	Past Mental Health support			-.064	-1.278	.203
	Employment Status			-.037	-.642	.521	Employment Status			-.001	-.027	.978
	PSWQ			**.730**	**12.839**	**<.001**	RRS			**.725**	**13.605**	**<.001**
Step 3		**.563**	**<.001**					**.625**	**<.001**			
	Deprivation Index			-.036	-.760	.448	Deprivation Index			-.064	-1.481	.140
	Age			.022	.310	.757	Age			.054	.826	.410
	Gender			-.040	-.806	.421	Gender			.026	.558	.577
	Ethnicity			.003	.054	.957	Ethnicity			.021	.488	.626
	Type of Diabetes			-.106	-1.783	.076	Type of Diabetes			.046	.808	.420
	Duration of diabetes			-.106	-1.783	.076	Duration of diabetes			-.050	-.909	.365
	Number of diabetes related complications			.098	2.025	.044	Number of diabetes related complications			**.138**	**3.022**	**.003**
	Past Mental Health support			-.022	-.423	.672	Past Mental Health support			-.072	-1.470	.143
	Employment Status			-.074	-1.265	.207	Employment Status			-.024	-.447	.656
	PSWQ			**.680**	**11.561**	**<.001**	RRS			**.674**	**12.378**	**<.001**
	SCS-MF			-.096	-1.226	.221	SCS-MF			.001	.013	.492

Anxiety (GAD-7 score)						Depression (PHQ-9 score)					
Variable	ΔR^2	Sig	Standardised βeta	*T*	Sig.	Variable	ΔR^2	Sig	Standardised βeta	*T*	Sig.
SCS-CH			-.030	-.437	.662	SCS-CH			.044	-.688	.492
SCS-SK			-.046	-.599	.550	SCS-SK			-.127	-1.782	.076

Note. GAD-7 = Generalised Anxiety Disorder 7 Scale ; PSWQ = Penn State Worry Questionnaire; RRS = Brief Ruminative Response Scale; *SCS subscales:* SK= Self-Kindness; CH = Common Humanity; MF = Mindfulness.

Contribution of Metacognitive Beliefs to Anxiety and Depression

Table 4 shows results from the two hierarchical regression models for anxiety and depression while controlling for sociodemographic and clinical variable and worry. Step 1 and 2 of the regression are the same as are show in Table 3 and the results are outlined in the self-compassion section above.

The final step added the MCQ-30 subscale scores and was significant for both the anxiety model (F = 28.302, df = 218, p<.001), accounting for an additional 6.9% of the variance, and for the depression model (F = 32.228, df = 216, p<.001), accounting for an additional 4.5% of the variance. In the final model, there were three independent predictors of anxiety: duration of diabetes (β = -.113, p<.05), worry (β = .430, p<.001) and NMCBS (β =.357, p<.001), and four of depression: number of diabetes related complications (β = .127, p<.05), rumination (β =.487, p<.001), PMCBS (β = -.111, p<.05) and NMCBS (β =.206, p<.05).

Table 4

Summary of Metacognitive Beliefs Hierarchical Regression Predicting Anxiety (GAD-7 Score) and Depression (PHQ-9 Score)

		Anxiety (GAD-7 score)						Depression (PHQ-9 score)				
	Variable	Δ R^2	Sig	Standardised βeta	*T*	Sig.	Variable	Δ R^2	Sig	Standardised βeta	*T*	Sig.
Step 1		**.193**	**<.001**					**.258**	**<.001**			
	Deprivation Index			**-.161**	**-2.554**	**.011**	Deprivation Index			-.107	-1.753	.081
	Age			**-.285**	**-3.162**	**.002**	Age			**-.257**	**-2.965**	**.003**
	Gender			.034	.519	.604	Gender			.078	1.239	.217
	Ethnicity			.045	.727	.468	Ethnicity			.091	1.523	.129
	Type of Diabetes			-.003	-.036	.971	Type of Diabetes			.100	1.243	.215
	Duration of diabetes			-.039	-.480	.632	Duration of diabetes			-.016	-.211	.833
	Number of diabetes related complications			.085	1.305	.193	Number of diabetes related complications			**.251**	**3.997**	**<.001**
	Past Mental Health support			**-.243**	**-3.643**	**<.001**	Past Mental Health support			**-.307**	**-4.774**	**<.001**
	Employment Status			.089	1.167	.244	Employment Status			.137	1.873	.062
Step 2		**.547**	**<.001**					**.607**	**<.001**			
	Deprivation Index			-.039	-.815	.416	Deprivation Index			-.073	-1.635	.104
	Age			.002	.028	.978	Age			.035	.532	.595

	Anxiety (GAD-7 score)					Depression (PHQ-9 score)					
	Variable	Δ R^2	Sig	Standardised βeta	*T*	Sig.	Variable	Δ R^2	Sig	Standardised βeta	*T*	Sig.
	Gender			-.048	-.974	.331	Gender			.006	.129	.898
	Ethnicity			-.009	-.185	.854	Ethnicity			.012	.274	.784
	Type of Diabetes			.010	.153	.878	Type of Diabetes			.049	.834	.405
	Duration of diabetes			-.110	-1.812	.071	Duration of diabetes			-.051	-.907	.366
	Number of diabetes related complications			**.104**	**2.119**	**.035**	Number of diabetes related complications			**.130**	**2.801**	**.006**
	Past Mental Health support			-.023	-.441	.660	Past Mental Health support			-.064	-1.278	.203
	Employment Status			-.037	-.642	.521	Employment Status			-.001	-.027	.978
	PSWQ			**.730**	**12.839**	**<.001**	RRS			**.725**	**13.605**	**<.001**
Step 3		**.616**	**<.001**					**.652**	**<.001**			
	Deprivation Index			-.041	-.912	.363	Deprivation Index			-.043	-1.008	.315
	Age			.034	.521	.603	Age			.051	.813	.417
	Gender			.015	.330	.742	Gender			.058	1.288	.199
	Ethnicity			-.024	-.555	.580	Ethnicity			.008	.202	.840
	Type of Diabetes			-.002	-.032	.975	Type of Diabetes			.052	.935	.351
	Duration of diabetes			**-.113**	**-2.017**	**.045**	Duration of diabetes			-.063	-1.176	.241

