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The Impact of Living with Type 2 Diabetes on Women's Health and Wellbeing during Their Reproductive Years

by

Aycan Celik

A thesis incorporating publications submitted for the degree of Doctor of Philosophy

King's College London

Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care

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Abstract

Background: Globally, sixty-million women of reproductive age live with diabetes, with most having type 2 diabetes (T2DM). Women may be exposed to increased potential adverse effects of T2DM with regard to their health and well-being, including pregnancy-related complications, disordered eating, diabetes distress, and stigma. However, limited research exists exploring the health needs and experiences of these women.

Aim: To understand how living with T2DM affects younger women's health perceptions and experiences during their reproductive years in order to identify their health needs and inform future interventions and care pathways to improve their health and wellbeing.

Methods: The study, informed by the Medical Research Council (MRC) framework, consisted of three stages for which a mixed method approach was used. Stage-1 included a mixed-methods systematic review exploring the impact of living with T2DM on women's health and wellbeing during their reproductive years (published paper 1). Stage-2 was a qualitative study design using semi-structured interviews, exploring the health needs, experiences, and views of women aged 18-45, and therefore of reproductive age, living with T2DM (published paper 2). Stage-3 included a cross-sectional study evaluating the relationships between psychosocial factors identified in the qualitative study and self-management behaviours among women of reproductive age living with T2DM. Participants completed validated questionnaires using an electronic survey to assess fatigue (FSS), disordered eating (SCOFF-5), stigma (DSAS-2), diabetes distress (DDS), anxiety (GAD-7), and self-management behaviours (SDSCA). Socio-demographic and diabetes history were also recorded. Eligibility criteria for stage-2 and -3 were women with T2DM, aged 18-45, living in either the UK or Türkiye who were able to speak and understand English or Turkish.

Results:

- A mixed methods systematic review consisted of 32 studies, including 21 quantitative, 10 qualitative, and one mixed-method study from eleven different countries, along with one multinational country including 11 Latin American countries. This review found wide-ranging health issues affecting women of reproductive age with T2DM, specifically cardiovascular issues, psychosocial issues such as diabetes distress and stigma, and reproductive health issues such as sexual

dysfunction and early menopause. However, this review identified an evidence gap in the literature, highlighting a lack of understanding of the diabetes experiences and health needs of young women of reproductive age. Furthermore, it reported a notable absence of intervention studies for this population, suggesting the development of more targeted and effective interventions. Therefore, this review has illustrated the need for further research to comprehensively explore the experiences of and views on living with T2DM in their reproductive years, identifying the health needs of these young women to inform the strategies and future interventions to improve their health and wellbeing.

- The qualitative study involved 36 women living in the UK and Türkiye with a median age of 37 years (age range 20-45 years). It identified two overarching themes, namely i) Perception of Self and Identity and ii) Poor Orientation of T2DM Care towards younger women's health needs. Women's perceptions of self and their disrupted identity exposed the gender and age-related health issues of fear surrounding fertility and pregnancy and the emotional burden of diabetes management. Women reported that their interactions with healthcare professionals were unhelpful because they were not age- and gender appropriate or focused. The women voiced ideas for enhancing current care, in particular, the need for more psychosocial and peer-based support. The study described significant levels of emotional burden and impacts on younger women's general health and diabetes-specific self-care and revealed an evidence gap surrounding the prevalence of these experiences.

- The cross-sectional study included ninety-two women with T2DM from the UK and Türkiye with a mean age of 35.5 years (SD = 7.2; range 19-45 years). Family history of T2DM was reported by 70% of participants and 47% had a diabetes duration of between 1-5 years. Seventy women (76%) reported having not attended a diabetes education course. Ninety-two percent of women reported disordered eating behaviours, and 65% reported diabetes distress. Fatigue was reported by 57% of women, stigma by 53%, and anxiety by 24%. This study highlighted a high prevalence of psychosocial factors identified in the qualitative study. The highly prevalent disordered eating was negatively associated with diabetes distress and anxiety but no correlation between self-management and disordered eating behaviours were

identified. Recruiting this population was challenging and did not reach our target. This limited the opportunity for subgroup analysis based on nationality.

Conclusion: This thesis provides novel evidence about the health needs, experiences, and views of young women of reproductive age living with T2DM. The care provided to this population of women needs to ensure that their wider reproductive health needs are optimally considered in the planning and delivery of care. Evidence from this thesis highlights areas where future interventions are required to improve women's health and wellbeing.

Research outputs

Papers published in peer-reviewed journals are incorporated into this thesis:

1) Celik, A., Forde, R., Racaru, S., Forbes, A., & Sturt, J. (2022). The impact of type 2 diabetes on women's health and well-being during their reproductive years: A mixed-methods systematic review. *Current Diabetes Reviews, 18*(2). https://doi.org/10.2174/1573399817666210118144743
2) Celik, A., Sturt, J., Temple, A., Forbes, A., & Forde, R. (2022). 'No one ever asks about something that actually is relevant to my life': A qualitative study of diabetes and diabetes care experiences of young women with type 2 diabetes during their reproductive years. *Diabetic Medicine*. e15017. https://doi.org/10.1111/dme.15017

Author contributions

The following table shows author contributions, with the name of the researchers involved in the different studies of this thesis, their backgrounds, and their roles in this research process.

Name	Background	Study of thesis involved with	Role in research process
Aycan Celik	PhD student	ALL	Study 1 – Planning stage (e.g., formulating the research question), developing the review protocol, database search, screening of papers, critical appraisal of the selected studies, data extraction, synthesis, and reporting of study findings, manuscript preparation and submission to the journal. Study 2 – Planning the study design and set up, development of the topic guide, qualitative data collection, data analysis (e.g., generating of codes and themes), interpretation of qualitative results, manuscript preparation and submission to the journal. Study 3 – Planning the study design and set up, creating the Qualtrics, quantitative data collection, data analysis plan, interpretations of quantitative results.
Professor Jackie Sturt	Head of Division, Care in Long Term Conditions and Professor of Behavioural Medicine in Nursing	ALL	1st PhD supervisor Study 1 – Planning stage, developing the review protocol, reviewing all included studies, interpretation of the findings, reviewing the manuscript. All authors read and approved the manuscript. Study 2 - Planning the study design and set up, development of the topic guide, data collection support, qualitative data analysis support, interpretation of qualitative results and reviewing the manuscript. All authors read and approved the manuscript. Study 3 - Planning the study design and set up, quantitative data collection support, interpretation of quantitative results.

Dr Rita Forde	Lecturer in Long Term Conditions and Reproductive Health; Diabetes Nurse	ALL	2nd PhD supervisor Study 1 – Planning stage, developing the review protocol, screening of papers, critical appraisal of the selected studies, reviewing all included studies, interpretation of the findings, reviewing the manuscript. All authors read and approved the manuscript. Study 2 - Planning the study design and set up, development of the topic guide, data collection support, qualitative data analysis support (e.g., coding the transcripts), interpretation of qualitative results and reviewing the manuscript. All authors read and approved the manuscript. Study 3 - Planning the study design and set up, quantitative data collection support, interpretation of quantitative results.
Professor Angus Forbes	Professor & Chair of Clinical Diabetes Nurse	ALL	3rd supervisor Study 1 – Planning stage, developing the review protocol, reviewing of all included studies, interpretation of the findings, reviewing the manuscript. All authors read and approved the manuscript. Study 2 - Planning the study design and set up, development of the topic guide, qualitative data analysis support, interpretation of qualitative results and reviewing the manuscript. All authors read and approved the manuscript. Study 3 - Planning the study design and set up, quantitative data collection support, data analysis plan, interpretation of quantitative results.
Simona Racaru	MSc Clinical Nursing; Registered Nurse	Study 1	Screening of papers, data extraction, critical appraisal of the selected studies, reviewing the manuscript. All authors read and approved the manuscript.
Aya Temple	Honorary Research Associate at Nursing and Midwifery; Dietitian	Study 2	Development of the topic guide, data collection support, reviewing the manuscript. All authors read and approved the manuscript.

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Author Declaration

The work presented in this thesis was undertaken as part of independent research funded by the Republic of Türkiye Ministry of National Education. The views expressed are those of the authors and not necessarily those of the Ministry of National Education (Türkiye).

The work presented in this thesis, to the best of my knowledge, is original and the author's own work.

This thesis has not been submitted in support of any academic award or qualification at any other university.

COVID-19 impact statement

The work in this thesis was impacted by the COVID-19 pandemic. Initially, I was planning to develop an intervention for women with T2DM, using the Experienced-based Co-design (EBCD) in accordance with the project's aims. The 'experienced-based' process would involve qualitative interviews with women of reproductive age living with T2DM. Through the co-design process, three workshops would be conducted: (1) with only healthcare professional (HCPs), (2) with only patients, and then (3) with both patients and HCPs. After that, small co-design groups would be sustained to implement the solutions to the priority issues highlighted at the co-design group and to work on improvements. Finally, all participants would be brought together to review and celebrate their achievement. Before the COVID-19 lockdown, I started to write the ethics documents (e.g., protocol) in order to apply the NHS R&D department, followed by the HRA ethics committee. But the United Kingdom (UK) embarked on the lockdown in March 2020. Afterwards, the HRA, including R&D department started to review COVID-19 projects rather than other health projects since the spread of virus was one of the biggest public health challenges to have been faced, and the COVID-19 projects help us to prevent the spread of virus and to develop vaccines and treatments. R&D/HRA recommended King's College London (KCL) PhD students apply to the KCL ethics committee in order to avoid delays.

During the pandemic, HCPs in particular were exposed to numerous biological, psychological, social, and behavioural risk factors, including higher workload, pathogen exposure, occupational burnout, and psychological distress. Considering these issues related to HCPs, and the uncertainty associated with the pandemic, I changed the original aim of the thesis (with the consensus of the supervisory team) to explore only women's experiences of living with T2DM, as well as the study design to qualitative interviews and a cross-sectional survey to comprehensively explore their experiences and health needs to inform future interventions. For this project, I applied to the KCL ethics committee, and the project was approved by the Psychiatry, Nursing, and Midwifery Research Ethics Subcommittee in light of the COVID-19 pandemic in June 2020. The ethics committee had temporally suspended all primary data collection that required face-to-face participant interactions. We embarked on the recruitment by online ways (e.g., social media) in July 2020. The COVID-19 pandemic had brought the challenges to the research process, including online recruitment process.

Further details of the impact of COVID-19 are discussed in Chapters 4 and 6 and throughout the thesis as relevant.