	Anxiety (GAD-7 score)					Depression (PHQ-9 score)				
Variable	Δ R^2	Sig	Standardised βeta	*T*	Sig.	Variable	Δ R^2	Sig	Standardised βeta	*T*	Sig.
Number of diabetes related complications			.060	1.304	.194	Number of diabetes related complications			**.127**	**2.858**	**.005**
Past Mental Health support			-.026	-.525	.600	Past Mental Health support			-.076	-1.617	.107
Employment Status			-.053	-.990	.323	Employment Status			-.016	-.301	.764
PSWQ			**.430**	**5.880**	**<.001**	RRS			**.487**	**7.178**	**<.001**
CC			.056	1.130	.260	CC			.091	1.902	.059
PMCBS			-.023	-.472	.638	PMCBS			**-.111**	**-2.457**	**.015**
CSC			-.024	-.455	.649	CSC			.017	.339	.735
NMCBS			**.357**	**4.616**	**<.001**	NMCBS			**.206**	**3.060**	**.003**
NC			.059	.994	.321	NC			.106	1,783	.076

Note. GAD-7 = Generalised Anxiety Disorder 7 Scale; PSWQ = Penn State Worry Questionnaire; RRS = Brief Ruminative Response Scale. *MCQ-30 subscales:* CC= Cognitive Confidence; PMBCS = Positive Metacognitive Beliefs; CSC = Cognitive Self-Consciousness; NMBCS = Negative Metacognitive Beliefs; NC= Need to Control Thoughts.

Discussion

This study explored whether metacognitive beliefs and self-compassion each separately contribute to anxiety and depression in people living with diabetes when controlling for known covariates including worry and rumination as well as clinical and demographic variables. Support was found for the hypotheses that self-compassion and metacognitive beliefs would each be positively associated with anxiety, depression, worry and rumination. In contrast to hypotheses, the positive subscales of the SCS did not account for a significant proportion of variance in anxiety or depression when controlling for sociodemographic and clinical variables, worry and rumination. However, support was found for the fit of the metacognitive model in accounting for depression and anxiety; worry and rumination partially mediated the relationship between NMCBS and anxiety and depression, and fully mediated the relationship between PMCBs and anxiety and depression, respectively.

Self-Compassion and Anxiety and Depression

Gilbert's model of self-compassion hypothesizes that greater levels of self-compassion increase the soothe system of the CFT systems model and reduces the threat system, hence reducing depression and anxiety (Gilbert, 2009; Johnson & O'Brien, 2013; Welford, 2010). Rumination is a key element of the threat system which would imply that higher levels of rumination should be associated with lower self-compassion. Therefore, it was expected that higher levels of self-compassion (CH, SK and MF) would be negatively correlated with anxiety and depression and rumination in people with diabetes. This hypothesis was supported. Our findings fit with previous literature in diabetes (Ferrari et al., 2017; Friis et al., 2015; Gillanders et al., 2015), epilepsy (Baker et al., 2019) and cancer (Brown et al., 2020; Pinto-Gouveia et al., 2014; Prezezdziecki et al., 2013). However, contrary to previous research, self-compassion did

not account for a significant proportion of variance in anxiety or depression in the current study after controlling for covariates including worry and rumination (Ferrari et al., 2017; Friis et al., 2015). However, these studies did not control for worry or rumination in their regression analysis and included self-compassion as a total score rather than individual subscales. Using the total SCS score is cautioned against due to the negative subscales inflating the relationship between self-compassion and mental health difficulties (Muris et al., 2018). There were also a greater number of variables included in the current study which might also explain the results, particularly considering that a high proportion of variance was already explained demographic and clinical variables before accounting for the influence of self-compassion.

Metacognitive Beliefs and Anxiety and Depression

The observed relationships between metacognitive beliefs, worry and rumination, and anxiety and depression are in keeping with previous research in diabetes (Cherry et al., 2023; Purewal & Fisher, 2018), cancer (Cook et al., 2015), cardiac conditions (Anderson et al., 2019), multiple sclerosis (Heffer-Rahn & Fisher, 2018), epilepsy (Fisher & Noble, 2017) and in a recent systematic review of physical health conditions (Capobianco et al., 2020). Longer duration of diabetes was negatively associated with anxiety which is in line with previous research (Martino et al., 2019), and could be suggestive of greater self-management (Aronson et al., 2019). Should this be confirmed temporally, this would indicate the importance of early intervention and identification of people with diabetes who are likely to experience anxiety.

Limitations

The current study used a cross-sectional design which means that it is not possible to determine causality; prospective studies including people with diabetes are needed to further explore temporal relationships among variables. Around 40% of people with diabetes in the

UK are said to have difficulties with their mental health (Whicher, O'Neill & Holt 2020). This is representative of those who took part in the current study as around 35% reported mild to severe anxiety and depression symptoms (the rest reporting minimal symptoms). Around half of the participants had one or more diabetes related complication which is in line with UK population who have diabetes (Whicher et al., 2020). While the participants were well represented in terms of type of diabetes, employment, gender and education levels, they were not representative of the general population with regard to ethnicity. The 2021 consensus found that 4% of the population of England and Wales are Black, 9.4% Asian and 74.4% White (Office for National Statistics, 2022), which is not reflected in the participants of this study. It is well-documented that there is over-representation of Caucasian groups in research (Hussain-Gambles & Leese, 2004) and caution should be taken with generalising results and future research should endeavour to include marginalised groups. A further limitation is that the current study relied on self-reported information regarding participants' diabetes diagnosis and other demographic factors; this could not be checked against medical records due to the study design and recruitment method which could mean there are errors in reporting.

Clinical Implications and Conclusions

The current study is the first to explore whether metacognitive beliefs and self-compassion can each separately contribute to anxiety and depression in people with diabetes over worry and rumination. The findings indicate that the S-REF model may form an appropriate theoretical framework for understanding distress experienced by adults with diabetes, but there is less robust support for the self-compassion model in understanding distress in this context. MCT, which is underpinned by the S-REF model, has been shown to be effective for reducing anxiety and depression in adults with cancer (Fisher et al., 2019) and cardiac conditions (Wells et al., 2022). The current study supports the possible utility of MCT

for people with diabetes, over and above therapies that focus on self-compassion. Further research examining the longitudinal fit of the S-REF model, incorporating a robust assessment of CAS activation, would be beneficial. Should findings indicate support for the fit of the S-REF model, it would be beneficial for pilot studies to then examine the effectiveness of MCT for people with diabetes prior to large scale intervention studies.

Having a diagnosis of diabetes, in most cases, requires life-long and daily management with the threat of possible long-term health consequences. The impact of living with diabetes on mental health is well documented and the NICE guidelines (2022) place importance of mental wellbeing being monitored and supported in this population. It is imperative that research informs practice so that people with diabetes are given the best possible support and treatment. This research indicates that it is beneficial for medical, nursing and other clinicians involved in diabetes care to consider that anxiety is likely to be higher in those who have a more recent diagnoses and that symptoms of depression may be higher for patients who have a greater number of diabetes-related conditions. The association of metacognitive beliefs, lower self-compassion and worry and rumination with anxiety and depression in this population is key for clinicians. For example, clinicians may benefit from noticing if patients talk about not being able to stop worrying or that worrying helps them to manage their diabetes (metacognitive beliefs), noticing when patients are expressing worry, rumination, being unkind to themselves (e.g. “I’m no good at managing my diabetes”) or expressing isolation in their experience (e.g. “no one else understands what I’m going through”). This may indicate that individuals may be more likely to experience anxiety and depression, which is well documented in the literature to impact on glycaemic control (Anderson *et al.,* 2002; Ducat, Philipson & Anderson, 2014; Indelicato *et al.,* 2017). Identifying possible risk factors for distress in this population has potential to lead to more timely conversations about mental well-being and possibly sooner referrals for mental health support and ultimately improving long-

term physical health, although longitudinal research is needed to confirm temporal precedence. For clinical psychologists, it is premature to recommend MCT for this population. However, with further research on the efficacy of this model in this population, MCT might be a model for clinical psychologists to consider when working with adults experiencing low mood or anxiety in the context of their condition.

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Appendices

Appendix I: Journal Guidelines: Frontiers in Psychology

Adapted including relevant sections only.

Author guidelines

General standards

Article type

Frontiers requires authors to select the appropriate article type for their manuscript and to comply with the article type descriptions defined in the journal's 'Article types' page, which can be seen from the 'For authors' menu on every Frontiers journal page. Please pay close attention to the word count limits.

Manuscript length

Frontiers encourages the authors to closely follow the article word count lengths given in the 'Article types' page of the journals. The manuscript length includes only the main body of the text, footnotes, and all citations within it, and excludes the abstract, section titles, figure and table captions, funding statement, acknowledgments, and references in the bibliography. Please indicate the number of words and the number of figures and tables included in your manuscript on the first page.

Title

The title should be concise, omitting terms that are implicit and, where possible, be a statement of the main result or conclusion presented in the manuscript.
Abbreviations should be avoided within the title.
Witty or creative titles are welcome, but only if relevant and within measure. Consider if a title meant to be thought-provoking might be misinterpreted as offensive or alarming. In extreme cases, the editorial office may veto a title and propose an alternative. Authors should avoid:
titles that are a mere question without giving the answer
unambitious titles, for example starting with 'Towards,' 'A description of,' 'A characterization of' or 'Preliminary study on'
vague titles, for example starting with 'Role of', 'Link between', or 'Effect of' that do not specify the role, link, or effect
including terms that are out of place, for example the taxonomic affiliation apart from species name.
For Corrigenda, General Commentaries, and Editorials, the title of your manuscript should have the following format:
'Corrigendum: Title of Original Article'
General Commentaries: 'Commentary: Title of Original Article' 'Response: Commentary: Title of Original Article'
'Editorial: Title of Research Topic'
The running title should be a maximum of five words in length.

Abstract

As a primary goal, the abstract should make the general significance and conceptual advance of the work clearly accessible to a broad readership. The abstract should be no longer than a single paragraph and should be structured, for example, according to the IMRAD format. For the specific structure of the abstract, authors should follow the requirements of the article type or journal to which they're submitting. Minimize the use of abbreviations and do not cite references, figures or

tables. For clinical trial articles, please include the unique identifier and the URL of the publicly-accessible website on which the trial is registered.

Keywords

All article types require a minimum of five and a maximum of eight keywords.

Text

The entire document should be single-spaced and must contain page and line numbers in order to facilitate the review process. The manuscript should be written using either Word or LaTeX. See above for templates.

Nomenclature

The use of abbreviations should be kept to a minimum. Non-standard abbreviations should be avoided unless they appear at least four times, and must be defined upon first use in the main text. Consider also giving a list of non-standard abbreviations at the end, immediately before the acknowledgments.

Equations should be inserted in editable format from the equation editor.

Italicize gene symbols and use the approved gene nomenclature where it is available. For human genes, please refer to the HUGO Gene Nomenclature Committee (HGNC). New symbols for human genes should be submitted to the HGNC here. Common alternative gene aliases may also be reported, but should not be used alone in place of the HGNC symbol. Nomenclature committees for other species are listed here. Protein products are not italicized.

We encourage the use of Standard International Units in all manuscripts.

Chemical compounds and biomolecules should be referred to using systematic nomenclature, preferably using the recommendations by the International Union of Pure and Applied Chemistry (IUPAC).

Astronomical objects should be referred to using the nomenclature given by the International Astronomical Union (IAU) provided here.

Life Science Identifiers (LSIDs) for ZOOBANK registered names or nomenclatural acts should be listed in the manuscript before the keywords. An LSID is represented as a uniform resource name (URN) with the following format:
urn:lsid:<Authority>:<Namespace>:<ObjectID>[:<Version>]
For more information on LSIDs please see the 'Code' section of our polices and publication ethics.

Sections

The manuscript is organized by headings and subheadings. The section headings should be those appropriate for your field and the research itself. You may insert up to 5 heading levels into your manuscript (i.e.,: 3.2.2.1.2 Heading Title).

For Original Research articles, it is recommended to organize your manuscript in the following sections or their equivalents for your field.

Introduction Succinct, with no subheadings.

Materials and methods This section may be divided by subheadings and should contain sufficient detail so that when read in conjunction with cited references, all procedures can be repeated. For experiments reporting results on animal or human subject research, an ethics approval statement should be included in this section.

Results This section may be divided by subheadings. Footnotes should not be used and must be transferred to the main text.

Discussion This section may be divided by subheadings. Discussions should cover the key findings of the study: discuss any prior research related to the subject to place the novelty of the discovery in the appropriate context, discuss the potential

shortcomings and limitations on their interpretations, discuss their integration into the current understanding of the problem and how this advances the current views, speculate on the future direction of the research, and freely postulate theories that could be tested in the future.

For further information, please check the descriptions defined in the journal's 'Article types' page, in the 'For authors' menu on every journal page.