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Abbreviations

DDS	**Diabetes Distress Scale**
DSAS	**Type 2 Diabetes Stigma Assessment Scale**
FSS	**Fatigue Severity Scale**
GAD	**Generalised Anxiety Disorder**
GDM	**Gestational Diabetes**
HbA1c	**Haemoglobin A1c**
HCPs	**Healthcare Professionals**
IDF	**International Diabetes Federation**
KCL	**King's College London**
Mmol/L	**Millimoles Per Litre (the unit of measurement of blood glucose level)**
MRC	**Medical Research Council**
NICE	**National Institute for Health and Care Excellence**
PPI	**Public and Patient Involvement**
SCOFF	**Sick, Control, One Stone, Fat, Food**
SD	**Standard Deviation**
SDSCA	**Summary of Diabetes Self-care Activities Assessment**
SPSS	**Statistical Package for Social Sciences**
T1DM	**Type 1 Diabetes**
T2DM	**Type 2 Diabetes**
UK	**United Kingdom**
WHO	**World Health Organization**

Chapter 1 – Introduction

1.1 Background to diabetes mellitus

Diabetes Mellitus (DM) is a chronic metabolic condition that occurs either when the body cannot effectively use the insulin it produces, or the pancreas does not produce enough insulin (WHO, 2022; IDF, 2021). DM has several subclassifications, including type 1, type 2, gestational diabetes, maturity onset diabetes of the young, and steroid-induced diabetes (Sapra & Bhandari, 2022). Type 2 diabetes (T2DM) is the most common type of diabetes and accounts for 90% of all cases of the condition (IDF, 2021). The pathophysiology of T2DM is complex, resulting in insulin deficiency and/or insulin resistance (Galicia-Gracia et al., 2020). In relation to the latter, the available insulin does not efficiently support the transport of glucose into muscle cells. Consequently, the pancreatic beta cells try to compensate by increasing the secretion of insulin to maintain optimal glycaemia. However, this results in both increased glucose and insulin levels as the glucose does not fully respond to circulating insulin (IDF, 2021; White et al., 2016). For some, this can eventually contribute to a decline in pancreatic beta cell function, resulting in the body producing less insulin, leading to higher blood glucose levels (Amatruda et al., 2021). Consequently, a diabetes diagnosis is associated with altered glucose metabolism resulting in hyperglycaemia (White et al., 2016; Lean et al., 2018; Kahn et al., 2014).

1.2 Epidemiology and risk factors of type 2 diabetes

Globally, the prevalence of T2DM is estimated to be around 537 million people (IDF, 2021). In 2021, an estimated 6.7 million deaths were directly related to diabetes alone, while more than 2.2 million deaths in 2012 were attributed to high blood glucose (WHO, 2022). About one out of 11 adults have diabetes, ranking it as the tenth major cause of mortality (IDF, 2021; Zheng et al., 2018; Khan et al., 2020). This represents an alarming rise in the past three decades when diabetes was ranked as the eighteenth-highest leading cause of mortality in 1990 globally (Khan et al., 2020). In the UK, the number of the people living with diabetes is over 4.8 million, which is equivalent to one in fourteen people (Diabetes UK, 2022). The

prevalence of people with diabetes in Türkiye has increased from 8.1% in 2011 to 14.5% in 2021 (IDF, 2021; Celik et al., 2022).

Genetic predisposition plays an important role in the risk of developing T2DM at early ages (Wilmot & Idris, 2014). Candler et al. (2018), in a UK study, reported that 81% of children and young people had a family history of T2DM (70% of with first-degree relatives), suggesting that genetics are a major driving factor underlying early onset T2DM. People of Asian ethnicity are also more likely to develop T2DM, despite generally having a much lower body mass index than white people (Diabetes UK, 2022). This is attributed to different fat distributions and percentages of fat in the body. Asian people have a higher body fat percentage at a given body mass index and higher abdominal adiposity than white people (Lee et al., 2011; Yoon et al., 2006; Chan et al., 2009). As a result, genetic background and ethnicity are attributed to the risk of developing T2DM (Prasad et al., 2022; Pyle & Kelsey, 2021; Zheng et al., 2018). Other driving factors in the increasing prevalence of T2DM include obesity, being overweight, physical inactivity, and increased consumption of processed foods (Beulens et al., 2021; Zheng et al., 2018; Wilmot & Idris, 2014). Specifically, it is estimated that the global prevalence of obesity will surpass 21% in women and 18% in men by 2025, which is the single strongest piece of evidence of developing T2DM in the majority of both developed and developing countries (Caleyachetty et al., 2021; Zheng et al., 2018). Other major risk factors include older age, low socio-economic status, components of metabolic syndrome (e.g., increased blood glucose, increased waist circumference), alcohol use, sleep deprivation, mental health conditions, polycystic ovary syndrome (PCOS), and gestational diabetes (GDM) (Parameswaran & Ray, 2022; Zheng et al., 2018; Diabetes UK, 2021; Lascar et al., 2018).

1.3 Long-term complications in type 2 diabetes

T2DM can result in complications because of a two- to fourfold increase in impaired macrovascular circulation and 10- to 20-fold impairment of microvascular circulation compared to people without diabetes (Gregg, 2019; Mbanya & Sobngwi, 2003). Microvascular complications, namely peripheral neuropathy, retinopathy, and nephropathy are caused by damage to the small blood vessels of nerves, the retina, and kidneys,

respectively. Macrovascular complications result in cardiac disease (ischemic heart disease), cerebrovascular disease, and peripheral vascular disease due to damage to the large vessels of the heart, brain, and legs, respectively (IDF, 2022). Approximately one in three people with diabetes will already have microvascular complications on diagnosis with T2DM, and the risk of developing cardiovascular complications is 2-2.5 times greater in people with diabetes compared to people without (Dal Canto, 2019). It is also documented that women with T2DM have greater increases of stroke mortality, myocardial infarction, and cardiovascular risk than men, compared to individuals without diabetes (Kautzky-Willer et al., 2016). A meta-analysis using the data of 64 studies (Peters et al., 2014) reported that the relative risk of incident coronary heart disease was 44% greater in women with diabetes than men with diabetes (Peters et al., 2014). Psychosocial stress appears to have greater impact on women with T2DM rather than on men with the same condition (Kautzky-Willer et al., 2016; Nanayakkara et al., 2018), and women tend to have a greater stress reactivity to various situations, such as work events, and stressful lives (Kamrul-Hasan et al., 2022). Additionally, women often assume gender-based roles such as unpaid caregivers in addition to their own diabetes self-management (Britton et al., 2022; Chivese et al., 2019). To illustrate, a cross-sectional study (n = 5,478) determining whether competing demands for time affect diabetes outcomes, including self-care behaviours, found that women who had any caregiving responsibilities (e.g., young children or a dependent adult) with or without employment responsibilities had higher haemoglobin A1c (HbA1c) levels (average HbA1c, 8.2 % (66 mmol/mol)) than women with no caregiving responsibilities (average HbA1c, 7.9%, (63 mmol/mol)) ($p = 0.02$) (McEwen et al., 2011). It has also been reported that there were more deaths attributable to diabetes in women (2.1 million) than men (1.8 million) in 2017 (IDF, 2017).

T2DM and diabetes-related complications are associated with substantial costs, both for healthcare systems and individuals. The global health costs attributed to diabetes are predicted to be about 1 trillion USD (IDF, 2021). In the UK, nearly 10% (£14 billion per annum) of the National Health Service (NHS) budget is estimated to be spent on managing diabetes (Murray et al., 2018; Diabetes Report, 2014). Overall, healthcare costs related to T2DM are increasing due to a combination of diabetes prevalence, diabetes-related complications, and an increasing number of consultations (Lin et al., 2020).

1.4 Type 2 diabetes in younger adults

Formerly considered a condition of older age, the incidence of T2DM in younger adults has increased considerably over the past three decades (Prasad et al., 2022; IDF, 2021; Lascar et al., 2018; Wilmot & Idris, 2014; Candler et al., 2018). This increase has been reported across the globe in high- and low-middle-income countries (Song & Frier, 2022; Yang et al., 2021; Lynch et al., 2020; Lascar et al., 2018). The International Diabetes Federation (2013) reported that roughly 63 million young adults aged 20 to 39 have T2DM, accounting for 16% of all adults with the condition. Diabetes UK estimated in 2018 that 6,836 children and young adults had T2DM, which is almost ten times higher than the estimates in 2016-17 when it was reported that 715 children and young adults in Wales and England had T2DM (Diabetes UK, 2018). Adult specialist services in the UK have witnessed similar results, with 24% of the diabetes population being under 40 years of age over a decade ago (Song & Hardisty 2009). Recently, the National Diabetes Audit (NDA) and the National Paediatric Diabetes Audit (NPDA) reported 121,220 young adults with T2DM below the age of 40. The proportion of early onset T2DM doubled in the UK from 6% to 12% between 1990 and 2010 (Song & Frier, 2022). In the United States, the incidence of T2DM among those aged 10-19 years increased by 7% each year from 2000 to 2013 (Mayer-Davis et al., 2017). A single centre study from Türkiye compared the incidence of T2DM among children and adolescents across three time periods and reported statistically significant increases in frequency of 1.9, 2.4, and 7.9% during 1999-2004, 2005-2010, and 2011-2016, respectively (Hatun et al., 2019). Young people with T2DM aged less than 40 are more likely to be female compared with people aged 40 or over (Lascar et al., 2018; NDA, 2021; Misra et al., 2022a; Tulloch-Reid et al., 2010). A study by Huebschmann et al. (2021) reported that approximately two-thirds of adolescents diagnosed with T2DM are female, consistent with data from the National Paediatric Diabetes Audit in the UK (NPDA, 2021). This higher incidence among females is reflected by the British Paediatric Surveillance Unit, who reported the incidence of T2DM had increased by 58% in girls compared with only 7% in boys between 2006 and 2015 (Candler et al., 2018). Recently, Misra et al. (2022a) reported that the percentage of women with T2DM up to 25 years of age accounts for 60% of T2DM cases (n = 9,805) in England.