Acknowledgments

This is a short text to acknowledge the contributions of specific colleagues, institutions, or agencies that aided the efforts of the authors. Should the content of the manuscript have previously appeared online, such as in a thesis or preprint, this should be mentioned here, in addition to listing the source within the reference list.

Contribution to the field statement

When you submit your manuscript, you will be required to briefly summarize in 200 words your manuscript's contribution to, and position in, the existing literature in your field. This should be written avoiding any technical language or non-standard acronyms. The aim should be to convey the meaning and importance of this research to a non-expert. While Frontiers evaluates articles using objective criteria, rather than impact or novelty, your statement should frame the question(s) you have addressed in your work in the context of the current body of knowledge, providing evidence that the findings – whether positive or negative – contribute to progress in your research discipline. This will help the chief editors to determine whether your manuscript fits within the scope of a specialty as defined in its mission statement; a detailed statement will also facilitate the identification of the editors and reviewers most appropriate to evaluate your work, ultimately expediting your manuscript's initial consideration.

Example statement on: Markram K and Markram H (2010) The Intense World Theory – a unifying theory of the neurobiology of autism. Front. Hum. Neurosci. 4:224. doi: 10.3389/fnhum.2010.00224

Autism spectrum disorders are a group of neurodevelopmental disorders that affect up to 1 in 100 individuals. People with autism display an array of symptoms encompassing emotional processing, sociability, perception and memory, and present as uniquely as the individual. No theory has suggested a single underlying neuropathology to account for these diverse symptoms. The Intense World Theory, proposed here, describes a unifying pathology producing the wide spectrum of manifestations observed in autists. This theory focuses on the neocortex, fundamental for higher cognitive functions, and the limbic system, key for processing emotions and social signals. Drawing on discoveries in animal models and neuroimaging studies in individuals with autism, we propose how a combination of genetics, toxin exposure and/or environmental stress could produce hyper-reactivity and hyper-plasticity in the microcircuits involved with perception, attention, memory and emotionality. These hyper-functioning circuits will eventually come to dominate their neighbors, leading to hyper-sensitivity to incoming stimuli, over-specialization in tasks and a hyper-preference syndrome. We make the case that this theory of enhanced brain function in autism explains many of the varied past results and resolves conflicting findings and views and makes some testable experimental predictions.

Figure and table guidelines

CC-BY license

All figures, tables, and images will be published under a Creative Commons CC-BY license, and permission must be obtained for use of copyrighted material from other sources (including re-published/adapted/modified/partial figures and images from the internet). It is the responsibility of the authors to acquire the licenses, follow any citation instructions requested by third-party rights holders, and cover any supplementary charges.
For additional information, please see the 'Image manipulation' section of our polices and publication ethics.

Figure requirements and style guidelines

Frontiers requires figures to be submitted individually, in the same order as they are referred to in the manuscript; the figures will then be automatically embedded at the end of the submitted manuscript. Kindly ensure that each figure is mentioned in the text and in numerical order.
For figures with more than one panel, panels should be clearly indicated using labels (A), (B), (C), (D), etc. However, do not embed the part labels over any part of the image, these labels will be replaced during typesetting according to Frontiers' journal style. For graphs, there must be a self-explanatory label (including units) along each axis.

Captions

Captions should be preceded by the appropriate label, for example 'Figure 1.' Figure captions should be placed at the end of the manuscript. Figure panels are referred to by bold capital letters in brackets: (A), (B), (C), (D), etc.

Table requirements and style guidelines

Tables should be inserted at the end of the manuscript in an editable format. An empty line should be left before and after the table.
Table captions must be placed immediately before the table. Captions should be preceded by the appropriate label, for example 'Table 1.' Please use only a single paragraph for the caption.
Kindly ensure that each table is mentioned in the text and in numerical order.

References

Frontiers' journals use one of two reference styles, either Harvard (author-date) or Vancouver (numbered). Please check our help center to find the correct style for the journal to which you are submitting.
All citations in the text, figures or tables must be in the reference list and vice-versa
The names of the first six authors followed by et al.

In-text citations

For works by a single author, include the surname, followed by the year
For works by two authors, include both surnames, followed by the year
For works by more than two authors, include only the surname of the first author followed by et al., followed by the year
For humanities and social sciences articles, include the page numbers.

Appendix II: Risk of Bias Tool

Quality of observational studies

General instructions: Grade each criterion as "Yes," "No," "Partially," or "Can't tell." Factors to consider when making an assessment are listed under each criterion. Note that some criteria will only apply to specify types of study. For example, power calculations are relevant for studies aiming to compare variables/ predictors of fear of hypoglycemia between two groups, or studies that look at correlates of fear of hypoglycemia sample. However, power calculations are not relevant in an uncontrolled study of a single sample where fear of hypoglycemia related data is only described (rather than featuring in any inferential statistics). Where a criterion only applies to a specific design, it is in italics.

1. **Unbiased selection of the cohort?**

   Factors that help reduce selection bias:

   - Inclusion/exclusion criteria
     - Clearly described
     - Criteria for defining diabetes diagnosis/ duration clearly outlined or previous literature outlining these criteria are referred to.
   - Recruitment strategy
     - Clearly described
     - Sample is representative of the population of interest

2. ***Sample size calculated (for controlled studies and where studies test for predictors/correlates of fear of hypoglycemia)?***

   Factors to consider:

- Were these measures implemented consistently across all study participants?

6. ***Adequate follow-up period (longitudinal studies only)?***

   Factors to consider:

   - Minimum adequate follow-up is 4-weeks for predictive studies.
   - A justification of the follow-up period length is preferable.
   - Follow-up period should be the same for all groups
     - OK if differences in follow-up time were adjusted for using statistical techniques, e.g., survival analysis.

7. **Missing data**

   Factors to consider:

   - Did missing data from any group exceed 20%?
   - In longitudinal studies consider attrition over time as a form of missing data. Note that the criteria of < 20% missing data may be unrealistic over longer follow-up periods.
   - If missing data is present and substantial, were steps taken to minimize bias (e.g., sensitivity analysis or imputation).

8. ***Analysis controls for confounding (controlled studies and where studies test for correlates of fear of hypoglycemia)?***

   Factors to consider for controlled studies:

   - Does the study identify and control for important confounding variables and effect modifiers? Confounding variables are risk factors that are correlated with measured variables and fear of hypoglycemia and may therefore bias the estimation of the effect of on outcome if unmeasured. These may include demographic and clinical variables (e.g., co-morbidity).

   Factors to consider for studies looking at predictors of fear of hypoglycemia :

- Did the authors report conducting a power analysis or describe some other basis for determining the adequacy of study group sizes for the primary outcome(s) of interest?
- Did the eventual sample size deviate by ≤ 10% of the sample size suggested by the power calculation?

3. **Adequate description of the cohort?**

   Consider whether the cohort is well-characterized in terms of baseline demographics?

   - Consider key clinical information such as duration of diabetes, HbA1c, insulin regimen,
   - Demographic information such as age, gender, ethnicity education or socio-economic.

4. **Adequate information for dependent variable?**

   Factors to consider:

   - Was the method used to ascertain fear of hypoglycemia clearly described? (Details should be sufficient to permit replication in new studies)
   - Were means reported? For subscale and total?
   - Were these measures implemented consistently across all study participants?

5. **Validated method for ascertaining outcome variables?**

   Factors to consider:

   - Was the method used to ascertain outcome/ predictor variables clearly described? (Details should be sufficient to permit replication in new studies)
   - Was a valid and reliable measure used to ascertain variables?
   - Were primary outcomes assessed using valid and reliable measures? Note that measures that consist of single items of scales taken from larger measures are likely to lack content validity and reliability.

- Did the study control for likely demographic and clinical confounders? For example, using multiple regression to adjust for demographic or clinical factors likely to be correlated with predictor and outcome?

9. ***Analytic methods appropriate (Controlled studies and where studies test for correlates of fear of hypoglycemia)?***

   Factors to consider:

   - Was the kind of analysis done appropriate for the kind of outcome data (categorical, continuous, etc.)?
   - Was the number of variables used in the analysis appropriate for the sample size? (The statistical techniques used must be appropriate to the data and take into account issues such as controlling for small sample size, clustering, rare outcomes, multiple comparison, and number of covariates for a given sample size)

Appendix III: Peer Review

D.Clin.Psychology Programme
Institute of Population Health
Eleanor Rathbone Building
University of Liverpool
https://www.liverpool.ac.uk/psychology/study/doctorate/

Kate Cotton
Clinical Psychology Trainee
Doctorate of Clinical Psychology Doctorate Programme
University of Liverpool
L69 3GB

11 August 2022

RE: The role of metacognitive beliefs and self-compassion in anxiety and depression for adults with Diabetes
Trainee: Kate Cotton
Supervisors: Peter Fisher, Gemma Cherry and Victoria Gray

Dear Kate,

Thank you for your notification of amendment to your proposal submitted to the Chair of the D.Clin.Psychol. Research Review Committee.

I can now confirm that your amended proposal version 4 (dated 01/07/2022) and budget meet the requirements of the committee and have been approved by the Committee Chair.

Please take this Chairs Action decision as ***final*** approval from the committee.

You may now progress to the next stages of your research.

I wish you well with your research project.

SGillespie

Dr Steven Gillespie
Vice Chair D.Clin.Psychol. Research Review Committee

Appendix IV: Ethics Committee

UNIVERSITY OF LIVERPOOL

Central University Research Ethics Committee C

10 November 2022

Dear Dr Cherry

I am pleased to inform you that your application for research ethics approval has been approved. Application details and conditions of approval can be found below. Appendix A contains a list of documents approved by the Committee.

Application Details

Reference:	11559
Project Title:	Diabetes, Depression, Anxiety, Self-compassion and Metacognitive Beliefs
Principal Investigator/Supervisor:	Dr Mary Cherry
Co-Investigator(s):	Ms Kate Cotton, Dr Peter Fisher
Lead Student Investigator:	-
Department:	Primary Care & Mental Health
Approval Date:	10/11/2022
Approval Expiry Date:	Five years from the approval date listed above

The application was **APPROVED** subject to the following conditions:

Conditions of approval

- All serious adverse events must be reported to the Committee (ethics@liverpool.ac.uk) in accordance with the procedure for reporting adverse events.
- If you wish to extend the duration of the study beyond the research ethics approval expiry date listed above, a new application should be submitted.
- If you wish to make an amendment to the study, please create and submit an amendment form using the research ethics system.
- If the named Principal Investigator or Supervisor changes, or leaves the employment of the University during the course of this approval, the approval will lapse. Therefore it will be necessary to create and submit an amendment form within the research ethics system.
- It is the responsibility of the Principal Investigator/Supervisor to inform all the investigators of the terms of the approval.

Kind regards,

Central University Research Ethics Committee C

CUREC-C (ethics@liverpool.ac.uk)

Appendix V: Research for the Future Participant Invite

Appendix VI: Participant Information Sheet

Participant Information Sheet

Version number & date: Version 2, 29th September 2022
Research ethics approval number: 1159
Title of the research project: Anxiety and Low Mood in Individuals with Diabetes
Name of researcher(s): Dr Peter Fisher, Dr Gemma Cherry, Kate Cotton

Invitation to Take Part

You are being invited to participate in a research study. Before you decide whether you would like to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and feel free to ask us if you would like more information or if there is anything that you do not understand. We would like to stress that you do not have to accept this invitation and should only take part if you want to.

Thank you for reading this.

What is the purpose of the study?

We are interested in why some people with Diabetes experience low mood and anxiety (worry). Other studies have found that the beliefs we hold about our thoughts or how kind we are to ourselves can be related to low mood and anxiety in those who have physical health conditions. We hope to explore this further in the current study with the hope that by better understanding these links, it will help to inform psychological therapy (helping people to manage their thoughts and emotions through talking) that is most helpful for those who need it.

Why have I been chosen to take part?

You have been asked to take part because you are aged 18 or older and have a diagnosis of Diabetes.

Do I have to take part?

Taking part is completely voluntary and you are under no obligation to take part. You are free to withdraw from the study during the study or up to two weeks after filling in the questionnaires. Unfortunately, it will not be possible to withdraw after this point as once your data has been analysed and published it will not be possible to remove it. However, this data will remain completely anonymous as will be explained in more detail below.

What will happen if I take part?

If you choose to take part then you will be asked to sign a consent form which outlines you have read all this information and understand what is involved in taking part.