The mechanisms posing development of T2DM in young adults is similar to those in older adults. However, early onset T2DM is associated with a more aggressive diabetes phenotype

than later onset, with a worse cardiovascular risk factor profile and higher risk of diabetes related to microvascular and macrovascular complications (Misra et al., 2022a; Lascar et al., 2018). In young adults with T2DM, the initial deterioration in beta cell function is characterised by a loss of first phase stimulated insulin secretion (Mayer-Davis et al., 2017). This means that loss of early insulin secretion initially leads to post-prandial hyperglycaemia which, as the condition progresses, worsens to clinical hyperglycaemia (Pratley & Weyer, 2001). In impaired fasting glycaemia, the first- and second-phase insulin secretion are approximately 50% and 30% lower respectively. Further, first phase insulin secretion in impaired glucose tolerance is approximately 40% lower than young adults with normal glucose tolerance, generally resulting in the worst clinical outcomes (Bacha et al., 2010). These findings are consistent with the Treatment Options for T2DM in Adolescents and Youth (TODAY) study, which describes the temporal changes in measures of beta cell function and insulin sensitivity over a four-year period among those using metformin, metformin plus rosiglitazone, and metformin plus lifestyle. A 20-35% annual decline in beta cell function in adolescents with T2DM has been reported, compared with the approximately 7% decline of older adults with T2DM (TODAY study group, 2013). The Search for Diabetes in Youth (SEARCH) study compared young adults with T2DM to those without diabetes and identified a higher prevalence of diabetes-related kidney disease and cardiovascular disease risk factors in the T2DM group (Amatruda et al., 2021; Hamman et al., 2014). Regarding diabetes microvascular complications in young adults (n = 500, mean age 26.4 years), the incidence of diabetic kidney disease, neuropathy, and retinopathy was 54.8%, 32.4%, and 13.7%, respectively (Bjornstad et al., 2021). Furthermore, youths with T2DM were likely to have a fourfold increased risk of renal disease versus youths with type 1 diabetes (T1DM) (Dart et al., 2012). It was recently identified that a 25% increase in the risks of hyperglycaemic crises, stroke, lower extremity amputation, and acute myocardial infarction over a 5-year period are most remarkable in individuals with T2DM aged 18-44 years (Davies et al., 2022). Therefore, young adults with T2DM, particularly young women, should be considered at high risk of diabetes-related complications, and treated accordingly (Norhammar, 2018; Davies et al., 2022; Gregg et al., 2019; Hou et al., 2022).

1.4.1 Risk factors for the development of type 2 diabetes in young adults

The risk factors of the development of T2DM are similar irrespective of age, and early onset T2DM is more prevalent in females (Misra et al. 2022a; Wilmot & Idris, 2014). Currently, there is a scarcity of population-based studies in this area (Misra et al., 2022b; Song & Frier, 2022; Wong et al., 2022; IDF, 2021). The following risk factors have been well documented.

Family history

A family history of T2DM plays an important part in the risk of developing the condition. Among UK adolescents with T2DM 56-71% have a parent or sibling living with T2DM, while 84% have a family history of T2DM (Shield et al., 2009; Haines et al., 2007). Likewise, in a study conducted in Türkiye the family history of T2DM in children (n = 227) was reported to be 86% (Hatun et al., 2019). In a large Scottish population-based cohort study, 61 gene variants related to the genetic risk of T2DM were associated with early onset T2DM and a younger age at initiation of insulin treatment (Zhou et al., 2014). Likewise, Diabetes UK (2022) reported that people who had a family history of T2DM are two to six times more likely to develop T2DM.

Ethnicity

People from South Asian, Black African, and African Caribbean backgrounds are at risk of developing T2DM at younger ages, compared with White ethnicity (WHO, 2022; Diabetes UK, 2021; Pham et al., 2019; Butler, 2017). This predisposition is also evident in the UK where T2DM diagnosis is three times more common in people of African-Caribbean and 2.5-5 times more common in people of South Asian (English et al., 2016; Khunti et al., 2013). A study by Goff (2019) documented the ethnicity and T2DM in the UK, found that the prevalence of T2DM in ethnic groups is three to five times higher than in the White British population. Importantly, almost 30% of those from minority ethnic groups diagnosed with T2DM were less than 40 years old (Goff, 2019). As such, a significantly greater proportion of people with minority ethnic backgrounds develop T2DM before the age of 40 years compared to White Europeans (approximately 8%) (Misra et al., 2022a; Paul et al., 2017;

Goff, 2019). They are also strongly affected by cultural factors, where in particular health beliefs, practices and linguistic differences of diverse populations can be significant barriers to participating in diabetes education and optimising self-management (Goff, 2019; Hasson et al., 2013; Lee et al., 2011; Krishnan et al., 2010).

Gestational diabetes mellitus

Gestational diabetes (GDM) is an independent and strong female risk factor for eventual progression of T2DM (Bellamy et al., 2009). GDM is diabetes that is first recognised in pregnancy. The incidence of GDM is estimated to be in one in every 23 pregnancies in the UK, with 2-7% of all pregnancies being affected by GDM, which increases the risk of adverse maternal outcomes (Bianco et al., 2020; Parsons et al., 2018). Whilst in most cases GDM resolves following birth, it leaves these women with a sevenfold increase in risk of developing T2DM within the following 10 years (Bellamy et al., 2009). Women with a history of GDM encounter a more than 70% higher risk of developing T2DM than women with prediabetes (Ratner et al., 2008). Another study reported that women with GDM are 7.4 times more likely to develop T2DM than women with a normoglycemic pregnancy (McMillan et al., 2018; Bellamy et al., 2009). Thus, current guidance from the UK National Institute for Health and Care Excellence (NICE, 2020) recommends that women with GDM should be offered screening for lifestyle advice to reduce the risk of future T2DM, and annual screening for diabetes (NICE, 2020).

Obesity

A dramatic increase in T2DM in the last three decades is strongly associated with the rise of the current 'obesogenic' environment, with the associated rapid rise in obesity because of the combined effects of increased access to high-calorie foods and reduced physical activity (Pillon et al., 2021). Certain environments are more 'obesogenic' than others, thus they are more likely to promote weight gain and obesity in the general population (Pillon et al., 2021; Mackenbach et al., 2014). Furthermore, genes play an important role in responding to changes in its environment. Variants in several genes may influence the behaviours (e.g., increased energy intake or a tendency to be sedentary) and metabolism (e.g., an increased

tendency to store body fat) (Castillo et al., 2017). A clear pattern of inherited obesity within a family may result from a specific variant of a single gene (monogenic obesity), while most obesity is caused by complex interactions among multiple genes and environmental factors (McCarthy, 2010). It is documented that the obesity gene variants increase susceptibility to common metabolic disease (e.g., T2DM) (Castillo et al., 2017). The obesity susceptibility genes interact with nutrients to alter regulation of central metabolism pathways to increase weight gain and to increase consumption of saturated fat or refined carbohydrates, contributing to obesity by increasing hunger and food intake (Castillo et al., 2017; Franks et al., 2013). Heritability estimates of obesity from twins or family studies range from 25% to 90%, meaning that a large proportion of obesity risk might be due to inherited factors (Qasim et al., 2017). Additionally, Kamruzzaman et al. (2022), in comparing the prevalence of T2DM and obesity in Bangladesh, found that the greatest increases in prevalence were in rural areas and poorer households. Globally, the prevalence of being overweight or obese among children and adolescents has dramatically increased to over 18% in 2016 (WHO, 2016). Importantly, a combination of genetic, obesogenic environments, lifestyle factors, and socio-economic factors play an important role in the development of obesity and T2DM (Olsson & Goedecke, 2020; Lascar et al., 2018; Gow et al., 2016; Swinburn et al., 2011; Willemsen et al., 2015; Elks et al., 2012).

Physical activity

Physical inactivity is a key factor for an increased risk of obesity and T2DM in young people (Lascar et al., 2018). A study exploring physical activity levels worldwide with data for adults (15 years and over) and for adolescents (13-15 years) from 105 countries reported that girls were less active than boys, with 20% of adolescents aged 13-15 years taking part in 60 minutes of moderate to vigorous activity per day (Hallal et al., 2012). Another study by Guthold et al. (2018) assessing levels of insufficient physical activity across countries with a pooled analysis of 358 population-based surveys with 1.9 million participants, described higher levels of insufficient physical activity among women in comparison to other groups. Furthermore, a cross-sectional cohort survey with 1420 young adults aged 20-38, reported that low levels of physical activity (less than 6.4 minutes, time on treadmill) was associated with the risk of developing T2DM, whereas improved fitness (more than 8.6 minutes, time

on treadmill) over 7 years was associated with a reduced risk of developing T2DM. The risk of developing T2DM, metabolic syndrome, and hypertension increase with decreasing physical activity in young adults aged 18-30 years (Carnethon et al., 2003). In a systematic review and meta-analysis study by Whipple et al. (2022), women consistently engaged in less physical activity than men across their lifespans. Among women, lack of motivation, social support, and embarrassment were frequently reported barriers to engaging in physical activity (Whipple et al., 2022). Thus, physical inactivity makes a significant contribution to the risk of developing of T2DM in young women.

1.5 Management of type 2 diabetes in young adults

T2DM management includes complex components with the aim of reducing the multiple, wide-ranging complications associated with the condition. Guidelines, specifically management of T2DM in children and adolescents (less than 18 years old) are available (Zeitler et al., 2018; Pena et al., 2020; Arslanian et al., 2018), whereas there is a limited evidence base on international guidelines for young adults aged less than 40 (Song & Frier, 2022). The guidance from the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) reported the management of hyperglycaemia in T2DM in adults. This guidance advocates individualised care of treatment targets/strategies and emphasises a patient-centred approach and shared decision making for the management of T2DM (Davies et al., 2022). Recently, Wong et al. (2022) outlined a consensus report about the management of T2DM in young adults aged 18-30 in Australia and highlighted that diabetes management recommendations for this group differ from recommendations for adults with T2DM. The management of T2DM should be considered within the context of the needs, preferences, and tolerances of each person with diabetes (Song & Frier, 2022; Inzucchi et al., 2015). The studies suggest that gender differences become crucial as women had poorer risk factor profiles, and thus suggesting the need to develop specific treatment guidelines for men and women (Duarte et al., 2019; Burner et al., 2013; Siddiqui et al., 2013; Choe et al., 2018). Gender differences in the healthcare provided for the prevention, management, and treatment of T2DM and its complications might

therefore contribute to women's greater excess relative risk of diabetes complications (Peters & Woodword, 2018; Suresh & Thankappan 2019).