You will then be asked to fill out six questionnaires either online by following the link provided, or we can send paper copies with pre-paid envelopes to return the responses. These involve answering different questions about how you think and feel. There is also a demographic questionnaire which will ask some information about your physical and mental

health. This is to help us to understand how different people's experiences might help them tc manage their Diabetes or any worries they might have. We estimate that the questionnaires will take approximately 30 minutes to complete but there is no time limit and you can take as long as you like to complete them. You can take part either by following the online link or if you would prefer, we can send you paper copies to complete and send back in a pre-paid envelope. If you would like paper copies please contact Kate Cotton via email (kate.cotton@liverpool.ac.uk) or via the postal address provided at the end of the information sheet. Once you have completed all of this information you can choose to provide your email to either or both be entered into a draw for one of four £50 love2shop vouchers to thank you for your time. Your email will be stored separate to your data so it is not identifiable to you.

Are there any risks in taking part?

There are no known risks to taking part in this study. However, some of the questions will ask about your mood which some people might find upsetting. If you do experience any distress taking part then we would recommend you contact your GP. Other helpful charities and organisations to contact should you experience any distress include:
Calling the NHS advice line on 111
Samaritans helpline by calling 116 123 (free, 24/7) or emailing jo@samaritans.org
Mind for general information about Mental Health on 0300 123 3393

Are there any benefits in taking part?

There are no known direct benefits to you in taking part in this study. However, we hope that by taking part in the research you will help to improve the support we can provide to people who have Diabetes who experience low mood or anxiety.

How will my data be used?
The University processes personal data as part of its research and teaching activities in accordance with the lawful basis of 'public task', and in accordance with the University's purpose of "advancing education, learning and research for the public benefit.

Under UK data protection legislation, the University acts as the Data Controller for personal data collected as part of the University's research. The Principal Investigator acts as the Data Processor for this study, and any queries relating to the handling of your personal data can be sent to Dr Gemma Cherry (gcherry@liverpool.ac.uk) or Dr Peter Fisher (plfisher@liverpool.ac.uk).

Further information on how your data will be used can be found in the table below.

How will my data be collected?	Your data will be collected through the online platform Qualtrics.
How will my data be stored?	Your data will be securely stored on a university server in accordance with University policy. Any copies on Qualtrics or paper versions will be deleted or shredded once the data is on the online database.
How long will my data be stored for?	Your data will be stored for up to 10 years and after this point it will be destroyed.

What measures are in place to protect the security and confidentiality of my data?	Your data will be stored on a secure University of Liverpool online server which only the researchers on this project will have access to. The only identifiable data will be your name on the consent form and your email (should you wish to provide it) which will be stored separately to the data you give and a number will be allocated to your data set so you will not be identifiable.
Will my data be anonymised?	Your data will be pseudo-anonymised by allocating a number to your data set, rather than your name which will only appear on the consent form which will be stored separately to your data.
How will my data be used?	Your data will be used as part of fulfilment of a doctorate in Clinical Psychology thesis which will be written up and published in a per reviewed journal. None of the information reported will be identifiable.
Who will have access to my data?	Only the researchers involved in the project will have access to your data.
Will my data be archived for use in other research projects in the future?	Yes, your data will be stored securely in the University server for 10 years and may be used for other projects in that time. But you will not be identifiable.
How will my data be destroyed?	Your data will be destroyed by deleting it from the University Server.

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:
by asking one of the research team
The Principal Investigators (people overseeing the study) will be responsible for looking after your data and you are welcome to contact either of them if you have any questions about this: Dr Peter Fisher (plfisher@liverpool.ac.uk) or Dr Gemma Cherry (gcherry@liverpool.ac.uk).

Expenses and / or payments

There should be no cost to you for taking part as taking part is either via an online survey you can do from home or by paper forms we will send you with pre-paid return envelopes. If you would like to supply your email, they will be entered into a draw for one of four £50 love2shop vouchers to thank you for your time. Of those who provide their emails, four will be selected at random to be given the vouchers.

What will happen to the results of the study?

The results of the study will be written up as part of a Doctorate in Clinical Psychology (qualification that allows someone to practice as a Clinical Psychologist) and will be published in a peer reviewed journal (where research is published and can be accessed). No one who has taken part will be identifiable to anyone reading the paper and your name will not appear anywhere. All who take part are welcome to hear about the results of the study if they would like and can receive a copy of the paper or brief overview of the results. Unfortunately we are not able to provide individual results related to the specific answers you give on the questionnaires. If you would be interested in this please contact Kate Cotton (kate.cotton@liverpool.ac.uk) who will be able to send you this information when it is available.

What will happen if I want to stop taking part?

If you decide you would no longer like to take part while completing the questionnaires you can stop your responses by closing the browser. However, all data already collected will be retained up until this point. If you complete the questionnaires and later decide you would like to withdraw your responses, you have up until two weeks after submitting to do so by emailing a member of the research team. As was explained above, once your data has been included in analysis and published it will not be possible to remove your data, however it will all remain anonymous. If you wish to withdraw from the study or discuss this further, please get in contact with the research team who will be able to help you.

What if I am unhappy or if there is a problem?

If you are unhappy, or if there is a problem, please feel free to let us know by contacting Kate Cotton (kate.cotton@liverpool.ac.uk), Dr Peter Fisher (plfisher@liverpool.ac.uk) or Dr Gemma Cherry (gcherry@liverpool.ac.uk) and we will try to help. If you remain unhappy or have a complaint which you feel you cannot come to us with then you should contact the Research Ethics and Integrity Office at ethics@liv.ac.uk. When contacting the Research Ethics and Integrity Office, please provide details of the name or description of the study (so that it can be identified), the researchers involved, and the details of the complaint you wish to make.

The University strives to maintain the highest standards of rigour in the processing of data. However, if you have any concerns about the way in which the University processes your personal data, it is important that you are aware of your right to lodge a complaint with the Information Commissioner's Office by calling 0303 123 1113.

Who can I contact if I have further questions?

If you have any further questions please feel free to contact any of the research team:

Kate Cotton Email: kate.cotton@liverpool.ac.uk
Dr Gemma Cherry Email: gcherry@liverpool.ac.uk
Dr Peter Fisher Email: plfisher@liverpool.ac.uk
Postal Address:
Kate Cotton (3rd Year)
Department of Clinical Psychology
Institute of Population Health
Eleanor Rathbone Build

University of Liverpool
Bedford Street South
Liverpool
L69 7ZA

Appendix VII: Participant Consent Forms

Participant consent form

Version number & date: Version 1, 1st July 2022
Research ethics approval number: 1159
Title of the research project: Anxiety and Low Mood in Individuals with Diabetes
Name of researcher(s): Dr Peter Fisher, Dr Gemma Cherry, Kate Cotton

Please tick box

1. I confirm that I have read and have understood the information sheet dated 1st July 2022, V1 for the above study, or it has been read to me. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that taking part in the study involves completing questionnaires as outlined in the information sheet. ☐
3. I understand that my participation is voluntary and that I am free to stop taking part and can withdraw from the study at any time without giving any reason and without my rights being affected. In addition, I understand that I can withdraw at any time by closing the browser window. Any data provided may still be used by the research team. ☐
4. I understand that I can ask for access to the information I provide and I can request the destruction of that information if I wish at any time prior to when data has been anonymised and analysed. I understand that following two weeks after taking part I will no longer be able to request access to or withdrawal of the information I provide. ☐
5. I understand that the information I provide will be held securely and in line with data protection requirements at the University of Liverpool until it is fully anonymised and then deposited in the Archive for sharing and use by other authorised researchers to support other research in the future. ☐
6. I understand that signed consent forms and questionnaires will be retained in a secure, password protected University of Liverpool computer only the named researchers can access for a minimum of 10 years. ☐
7. I agree to take part in the above study. ☐

Participant name	Date	Signature
Name of person taking consent	Date	Signature

Principal Investigators
Dr Peter Fisher & Dr Gemma Cherry
University of Liverpool
Department of Clinical Psychology
Institute of Population Health

Student Investigator
Kate Cotton
University of Liverpool
Department of Clinical Psychology
Institute of Population Health

Eleanor Rathbone Building
University of Liverpool

plfisher@liverpool.ac.uk; gcherry@liverpool.ac.uk

Eleanor Rathbone Building
University of Liverpool

kate.cotton@liverpool.ac.uk

Appendix VIII: De-briefing sheet

Debriefing Sheet

Study Title: Anxiety and Low Mood in Adults with Diabetes

From your answer, it seems like it might not be right for you to take part in the study at this point. If you would like to ask any questions please contact kate.cotton@liverpool.ac.uk.

If you feel any distress after taking part or are worried about your physical or mental health, please contact your GP or other professionals involved in your care. The following charities are also helpful to provide support and advice:

- Calling the NHS advice line on 111
- Samaritans helpline by calling 116 123 (free, 24/7) or emailing jo@samaritans.org
- Mind for general information about Mental Health on 0300 123 3393

Finally, if you would like to discuss anything further please feel free to contact a member of the research team whose details are below.

Many thanks from the research team:

Kate Cotton Email: kate.cotton@liverpool.ac.uk
Dr Gemma Cherry Email: gcherry@liverpool.ac.uk
Dr Peter Fisher Email: plfisher@liverpool.ac.uk

Appendix IX: Self-Compassion Scale (SCS)

HOW I TYPICALLY ACT TOWARDS MYSELF IN DIFFICULT TIMES

Please read each statement carefully before answering. To the left of each item, indicate how often you behave in the stated manner, using the following scale:

Almost always **Almost never**

1 2 3 4 5

_____ 1. I'm disapproving and judgmental about my own flaws and inadequacies.
_____ 2. When I'm feeling down I tend to obsess and fixate on everything that's wrong.
_____ 3. When things are going badly for me, I see the difficulties as part of life that everyone goes through.
_____ 4. When I think about my inadequacies, it tends to make me feel more separate and cut off from the rest of the world.
_____ 5. I try to be loving towards myself when I'm feeling emotional pain.
_____ 6. When I fail at something important to me I become consumed by feelings of inadequacy.
_____ 7. When I'm down and out, I remind myself that there are lots of other people in the world feeling like I am.
_____ 8. When times are really difficult, I tend to be tough on myself.
_____ 9. When something upsets me I try to keep my emotions in balance.
_____ 10. When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people.
_____ 11. I'm intolerant and impatient towards those aspects of my personality I don't like.
_____ 12. When I'm going through a very hard time, I give myself the caring and tenderness I need.
_____ 13. When I'm feeling down, I tend to feel like most other people are probably happier than I am.
_____ 14. When something painful happens I try to take a balanced view of the situation.
_____ 15. I try to see my failings as part of the human condition.
_____ 16. When I see aspects of myself that I don't like, I get down on myself.
_____ 17. When I fail at something important to me I try to keep things in perspective.

_____ 18. When I'm really struggling, I tend to feel like other people must be having an easier time of it.

_____ 19. I'm kind to myself when I'm experiencing suffering.
_____ 20. When something upsets me I get carried away with my feelings.
_____ 21. I can be a bit cold-hearted towards myself when I'm experiencing suffering.
_____ 22. When I'm feeling down I try to approach my feelings with curiosity and openness.
_____ 23. I'm tolerant of my own flaws and inadequacies.
_____ 24. When something painful happens I tend to blow the incident out of proportion.
_____ 25. When I fail at something that's important to me, I tend to feel alone in my failure.
_____ 26. I try to be understanding and patient towards those aspects of my personality I don't like.

Appendix X: Metacognitions Questionnaire (MCQ-30)

Adrian Wells & Samantha Cartwright-Hatton

This questionnaire is concerned with beliefs people have about their thinking. Listed below are a number of beliefs that people have expressed. Please read each item and say how much you generally agree with it by circling the appropriate number.
Please respond to all items, there are no right or wrong answers.

		Do not agree	Agree slightly	Agree moderately	Agree very much
1.	Worrying helps me to avoid problems in the future	1	2	3	4
2.	My worrying is dangerous for me	1	2	3	4
3.	I think a lot about my thoughts	1	2	3	4
4.	I could make myself sick with worrying	1	2	3	4
5.	I am aware of the way my mind works when I am thinking through a problem	1	2	3	4
6.	If I did not control a worrying thought, and then it happened, it would be my fault	1	2	3	4
7.	I need to worry in order to remain organised	1	2	3	4
8.	I have little confidence in my memory for words and names	1	2	3	4
9.	My worrying thoughts persist, no matter how I try and stop them	1	2	3	4
10.	Worrying helps me to get things sorted out in my mind	1	2	3	4
11.	I cannot ignore my worrying thoughts	1	2	3	4
12.	I monitor my thoughts	1	2	3	4
13.	I should be in control of my thoughts all of the time	1	2	3	4

		Do not agree	Agree slightly	Agree moderately	Agree very much
14.	My memory can misled me at times	1	2	3	4
15.	My worrying could make me go mad	1	2	3	4
16.	I am constantly aware of my thinking	1	2	3	4
17.	I have a poor memory	1	2	3	4
18.	I pay close attention to the way my mind works	1	2	3	4
19.	Worrying helps me cope	1	2	3	4
20.	Not being able to control my thoughts is a sign of weakness	1	2	3	4
21.	When I start worrying, I cannot stop	1	2	3	4
22.	I will be punished for not controlling certain thoughts	1	2	3	4
23.	Worrying helps me to solve problems	1	2	3	4
24.	I have little confidence in my memory for places	1	2	3	4
25.	It is bad to think certain thoughts	1	2	3	4
26.	I do not trust my memory	1	2	3	4
27.	If I could not control my thoughts, I would not be able to function	1	2	3	4
28.	I need to worry, in order to work well	1	2	3	4
29.	I have little confidence in my memory for actions	1	2	3	4
30.	I constantly examine my thoughts	1	2	3	4

Please ensure that you have responded to all items – Thank You.