1.5.1 Non-pharmacological management

Optimising glycaemia

Diabetes complications are related to glycaemia (also referred to as glycaemic level), measured as glycated haemoglobin (HbA1c), which is a representation of mean glucose levels over the previous three months. Given the faster decline in beta cell function (up to 20-35% per year) and the high risk of diabetes complications among young adults, it is recommended to aim for a HbA1c level of 6.5% (48 mmol/mol) for adults with T2DM, managed either by lifestyle and diet alone or in combination with a single medicine not associated with hypoglycaemia (Wong et al., 2022; NICE, 2015; Imran et al., 2018). Due to the progressive beta cell decline, regular three-monthly HbA1c monitoring is warranted for young adults with T2DM (Wong et al., 2022).

Young women with T2DM are at risk of diabetes complications, emphasising the importance of optimal glycaemia (Arslanian et al., 2018). Prospective randomised trials have reported the association between glycaemic targets and diabetes complications in people with T2DM. Zeitler et al. (2022) demonstrated that youths with early onset T2DM were at risk of deteriorating glycaemia (a rise in HbA1c of > 0.5% related to loss of optimal glycaemia within three and six months of diabetes therapy). It is documented that young women with T2DM have twice the risk of diabetes complications, such as pre-eclampsia (during pregnancy) and cardiovascular risk, compared to the general population (Thong et al., 2020; Lascar et al., 2018). Therefore, attaining recommended glycaemic targets yields significant and enduring reductions in the onset and progression of macrovascular complications in young women with this more aggressive phenotype of T2DM (Thong et al., 2020; Misra et al., 2022a; Wong et al., 2022).

In the UK Prospective Study (UKPDS), people with T2DM in the intensive treatment arm showed an HbA1c level of 7.0% compared with 7.9% in those with conventional treatment over 10 years of follow-up. Each 1% reduction in mean HbA1c was associated with

reductions in 37% for microvascular complications, 14% for myocardial infarction, and 21% for any end point related to diabetes (Stratton, 2000). The UKPDS 10 years' follow-up demonstrated that the strict glycaemic management led to a 25% risk reduction in microvascular complications. The Action in Diabetes and Diamicron MR Controlled Evaluation (ADVANCE) trial builds on the information gained by the UKPDS, where intensive therapy achieved a mean HbA1c of 6.5% (< 48 mmol/mol) safely with no increase in mortality compared with standard therapy. Moreover, there is no significant effect in reducing macrovascular disease, however intensive therapy reduced diabetic retinopathy by 20%, demonstrating a larger effect in preventing microvascular complications apart from macrovascular complications (Heller, 2009). Given the high risk of complications among young women, the HbA1c target should be ≤ 6.5% (48 mmol/mol) (Thong et al., 2020; Wong et al., 2022).

Dietary advice

A healthy balanced diet and optimising weight are fundamental elements of the management of T2DM to optimise glycaemia (Rafiullah et al., 2022; Raveendran, 2018; NICE, 2015). As T2DM is commonly associated with those who are overweight or obese, the importance of weight reduction and/or maintaining a healthy weight is often the cornerstone of diabetes management. Optimising weight is also linked to improvements in glycaemia as well as preventing or delaying cardiovascular complications (Forouhi et al., 2018). NICE (2015) clinical guidance recommends 5-10% body weight reduction in people who are overweight and have T2DM. It is well documented that there is a paucity of research for one specific macronutrient approach in young adults with T2DM (Wong et al., 2022). The very low energy diet approach has demonstrated benefit in youths with obesity and newly diagnosed T2DM (Gow et al., 2021; Andela et al., 2019). However, evidence for long-term effects of this approach is lacking at present, suggesting future research to strengthen the evidence base about this dietary approach would be appropriate. Similarly, reducing carbohydrate intake for the treatment of T2DM has been an area of intense interest because, of all the macronutrients, carbohydrates have the greatest effect on insulin levels and blood glucose. Findings from a review by the American Diabetes Association (ADA) assessing the low carbohydrate diet (less than 40% calories from carbohydrates) interventions on the comparison diet (usually a fat diet) demonstrated greater improvement

in HbA1c on the low carbohydrate diet and a greater reduction in the use of medicines to lower glucose (Wheeler et al., 2012). A study of this review reported a decrease in mean HbA1c from 7.3% to 6.8% (p = 0.006) over just 14 days on a low carbohydrate diet (Boden et al., 2005). Furthermore, a systematic review and meta-analysis of 54 randomised control trials (RCTs) to evaluate dietary behaviour for people with T2DM associated with changes in HbA1c and body weight found that the changing dietary environment showed a greater reduction in HbA1c of 0.5% (5.5 mmol/mol), meaning dietary interventions achieved a clinically significant reduction in HbA1c (Cradock et al., 2017). However, young adults with T2DM in these studies were not well represented (Wong et al., 2022).

Physical activity

Regular physical activity improves blood glucose levels, blood pressure, cardiovascular issues, mortality, and quality of life (Najafipour et al., 2017; Colberg et al., 2016; Hamasaki, 2016; ADA, 2022). Current national and international guidelines recommend exercise training for people with T2DM (Ryden et al., 2013; NICE, 2015; Hansen et al., 2013). However, randomised trials assessing exercise interventions in youths with T2DM are limited and inconclusive (Wong et al., 2022), even though the benefits are likely similar to those in adults. For example, findings from a systematic review and meta-analysis of 37 studies reported that both supervised aerobic and supervised resistance exercises demonstrated a significant reduction in HbA1c when compared no exercise (30% and 30% lower, respectively) (Pan et al., 2018). Additionally, Umpierre et al. (2011) also conducted a systematic review and meta-analysis of 47 RCTs assessing associations of structured training regimes (resistance, aerobic or both) and physical activity advice with or without dietary advice on HbA1c in people with T2DM. This study reported that a structured exercise duration of more than 150 minutes per week was associated with HbA1c reductions of 0.89%, whereas a structured exercise duration of 150 minutes or less per week were associated with HbA1c reductions of 0.36%. A sustained weight loss of 7-10% in people with excess weight is expected to provide benefits with regard to blood glucose and cardiovascular risk factors in young adults with T2DM (Wong et al., 2022; Colberg et al., 2016). However, youths with T2DM were underrepresented in the prominent research trials that underpin T2DM management guidelines (e.g., lifestyle interventions such as exercise training) (Sargeant et al., 2020).

Bariatric surgery

Evidence shows that bariatric or metabolic surgery is a very effective therapeutic option for obesity and improving metabolic indices (Diabetes UK, 2021; Mingrone et al., 2015; Courcoulas et al., 2015), even though long-term data for adolescents and young adults with T2DM is limited. There are several types of surgical procedures, including Roux-en-Y gastric bypass (RYGB), laparoscopic adjustable gastric banding (LAGB), bilio-pancreatic diversion (BPD), and laparoscopic sleeve gastrectomy (LSG). It is interesting to note that these procedures can result in the remission of T2DM (Backman et al., 2019; Raveendran, 2018). In a review of literature related to the effects of bariatric surgery on T2DM, remission rates were reported to be 66.7% after surgery (Puzziferri et al., 2014). The Swedish obese subject (SOS) study reported that 30.4% of participants were in remission after 15 years' follow-up compared to 72.3% at 2 years after surgery (Sjöström et al., 2014). There are also studies suggesting that bariatric surgery prevents or delays the development of T2DM. The SOS study reported that bariatric surgery, compared to usual care, reduces the long-term incidence of T2DM by 78% in obese people at 15 years' follow-up (Carlsson et al., 2012). Other studies (Misra et al., 2022b; Shah et al., 2016; Stefater & Inge, 2018) highlighted that the role of targeting remission of early onset T2DM through bariatric surgery is unclear, and further research is needed to include well-designed, prospective, controlled studies with sufficient sample sizes to definitively assess both the benefits and risks of surgery in young adults with T2DM.

Diabetes self-management education

Diabetes self-management education which is a continuing process to provide and facilitate the ability, skill, and the knowledge required for diabetes self-management is considered the cornerstone of diabetes care (Wong et al., 2022; Powers et al., 2015; Wahowiak, 2018; NICE, 2022). However, there are limited educational resources specific to young adults with T2DM nor is there evidence to inform effective educational approaches (Wong et al., 2022). Structured education programmes were generally designed for older ages and unlikely to meet the needs of younger age groups (Wong et al., 2022). Practically, this education is necessary to prevent long-term complications and enable a healthy reproductive plan in women of reproductive age living with T2DM from puberty until menopause (William & Creider, 2020). Pregnancy, for example, involves significant changes, such as transition from

oral hypoglycaemic to insulin therapy, and the self-management burden is significantly increased during this period for women with T2DM as perinatal outcomes are affected by maternal glycaemia (Sushko et al., 2021; Nooseisai et al., 2021). This diabetes education process involves the life experiences, goals, and needs of the people with T2DM and is based on evidence-based standards (Yazdani et al., 2021; Grillo et al., 2013; Vos et al., 2016; Powers et al., 2015). Therefore, diabetes self-management for those who have already been diagnosed with diabetes plays a significant role in regulating blood glucose as well as being an important factor in the long-term complications for women with T2DM (William & Creider, 2020; Jakubowski et al., 2022; Chrvala et al., 2016; Lanre-Ogungbie et al., 2020). Although there is a developing body of evidence demonstrating that increasing self-care management improves emotional, biological, and cognitive outcomes (Powers et al., 2016), there is limited research on self-management interventions amongst women of reproductive age living with T2DM, which is especially relevant as the prevalence of T2DM is increasing in this high-risk group worldwide (Sushko et al., 2021).

1.5.2 Pharmacological management

T2DM has generally been treated in a stepwise manner starting with lifestyle modifications, proceeding the use of one oral antidiabetic agent followed by a combination of two or more oral agents before insulin is considered (NICE, 2022; Davies et al., 2022; Chan et al., 2003). It is crucial to establish treatment goals early for optimal management of T2DM in order to determine whether the goals of therapy are being met or when to modify therapy. NICE (2022) guidelines recommend the treatment for people with T2DM who are unable to reach glycaemic targets through lifestyle interventions alone. For young adults, the faster decline in beta cell function may result in an earlier titration from monotherapy to more complex treatment regimens (Wong et al., 2022; TODAY study group, 2013). A study conducted by Misra et al. (2022b) highlighted that considerable research is needed to better understand how to manage early onset T2DM, where practically, a priority area is to understand which drug classes might be better placed to treat early onset T2DM. Given the unknown teratogenic effects of the newer drug agents, Wong et al. (2022) pointed out that the need for effective contraceptive advice is a requirement in women.

1.6 Type 2 diabetes and young women's health and wellbeing

1.6.1 Prevalence of type 2 diabetes among women of reproductive age

The prevalence of T2DM among women of reproductive age is rising with an increase in overweight and obesity levels (nearly 15% in women and 11% in men), in addition to changes in socio-economic status and lifestyle (NDA, 2021; Amugsi et al., 2017; Chivese et al., 2019; WHO, 2022). Consequently, there are now many more women of reproductive age living with T2DM, with two out of five women living with diabetes during reproductive years, accounting for 60 million women worldwide (Coulthard & Hawthorne, 2008; Htike et al., 2015; Ogurtsova et al., 2017). The World Health Organization (WHO, 2017) global conference on noncommunicable disease as a sustainable development priority recommended a gender-based approach in prevention and treatment policies, identifying the differential effects of diabetes on gender in 2018 to 2030 (Saran et al., 2021). The IDF's World Diabetes Day (IDF, 2017) focused on women and diabetes and estimated that there are 199 million women aged 20-79 years living with diabetes worldwide, which is projected to increase to 313 million by 2040.

Despite the increasing prevalence of T2DM among women under the age of 45, their experiences and healthcare needs remain under-researched (Misra et al. 2022a; Thong et al., 2020; Celik et al., 2022).

1.6.2 Type 2 diabetes related health issues at reproductive age

Diabetes related complications

As one of today's dominant health issues, T2DM among women of reproductive age leads to multiple challenges that can impact mental and physical well-being along with reproductive health (Chivese et al., 2019; Htike et al., 2015; Stenhouse, 2012; Lascar et al., 2018). Firstly, a younger age at onset of diabetes in women was strongly associated with increased prevalence of multiple diabetes complications compared to women given in mid- or later life diagnosis (Elyasi et al., 2015). Previous studies reported that women with early onset diabetes were prone to develop more complications ($p < 0.0003$) (Cheema et al., 2018;

Hillier & Pedula, 2001; Zou et al., 2016). Younger women with T2DM have a 14-fold higher risk of having a myocardial infarction than the age- and sex-matched population without diabetes (Hillier & Pedula, 2001).

Menstrual cycle/Hormonal changes

The earlier onset of T2DM in women, particularly in the second and third decades of their lives, overlaps with the reproductive life stage, with associated fertility and pregnancy implications (Cretu et al., 2020; Thong et al., 2020). Thus, women of reproductive age living with T2DM face additional burdens as they often experience some form of menstrual dysfunction, the burden of pregnancy, and cyclical hormonal changes prior to menopause (Kapur & Seshiah, 2017; Sahrakorpi et al., 2017; Shim et al., 2011). The prevalence of menstrual irregularity is considerably higher in women with T2DM than women without. Additionally, higher concentrations of follicle-stimulating hormone (FSH) were reported in women with T2DM compared to those without diabetes (Isık et al., 2012), indicating a lower degree of ovarian reserve. However, few studies have explored fertility in women with T2DM, or the association between the age of natural menopause and T2DM. Therefore, evidence gaps exist relating to reproductive issues in women with T2DM, and recognition of a specific need by partners, families, and HCPs (Cretu et al., 2020; Thong et al., 2020).

Pregnancy and perinatal care

The incidence of T2DM pregnancies is increasing, globally. The most recent National Pregnancy in Diabetes (NPID, 2021) audit reported that more than 50% of the women with diabetes had T2DM compared with the UK Confidential Enquiry into Maternal Child Health (CEMACH, 2007) report in 2007, in which only 30% of the women included had T2DM. A systematic review including the data from 17 countries in North America, Europe, the Middle East, and North Africa, Australasia, Asia, and Africa, found that the prevalence of pre-existing diabetes in pregnancy has doubled between 1990 and 2020 (Chivese et al., 2022). This proportion will continue to increase as the age of onset of T2DM decreases in women (Chivese et al., 2022; NPID, 2021). Women with T2DM are less likely to receive adequate pregnancy counselling, contraceptive advice, folic acid supplementation, or a test of

glycaemic control in the six months before pregnancy compared to women with T1DM (Flynn et al., 2022; Murphy et al., 2017; Forde et al., 2022; Bapayeva et al., 2022). This contributes to both adverse maternal and neonatal outcomes, for example, the rate of neonatal death was higher in mothers with T2DM (11.2%) than in those with T1DM (7.4%) (Murphy et al., 2021; Feig et al., 2014; Jang et al., 2018; Macintosh et al., 2006). Pregnant women with T2DM had a threefold increase in perinatal death across all trimesters and a twofold increase in the rate of congenital anomaly compared to women without diabetes (Murphy et al. 2021). 26% of pregnancies among women with T2DM resulted in large gestational-age babies, where 50% of births were by caesarean section and 15% of infants are admitted to neonatal care (NPID, 2021). Pre-pregnancy care is therefore vital to improve maternal and neonatal outcomes (Murphy et al., 2021; Forde et al., 2022; Holmes et al., 2017; Yamamoto et al., 2018).

Psychosocial health issues

Depression symptoms and diabetes distress are particularly common among the T2DM population (Sturt et al., 2015). The prevalence of symptoms of depression in people with T2DM is in the region of 20%-30% (Yang et al., 2022) and 36% experience elevated diabetes distress (Perrin et al., 2017). Younger women with T2DM experience high levels of diabetes distress and depression stemming from their worries about the future and feelings of guilt as a consequence of living with diabetes (Aljuaid et al., 2018; Ke et al., 2019; Nanayakkara et al., 2018; Wilmot & Idris, 2014). For example, a cross-sectional study including 638 participants with T2DM (mean age: 26.8 years) found that a greater percentage of those who had high diabetes distress were female ($p = 0.002$) and had anxiety symptoms ($p = 0.036$) (Trief et al., 2022).

Younger women with T2DM are more likely to experience sexual problems compared to those without diabetes. A meta-analysis of 25 studies demonstrated that the prevalence of sexual dysfunctions in women with T2DM was 68.6% (Rahmanian et al., 2019). Psychological issues are also common in women with T2DM who have sexual dysfunction, for instance, 95.8% of included women ($n = 150$) reported anxiety (Elyasi et al., 2015). Sexual health is thus an important part of diabetes care which is neglected in women (Meeking et al., 2013).

As a result, women are more vulnerable to the adverse effects of T2DM (Kapur & Seshiah, 2017), and therefore effective interventions or care pathways are needed to deal with the challenges faced by women of reproductive age living with T2DM (Thong et al., 2020; Song & Frier, 2022; Misra et al., 2022b; Rollo et al., 2016).

1.6.3 Interventions to improve diabetes and health outcomes

In line with earlier studies, the use of online diabetes interventions can yield a clinically significant improvement in diabetes outcomes among people with T2DM (Carpenter et al., 2019; Celik et al., 2020; Turner et al., 2018). There are several Women' Wellness Programmes, which aim to enhance a healthy lifestyle and to promote health outcomes. For example, the Young Women's Wellness Programme is designed to help young women adopt healthy lifestyles by exposing them to a carefully planned programme, including access to resources and a network of peers and mentors (Xenakis & Goldberg, 2010). In addition, the Women's Wellness After Cancer Programme is effective in enhancing health-related quality of life in women previously treated for blood, breast, and gynaecological cancer (Anderson et al., 2017). The HeLP-Diabetes programme was also developed for people with T2DM (aged 19-81 years) at all stages of their diabetes journey and is an effective self-management support programme such as producing an improvement in HbA1c levels at 12 months in the intervention group (0.24%) (Murray et al., 2018). However, none of the existing interventions specifically address the needs of women of reproductive age living with T2DM. As such, the diabetes interventions/care pathways directed towards women of reproductive age living with T2DM may be helpful to both reach these women and improve women's health with T2DM (Misra et al., 2022b; Chivese et al., 2019; Rollo et al., 2016; Mattsson et al., 2021; William & Kreider, 2020).

1.6.4 Current practice of diabetes care for women with reproductive age living with type 2 diabetes

Despite a concerning increase in cases of early onset T2DM among young women, there is limited evidence regarding the optimal treatment and management of this population (Misra

et al., 2022b). Current models of diabetes care were developed to improve diabetes outcomes in children and adolescents less than 18 years old or directed mainly towards those of older age (Song & Frier, 2022; Wong et al., 2022; IDF, 2021). For women with T2DM in the UK, currently, the location of their care is highly variable in adult specialist services and primary care, and only national guidelines with a focus on this group aim to improve diabetes pregnancy outcomes (Misra et al., 2022b). For instance, the NICE guideline covers managing diabetes and its complications in women with GDM and help women with diabetes from the preconception to postnatal stages, including self-monitoring of blood glucose and folic acid intake, and contraception (NICE, 2020). This guideline also includes care and management for adults aged 18 and over living with T2DM, and focuses on patient education, dietary advice, managing cardiovascular risks, and identifying and managing long-term complications. However, the T2DM NICE guidelines are generic and do not include care for younger women with T2DM. Additionally, in the UK there are diabetes courses such as Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) which is a group course for up to 10 people with T2DM that helps to increase knowledge and understanding of what having diabetes means (Davies et al., 2008). The X-PERT Diabetes programme is also designed to improve diabetes management (e.g., how physical activity can help) in people with T2DM in the UK (Deakin et al., 2006). However, the reproductive health issues in women with T2DM have not been involved in previous diabetes programmes such as DESMOND and X-PERT.

The Quality and Outcomes Framework (QOF), introduced in the UK in 2004, is the part of the General Medical Services (GMS) contract for general practices. It provides a national framework for delivering quality clinical care in primary care settings, offering incentives to general practitioner (GP) practices for the provision of the quality of care. These incentives include maintaining a register of adults with T2DM, recording that a set percentage of those who are newly diagnosed have been referred to a structured education programme (Davies et al., 2008) within nine months of entry on to the diabetes register and recording the targets for blood pressure, cholesterol, and HbA1c (Diabetes UK, 2018). However, there is no indicator of the QOF, including specific aspects of care for younger women such as pre-pregnancy care, which can create a challenge to the delivery of routine care (Misra et al., 2022b).