Appendix XI: The Brief 5-item Penn State Worry Questionnaire (PSWQ)

The brief PSWQ Instructions: Rate each of the following statements on a scale of 1 (*not at all typical of me)* to 5 *(very typical of me).* Please do not leave any item blank.

	Not at all typical				Very typical of me
1. Many situations make me worry	1	2	3	4	5
2. I know I should not worry about things, but I just cannot help it	1	2	3	4	5
3. When I am under pressure I worry a lot	1	2	3	4	5
4. I have been a worrier all my life	1	2	3	4	5
5. I notice that I have been worrying about things	1	2	3	4	5

Appendix XII: The Brief 5-item Rumination Response Scale

The Brief 5-iem Ruminative Response Scale (RRS)

The brief RRS. People think and do many different things when they feel depressed. Please read each of the items below and indicate whether you almost never, sometimes, often, or almost always think or do each one when you feel down, sad, or depressed. Please indicate what you generally do, not what you think you should do.

	Almost never	Sometimes	Often	Always
1. Think about how alone you feel	[]	[]	[]	[]
2. Think about your feelings of fatigue and achiness	[]	[]	[]	[]
3. Think about how sad you feel	[]	[]	[]	[]
4. Think about all your shortcomings, failings, faults, mistakes	[]	[]	[]	[]
5. Think about how angry you are with yourself	[]	[]	[]	[]

Appendix XIII: Patient Health Questionnaire (PHQ-9)

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
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
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
☐	☐	☐	☐

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

Appendix XIV: Generalised Anxiety Disorder Assessment (GAD-7)

GAD-7 Anxiety

Over the last two weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid, as if something awful might happen	0	1	2	3

Column totals _____ + _____ + _____ + _____ =

Total score _____

If you checked any problems, how difficult have they made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
☐	☐	☐	☐

Source: Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PRIME-MD-PHQ). The PHQ was developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke, and colleagues. For research information, contact Dr. Spitzer at ris8@columbia.edu. PRIME-MD® is a trademark of Pfizer Inc. Copyright© 1999 Pfizer Inc. All rights reserved. Reproduced with permission

Scoring GAD-7 Anxiety Severity

This is calculated by assigning scores of 0, 1, 2, and 3 to the response categories, respectively, of "not at all," "several days," "more than half the days," and "nearly every day."
GAD-7 total score for the seven items ranges from 0 to 21.

0–4: minimal anxiety

5–9: mild anxiety

10–14: moderate anxiety

15–21: severe anxiety

Appendix XV: Demographics

Demographic Questionnaire

Study Number:

Date of Birth:

Postcode (for Social Deprivation Index):

How would you describe your gender identity? (please circle)

Male (including trans-male) Female (including trans-female) Non-binary

Prefer not to say

How would you describe your ethnicity?

White

1. Welsh/English/Scottish/Northern Irish/British
2. Irish
3. Gypsy or Irish Traveller
4. Any other White background, please describe

Mixed/Multiple ethnic groups

5. White and Black Caribbean
6. White and Black African
7. White and Asian
8. Any other Mixed/Multiple ethnic background, please describe

Asian/Asian British

9. Indian
10. Pakistani

11. Bangladeshi

12. Chinese

13. Any other Asian background, please describe

Black/African/Caribbean/Black British

14. African

15. Caribbean

16. Any other Black/African/Caribbean background, please describe

Other ethnic group

17. Arab

18. Any other ethnic group, please describe

Prefer not to say

How would you describe your relationship status?

- single, never married or never had a civil partnership
- married, including separated (this category includes those in both opposite- and same-sex marriages)
- civil partnered, including separated
- divorced, including those who have legally dissolved their civil partnership
- widowed, including surviving civil partners

What type of Diabetes do you have?

Type 1
Type 2
Gestational Diabetes
Other type _____

What age were you when you were diagnosed with Diabetes?

Other vocational / work related qualifications and non-UK / foreign qualifications

_____

Do you manage your Diabetes on your own or do you have help from anyone? Please circle

On my own Help from someone else

If you have help from someone else, could you give details of their relationship to you and briefly how they help?

Do you have any other medical conditions?

Yes No

If Yes, please give details

Are you currently having any psychological support for anxiety (worry) or depression (feeling down)?

Yes No

If Yes, please give details

Have you had any psychological support for anxiety or depression in the past?

Yes No

_____ years _____ months

Do you have any of the following Diabetes related complications?

Chronic kidney disease
Nerve difficulties (Neuropathy):
Lack of feeling/ sensation or numbness in feet/ lower limbs
Issues of Gut function
Excessive sweating

Foot problems (e.g. foot/toe amputation, foot lesion)

Eye damage (have you been told that diabetes had affected your eyes or had retinopathy or cataracts)

Cardiovascular issues (Heart attack, chest pain, coronary heart disease, congestive heart failure)

Stroke

Other, please specify _____

Are you currently employed?

No Yes – Part-time Yes – Full-time

What is your highest level of educational attainment?

No formal qualifications

1-4 GCSEs, Scottish Standard Grade or equivalent qualifications

5 or more GCSEs, Scottish Higher, Scottish Advanced Higher or equivalent qualifications

Apprenticeships

2 or more A-levels, , HNC, HND, SVQ level 4 or equivalent qualifications

First or higher degree, professional qualifications or other equivalent higher education qualifications.

If Yes, please give details

Are you currently taking an medication to help with anxiety or depression?

Yes No

If Yes, please give details

Have you taken any medication in the past to help with anxiety or depression?

Yes No

If Yes, please give details