Likewise, all people with T2DM in Türkiye, are covered by the national social security and do not need to pay for most of their diabetes care. People with diabetes, irrespective of type, are treated in primary, secondary, and tertiary care settings, where diabetes education is also provided. Diabetes education programmes are provided by diabetes nurse educators in both out- and in-patients setting in almost all hospitals in the country (Celik S., 2022; IDF, 2019). Diabetes nurse educators provide group education, including self-management activities within the scope of the 'Patient/Diabetes School' programme rolled out by the Ministry of Health Hospitals (Celik S., 2022). This programme aims to improve the skills of people with diabetes about diabetes self-care activities, and gain self-confidence and knowledge about diabetes, and be involved in the decision-making process (İstek & Karakurt, 2018; Sivrikaya & Ergün, 2018). Another diabetes programme is that the peer-to-peer education programme, supported by Türkiye Diabetes Foundation and the World Diabetes Foundation involves people with diabetes and peer educators for the delivery of the education (Yılmaz et al., 2012; IDF, 2021). It educates peer educators to educate people with diabetes through a structured education programme. Peer educators were the key elements of the programme and received medical training modules covering major topics including diabetes, nutrition, exercise, acute and chronic complications, and self-management activities. This programme is orientated towards a heterogenous diabetes population. Despite the adverse risk profile for women of reproductive age living with T2DM, current guidelines/programmes for the management and treatment of T2DM in adults make no age- and gender-related treatment and management recommendations (Misra et al., 2022b).

Reflection on my own personal background

I graduated with a bachelor's degree from the Suleyman Demirel University, Faculty of Health Sciences under the Department of Nursing in Türkiye (2014). I spent four years of undergraduate nursing studies taking a variety of theoretical, practice- and laboratory-based modules. I had a special interest in learning more about diabetes and its management. Having completed my bachelor's degree, I decided to continue my education and applied for a scholarship programme offered by the Türkiye Ministry of National Education to educate academicians abroad. I was awarded a scholarship from the Republic of Türkiye Ministry of National Education to undertake my MSc and PhD studies in the UK. I completed an MSc

(Clinical Nursing) at KCL in 2018. I was interested in T2DM and self-management education, thus the overall aim of my master thesis was to explore the impact of Internet-based self-management interventions on health outcomes for middle-aged adults with T2DM. During my MSc dissertation project, I gained experience in research methods, and all courses set the foundation of my knowledge with the help of the professional academic staff and the modules provided in the programme. I had an observational clinical placement at St Thomas Hospital as a part of the Clinical Nursing programme. I learnt how to observe without being inclusive and how to interact with clinical people with T2DM. Specifically, diabetes service increased my curiosity in terms of needing to understand what living with diabetes is like for people and the different factors that can affect it. Having completed my MSc degree, I started a PhD programme at KCL in January 2019. The motivation for my PhD study was influenced by my MSc project and clinical placement. I am interested in understanding how T2DM affects younger women as there is a paucity of evidence regarding the diabetes experiences and views of this population. Thus, my PhD study focused on the experiences and health needs of younger women with T2DM during their reproductive years. My doctoral project was funded by the Republic of Türkiye Ministry of National Education; therefore, my research findings are relevant to delivery of healthcare in Türkiye and the UK, which have a high prevalence of young women with T2DM. Data were collected from both countries via online methods, allowing the perspective of the study to be widened in relation to the experiences and health needs explored.

1.7 Chapter summary

This chapter has presented an overview of diabetes and its complications, risk factors, and impacts on women's health and wellbeing. The prevalence of T2DM among young women is rapidly increasing, therefore many more women of reproductive age are living with T2DM worldwide. T2DM in young women (18-45 years) is a more aggressive condition than that at older age, with a greater associated cardiovascular risk and psychological issues. This chapter highlights the need of intervention development to reach younger women with T2DM and improve their health and wellbeing. However, the health needs of these women are under-researched, thus this thesis facilitates a more comprehensive understanding of the

experiences and health needs of women living with T2DM. The insights generated from this thesis could help to identify strategies that could enhance women's health and wellbeing. An overall rationale and overarching aim of the study and its objectives is presented below in this chapter. The next chapter will present a systematic review of the existing literature on the impact of living with T2DM amongst women of reproductive age. This approach helps to identify the known health issues and risk factors from previous empirical studies, along with the identification of gaps in the literature.

1.8 Thesis aims and objectives

The overarching aim of this thesis is to comprehensively explore the experiences and health needs of women living with T2DM during their reproductive years and to identify strategies for future intervention in these regards (Table 1).

Table 1 Overview of thesis stages and associated studies

Stage 1	A mixed-methods systematic review	PhD
Stage 2	Qualitative interviews	
Stage 3	A cross-sectional study	

To achieve the overarching study aim, this thesis included three stages whose aims, and objectives are outlined below.

<u>Stage 1:</u> A mixed-methods systematic review – (published study 1: *The impact of type 2 diabetes on women's health and wellbeing during their reproductive years: A mixed-methods systematic review. Current Diabetes Reviews*)

Aim: To understand the known impact of living with T2DM on younger women's health and wellbeing during reproductive years.

Objectives:

- To identify the health issues encountered by women living with T2DM during their reproductive years
- To determine the modifiable risk factors associated with living with T2DM
- To identify potential evidence gaps in the literature
- To specify possible targets for interventions to meet age- and gender-specific diabetes-related health needs.

<u>Stage 2:</u> Qualitative semi-structured interviews (published study 2: *'No one ever asks about something that actually is relevant to my life': A qualitative study of diabetes and diabetes care experiences of young women with type 2 diabetes during their reproductive years. Diabetic Medicine*)

Aim: To explore the health needs, experiences, and views of women with T2DM in relation to diabetes, reproductive health, and mental wellbeing.

Objectives:

- To explore the impact of living with T2DM on women's health and wellbeing during their reproductive years
- To identify health issues important to women currently unidentified and/or explored in the literature
- To identify what women with T2DM need to improve diabetes management during their reproductive years
- To identify the necessary components of possible care pathways/interventions.

<u>Stage 3:</u> A cross-sectional study (study 3: Relationships between psychosocial health factors and self-management behaviours in younger women of reproductive age living with type 2 diabetes)

Aim: To assess the prevalence and correlates of psychosocial factors and self-management behaviours in women with T2DM.

Objectives:

- To identify the prevalence of psychosocial factors in women of reproductive age who are living with T2DM
- To investigate the relationship between identified psychosocial factors and self-management behaviours in women of reproductive age with T2DM (adjusting for age, duration of diabetes, and socio-demographic characteristics).

1.9 Organisation of the thesis

The thesis consists of seven chapters.

Chapter 1 presents an introduction to the general background of diabetes, epidemiology, long-term complications, risk factors for developing T2DM amongst younger adults, and the impact of T2DM on young women's health and wellbeing. It provides a statement of the problem and presents the thesis aim and objectives. Subsequently, it provides the scope of the research and an outline of the PhD thesis.

Chapter 2 incorporates a published systematic review to understand what is currently known about the health and health needs of this population. The paper is prefaced by synthesising all known diabetes-related health issues identified from the existing literature and concludes with a fuller discussion of the findings.

Chapter 3 discusses the main theoretical framework used for this work and justifies the methods and research designs employed.

Chapter 4 incorporates a published qualitative study to explore how women with T2DM perceive and manage diabetes, and how diabetes affects their health and wellbeing.

Chapter 5 presents a cross-sectional study to assess psychosocial, self-management activities, clinical, and socio-demographic factors associated with living with T2DM. It includes valid and reliable measures of the psychosocial health issues and diabetes self-management identified from the qualitative study.

Chapter 6 discusses and draws upon the overall thesis findings by synthesising the data from the systematic review and results of qualitative and quantitative studies, and it also presents an in-depth interpretation of young women's perceived health needs regarding living with T2DM in the general health and reproductive health contexts. It then concludes by highlighting the thesis strengths and limitations.

Chapter 7 summarises the key findings of the thesis and highlights implications for clinical practice and further research, along with outlining the dissemination plans and conference papers.

Chapter 2 – Systematic review

2.1 Chapter overview

The preceding chapter outlined that the prevalence of T2DM in women of reproductive age is dramatically increasing, and that this population are at risk of adverse diabetes outcomes related to T2DM. However, there was no previous systematic review that addressed the health needs, impacts, or experiences of living with T2DM as a younger woman. Therefore, there is a need to better understand the impact of living with T2DM on young women's health and wellbeing to improve their health and diabetes outcomes. This chapter presents a mixed-methods systematic review reporting the health issues encountered by women with T2DM during their reproductive years. This review aims to review the studies reporting the known impact of living with T2DM on the health of young women and aims to guide the development of an intervention which will be underpinned by the MRC framework (Craig et al., 2008). This chapter includes the first publication from this PhD study entitled: The impact of living with Type 2 diabetes on women's health and wellbeing during their reproductive years (Celik et al., 2022). The chapter provides the justification for the conduct of systematic review, including the databases and search terms used. Finally, the findings are further discussed with regard to the thesis implications and summarised at the end of this chapter. Supplementary tables related to the systematic review are presented in Appendix A.

2.2 Rationale for systematic review

A systematic review of the literature is key to synthesising and critically apprising the evidence, as suggested by the MRC framework (Craig et al., 2008). A systematic review provides a clear summary and synthesis of review outcomes. It is undertaken using transparent, explicit, precise, and systematic methods, using a detailed plan and search strategy. The purpose of a systematic review is to answer a particular research question by collecting evidence from all relevant studies (Impellizzeri & Bizzini, 2012; Akobeng, 2005; Burns et al., 2012). Systematic review methodology is comprehensive and of high quality, and aims to minimise bias, such as presenting the research question(s), identifying, selecting,

critically apprising, and synthesising all the relevant published studies related to the review questions, therefore enhancing the reliability of the results compared to other type of reviews (Siddaway et al., 2019; Clarke, 2011; Higgins & Green, 2011; Rudnicka & Owen, 2012). Reviewing the existing literature can provide invaluable information regarding how living with chronic conditions affects people's health and everyday lives (Gonzalez-Gonzalez et al., 2021). Given the need to identify the known health issues associated with living with T2DM among young women of reproductive years, a systematic review was undertaken rather than another type of review (e.g., scoping reviews).

Although systematic reviews are considered the highest level of evidence in research hierarchy, supporting healthcare providers to better evidence-based clinical care (Burns et al., 2012), there are certain limitations, such as heterogeneity, selection of studies, and inappropriate subgroup analysis (Gopalakrishinan & Ganeshkumar, 2013). To minimise these limitations, this review took a transparent approach with clear aims and predetermined eligibility criteria for studies, and conducted a rigorous database search to find all the eligible studies. A systematic approach to the synthesis of the included studies was undertaken (Moher et al., 2009).

2.3 Justification for the search strategy

A fundamental aspect of a systematic review is to capture as many of the relevant studies on a specific research area as possible. Hence, when undertaking a systematic review, it is advised to search multiple databases as well as searching additional sources, including reference lists and citations of eligible studies (Bramer et al., 2017; Stevinson & Lawlor, 2004; Levay et al., 2015). For this review, systematic searches were conducted in six different databases via Ovid and EBSCO interfaces in the following databases: MEDLINE, PsycINFO, EMBASE, CINAHL, Web of Science, and Maternity and Infant Care. MEDLINE includes nursing, medical, and health journals and provides coverage on European publications with a wide amount of psychology and biomedical papers (Polit & Beck, 2012), thus it was selected as the first-choice database for the search of articles related to diabetes. PsycINFO was chosen for its focus on psychological, social, behavioural, and health sciences, which was helpful in obtaining papers related to health and wellbeing for women living with

T2DM (Watson & Richardson, 1999). EMBASE is a medical literature database produced by the healthcare information service in European publications, including journals of professional and complementary medicine (Marcana et al., 2013; Burnham & Shearer, 1993; Sampson, 2003). CINAHL is used for retrieval of relevant articles about women with T2DM conducted by international nursing and allied health professionals (Briscoe & Cooper, 2014). Web of Science was also selected due to its multidisciplinary coverage that includes the various journals of medical, social, and scientific science, including the humanities (Falagas et al., 2007). Maternity and Infant Care, which is the world's largest midwifery-specific database, was chosen as it includes academic journals related to women's health and a wide range of grey literature drawn from information sources as well as being a resource used by maternity healthcare providers to support their research and practice (Coates & Foureur, 2019). Finally, the reference lists of studies included in this review were also searched to capture all available data for this study.

Using well-developed search strategies to enhance the likelihood of capturing all the relevant studies on a research topic is necessary when conducting a systematic review. The full search strategy for each database is presented in Appendix A.1.1. A preliminary exercise to test search strategy was carried out using the MEDLINE database. The preliminary search provided common key words related to women with T2DM. Montori et al. (2005) reported that the MEDLINE database has close to perfect sensitivity and specificity or with high precision when using empirical search strategies. The search terms were then developed and discussed with the supervisory team and an information specialist to identify the most appropriate terms and combination of terms. Additionally, the replication of a search conducted in a previous systematic review has been recommended to increase the validity of systematic review methodology (Staples & Niazi, 2008). However, there is paucity of systematic reviews conducted in this field. Retrieving relevant studies can be challenging and replicating some of the search terms from other reviews can be helpful. Thus, some search terms (e.g., reproductive) replicated the rigorous methodology used by a previous systematic review in the field by Forde et al. (2016) that assessed the experiences of pre-pregnancy care of women with T2DM. Collectively, these informed the search strategy and the inclusion and exclusion criteria as based on the literature.

The study presented in this chapter is presented in the following article:

Celik, A., Forde, R., Racaru, S., Forbes, A., & Sturt, J. (2022). The Impact of Type 2 Diabetes on Women's Health and Well-being During Their Reproductive Years: A Mixed-methods Systematic Review. *Current Diabetes Reviews*, *18*(2), 31-51.

2.4 Published article

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SYSTEMATIC REVIEW ARTICLE

The Impact of Type 2 Diabetes on Women's Health and Well-being During Their Reproductive Years: A Mixed-methods Systematic Review

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Abstract: ***Background*:** The incidence of Type 2 Diabetes (T2DM) among younger women now accounts for 40% of females with T2DM. Women of reproductive age with T2DM have additional health considerations and their needs may differ from older populations.

***Objectives*:** The aims were (1) to identify the health issues encountered by women aged 16-45 years living with T2DM; (2) to determine the modifiable risk factors associated with living with diabetes; (3) to specify ideas for interventions to meet age and gender-specific diabetes-related healthcare needs.

***Methods*:** A systematic search was performed in the following databases; MEDLINE, PsycINFO, EMBASE, CINAHL, Web of Science, and Maternity and Infant Care. Databases were searched without time and study design limits. The Mixed Methods Appraisal Tool was used to assess the methodological quality of included studies. Data were narratively synthesised due to mixed methods evidence included.

***Results*:** A total of 32 papers were included in the review from which six domains were identified from the synthesis: (1) diabetes related modifiable risk factors: blood glucose, cardiovascular risk, neuropathy/nephropathy/retinopathy, diabetes self-management barriers (2) reproductive health: diabetes care before pregnancy, pre-pregnancy care barriers and expectations of women, contraceptive use (3) psychosocial wellbeing: depression symptoms and diabetes distress, perception of T2DM, emotional concerns about pregnancy (4) sexual function; (5) menopause; (6) sociocultural factors: social support, cultural norms.

***Conclusion*:** This review highlighted specific health issues affecting women of reproductive age with T2DM and which represent an important focus for health services research and health care delivery. Future research needs to address identified health domains to improve women's health and well-being living with T2DM.

Keywords: Type 2 diabetes, women, social culture factors, reproductive, healthcare needs, menopause.

1. INTRODUCTION

Diabetes mellitus is a high prevalence of non-communicable condition that affects over 450 million people globally [1]. The majority of people living with diabetes have T2DM, accounting for 90% of the total diabetes population [1]. T2DM has the potential to cause microvascular and macrovascular complications, including cardiovascular disease (*e.g.*, myocardial infarction), peripheral vascular disease (leading to leg ulcers, infection and amputation), nephropathy, retinopathy and neuropathy [2, 3]. People with T2DM are also at increased risk of mental health problems with the high level of depression and anxiety compared with people without diabetes and high levels of diabetes-related distress [4-6]. Diabetes is also a very high-cost disease accounting for 5-10% of health care expenditure [1, 4, 7, 8]

While T2DM has its greatest prevalence among older people (aged > 60 years), its incidence in younger adults is increasing [7, 9-13]. The International Diabetes Federation (IDF) estimates that of 463 million adults with T2DM, approximately 4-8% are aged 20-44 years, especially in Africa, South-east Asia and Western Pacific regions [11]. In the UK, the number of younger adults (<40 years) newly diagnosed with T2DM has increased to over 28,285 [14, 15].

The modifiable risk factors for T2DM are on the rise in younger age worldwide. In particular, overweight and obesity are the major driving factors of increased diabetes in younger adults, especially among women [7, 15-20]. Hence, the prevalence of T2DM among women of reproductive age

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is rising with an increase in overweight and obesity levels where more women are obese compared to men (nearly 15% and 11%, respectively) [20-24]. Further, across the world's population, 2 in 5 women with diabetes are of reproductive age at any point in time, accounting for over 60 million women globally [25]. Given the increasing prevalence of T2DM in women of reproductive age, more women may be exposed to potential adverse effects of T2DM on their health and well-being [11].

Healthcare professionals need to understand how women of reproductive age live with and manage T2DM [26-29]. With a more attuned understanding, healthcare providers can adapt the care and education support provided to better meet the physical and emotional needs of this group [29]. It is also important to understand the physical and psychological experiences of women with T2DM for effective management of their condition [30, 31].

A systematic review by Li *et al.*, explored the experiences of older women living and coping with T2DM. They reported that women are challenged by their multi-caregiving roles and the complexity of managing their diabetes [32]. Suresh & Thankappan identified the challenges encountered by women in accessing T2DM care [33]. They concluded that women with T2DM faced personal, health system, economic, and psychological barriers. Another study looked at the experiences and views of pre-pregnancy care for women with T2DM and healthcare professionals [34]. The findings emphasise the importance of pre-pregnancy care, and women' beliefs, emotional concerns and social factors need to be considered to ensure the benefit from pre-pregnancy care. Chivese *et al.*, also emphasized the need for interventions to prevent and control diabetes in African women of reproductive age due to the significant prevalence of T2DM among this population [35].

Consequently, previous systematic reviews focused on a heterogenic population ranging from younger to older women with T2DM [32, 33]. They also focused on the dietary changes to manage diabetes, the prevalence of diabetes or pre-pregnancy care as the outcome of interest [34-36]. However, the needs of women of reproductive age living with T2DM are under-researched. Thus, this systematic review aims (i) to review the evidence to better understand the impact of living with T2DM on women's health and well-being during reproductive years (ii) to address gaps in evidence by researching what is known about women living with T2DM from the current literature. In this regard, the study seeks out an answer to the following research question; What is the impact of living with T2DM on women's health and well-being during their reproductive years?

1.1. Objectives

This study aims to systematically review and synthesise the evidence of data from quantitative and qualitative studies reporting the known impact of T2DM on health of women aged 16-45 years. The aims are: (1) determining the modifiable risk factors associated with living with diabetes, (2) identification of the health issues encountered by these women, (3) establishing the barriers and facilitators influencing their diabetes management and (4) specifying ideas for effective interventions for promoting age and gender-specific diabetes-related healthcare.

2. METHODS

A mixed-methods approach integrating the findings of qualitative and quantitative studies was followed using a narrative synthesis [37-40]. The review was conducted and reported following the adopted Preferred Reporting Items for Systematic Review and Meta-analyses (PRISMA) of qualitative and quantitative evidence [41]. For transparency, the protocol of this review was registered at the International Prospective Register of Systematic Reviews (PROSPERO) database (Registration number: CRD42019146535).

2.1. Inclusion and Exclusion Criteria

The following inclusion criteria were applied: (i) studies reporting the health and well-being of women of reproductive age (over the age of 16 years, study population mean age: ≤ 45 years old) with a diagnosis of T2DM; (ii) any of the following outcomes were studied: (a) metabolic outcomes (*e.g.*, glycaemic control, microvascular and macrovascular complications related to diabetes); (b) reproductive health (*e.g.*, pre-pregnancy care or contraception); (c) gender-specific health needs (*e.g.*, physical and psychological outcomes, or sexual problems); (iii) qualitative and quantitative studies reporting data from/on women of reproductive age with T2DM.

The following exclusion criteria were applied: (i) studies reporting on mixed samples where data on women with T2DM were not presented separately from those with other conditions (*e.g.*, type 1 diabetes and gestational diabetes); (ii) studies involving views from only health care professionals; (iii) studies including women with a mean age greater than 45 years; (iv) studies investigating an independent condition associated with T2DM rather than the impact of T2DM (*e.g.*, polycystic ovary syndrome, cancer); (v) studies including literature review, systematic review, review articles and abstracts that do not supply enough information to evaluate the study.

2.2. Search Strategy

A systematic search was performed in the following databases: MEDLINE, PsycINFO, EMBASE, CINAHL, Web of Science, and Maternity and Infant Care. Databases were searched without time and study design limits. Database searches were performed from 1946 to July 2020. Only studies reported in the English language were included because of limitations of translation resources. A systematic database search was undertaken using a combination of Medical Subject Heading (MeSH) that included all sub-terms and sub-heading, and free texts, and truncation and Boolean operator. The following research terms and operators were used: Type 2 diabetes* OR noninsulin dependent diabetes AND women OR female* AND reproductive* OR child bear* age OR sex OR gender differ*. Reference lists of the

identified studies were scanned to identify any additional studies. Topic experts were asked for recommendations of literature, to check the list to identify any known missing study [42].

2.3. Quality Assessment

The Mixed Methods Appraisal Tool (MMAT) was used to assess the methodological quality of included studies. This tool allows researchers to appraise studies with diverse designs [43-45]. The MMAT has established content validity and reliability and has been piloted across all methodologies [45, 46].

An overall quality score for each study was based on the methodological domain-specific criteria. Each criterion is rated on a scale of 'yes', 'no' and 'can't tell'. The quality score is 1/4, which means that one criterion is met (25%). When the quality score is 4/4, it means that all four criteria are met (100%) [47].

Two independent reviewers (AC, SR) undertook the critical appraisal of all included studies. To facilitate comparison of appraisal scores, both reviewers recorded their rationale for study scores and the relevant location in the full-text article. Discrepancies in study quality were resolved through discussion with a third reviewer (RF). The studies were not excluded on the basis of quality assessment as they could still offer valuable insight [48].

2.4. Data Extraction

All studies from the searching process were initially screened by reviewing titles and abstracts to identify relevant studies by one reviewer (AC). The full texts of these potentially relevant studies were retrieved and reviewed by three reviewers (AC, RF, SR). Disagreements were resolved by discussion with other reviewers (JS, AF). For the qualitative and quantitative studies, two standardized, pre-piloted templates were used to undertake data extraction. A single reviewer (AC) was involved in data extraction and uncertainties were resolved in discussion with a second and third reviewers (JS, RF).

The following characteristics were extracted: author, year, country, study design/methods, aims of study, the characteristics of the study sample (*e.g.*, sample size, age range, diabetes duration), main results and themes.

2.5. Data Synthesis

All the data reporting life experiences, health and well-being of women with T2DM were included in this review. Due to heterogeneity in the included study aims and research designs and reported outcomes, a meta-analysis is not appropriate for the quantitative studies. Thus, a narrative synthesis was conducted to present the results of the included studies. The overall approach to synthesis was followed by the data-based converting synthesis design [49], which is becoming the most common type of mixed methods synthesis design. In this synthesis design, all extracted data from the included qualitative and quantitative studies are analysed using the same synthesis method, and the results are presented together. Data transformation is involved since only one synthesis method is used (*e.g.*, quantitative data are transformed into qualitative data such as themes) [49]. Accordingly, a narrative synthesis of qualitative and quantitative studies was completed as described below.

Quantitative and qualitative data were tabulated in a spreadsheet to capture variables investigated. The findings of each study were presented whether they have similar or different findings and analysed in a complementary manner. After that, data were transformed into the narrative interpretation of qualitative results. The results were presented together in the results section. One reviewer (AC) conducted the initial data synthesis, which was then discussed with all reviewers.

3. RESULTS

3.1. Study Selection

A total of 6505 citations were identified from database searches. After 479 duplicates were removed, 6026 titles and abstracts were screened against the inclusion and exclusion criteria which led to the exclusion of 5895 articles. The full texts of the remaining 131 papers were screened for eligibility, and 105 articles were excluded because they did not meet the age range criterion. Further 6 studies were identified through screening the reference lists of the included and relevant studies and the recommendations of topic experts. In total, 32 studies met the inclusion criteria and were included in the systematic review (Fig. **1**) [41].

3.2. Study and Participant Characteristics

Of the 32 eligible studies identified, one was a multinational study including 11 Latin American countries, and the remaining studies were conducted in the following 11 countries: the United States (n = 7), the United Kingdom (n = 9), Turkey (n = 4), Ireland (n = 1), Iran (n = 3), Malaysia (n = 1), Poland (n = 1), Italy (n = 1), Argentina (n= 1), South Africa (n = 1), India (n = 2). The most frequently used methodological design was quantitative (21 studies) and 10 studies were qualitative and one used a mixed method. Study characteristics are presented in Table **1**. Studies were published between 2000 and 2020. The sample size in the included studies ranged from 11 to 14,463 participants and included a total of 30,855 women, of which 19,318 women had T2DM, who are the focus of this review. The focus of the studies were sexual dysfunction (n = 9), blood glucose (n=14), self-care (n=7), cardiovascular risk (n=3), pre-pregnancy care (n=9), contraceptive use (n=3), diabetes complications (n=7), early menopause (n=2), psychological impacts (n=6), and sociocultural impacts (n=6). The lowest mean age of study participants was 30 years [50, 51], and the oldest age was 45 years [52].

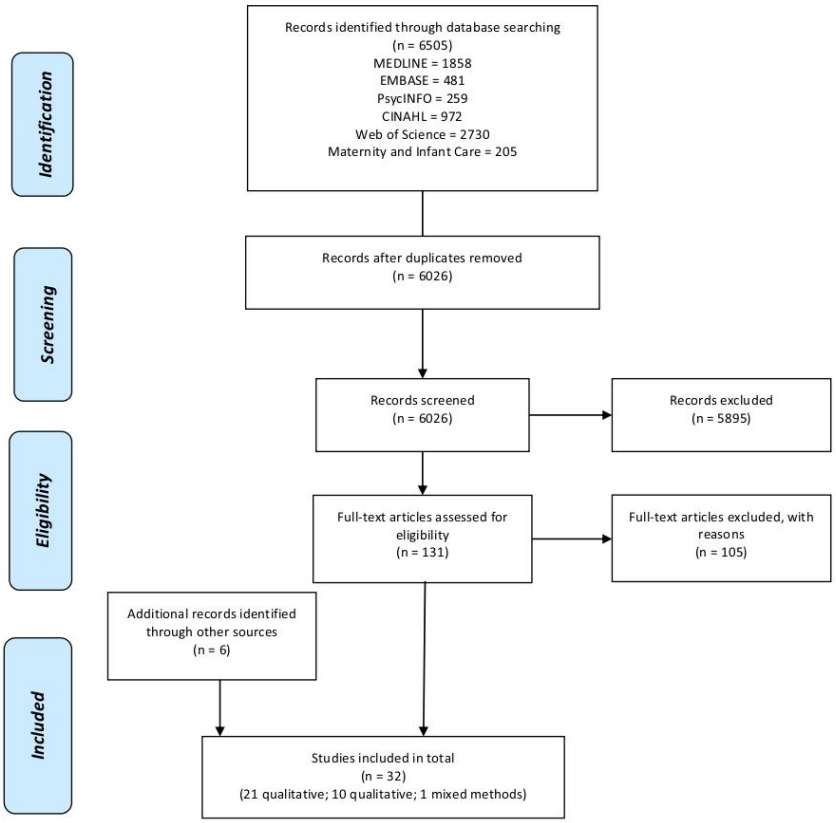

Fig. (1). PRISMA 2009 flow diagram.

3.3. Quality Assessment

The methodological quality of included studies was assessed using the MMAT scoring system [47]. Ten studies were assessed against qualitative criteria, sixteen against non-randomized quantitative criteria, five studies against descriptive quantitative studies, and one study against mixed-methods criteria. The methodological quality of the 32 studies ranged from 25 to 100%. Within this systematic review, four studies were rated 25% (low quality), eleven studies were rated 50% (moderate quality), fourteen studies were rated 75% (moderate quality), and three studies were rated 100% (high quality). The majority of the included qualitative studies (n=10) failed to identify the potential impact of the researchers' epistemology perspective in terms of study design. Of the studies employing quantitative methodologies, three studies did not report establishing an appropriate sample strategy to achieve statistical power; fifteen studies failed to ensure similar participants in groups. Also, the validity of the measures used in the research was not considered in five of the included quantitative studies; the response rate was not reported in nine studies. As a result, the overall quality of studies was moderate according to the MMAT criteria.

3.4. Synthesis Findings: The Impact of Living with Type 2 Diabetes on Women's Health and Well-being

The findings of the included studies were tabulated in a spreadsheet, and then these data were narratively synthesised. In total, 6 main domains were identified from the synthesis of the data: (1) diabetes-related modifiable risk factors (2) reproductive health (3) psychosocial wellbeing; (4) sexual function; (5) menopause; and (6) sociocultural factors (Table **2**).

Table 1. Characteristics of included studies.

Author/Year/ Country/Refs.	Study Design / Methods	Population and Setting	Study Focus	Aims	Main Results / Themes
Impact of Hormonal Variability on Blood Glucose					
Gugapriya *et al*., 2014 India [53]	Prospective observational study	Sample size: 50 women with T2DM Age range (mean, SD): 19-50 years (38±6.49) Diabetes duration: ND Setting: Outpatient clinic	Menstrual cycle	To assess the variability in glycemic control during different phases of the menstrual cycle in women with T2DM using high sensitivity C- reactive protein levels.	- There was an increase in glucose level during the luteal phase of menstrual cycle mediated by hormones ($p<0.05$) - Women with T2DM of reproductive age group had suboptimal glucose control during the luteal phase mediated by endogenous progesterone hormone than other phases.
Cardiovascular Risk					
Garcia *et al*., (2014) Argentina [54]	Cross-sectional	Sample size: 1256 women (293 with diabetes and 963 controls). Age range: (< 40, 40-49, 50-59, and > 60 years). Sample size for <40 years: 27 controls and 10 with diabetes Mean age (SD) for < 40 years group: 34 (1) controls, 35 (1) with diabetes. Duration diabetes: ND Setting: Hospital clinic	Cardiovascular risk	(1) To estimate the prevalence of cardiovascular risk factors among premenopausal and menopausal Argentinean women with and without T2DM and (2) to assess the contribution of total plaque area (TPA) to risk stratification when added to a Framingham risk score (FRS).	- TPA was 75% higher in women with T2DM. - The Framingham risk score (FRS) ($P < 0.05$) and post-test risk scores for acute myocardial infarction ($P < 0.05$) and stroke ($P < 0.05$) were also elevated in the youngest group with diabetes. - Women with T2DM of pre--menopausal age were at intermediate or higher risk of developing a cardiovascular event compared to women without diabetes.
Self-management Activities and Psychological Wellbeing					
Majeed-Aris *et al*., (2015) UK [52]	An explorative qualitative study	Sample size: 15 British--Pakistani women with T2DM Age range (mean, SD): first generation 10 participants were 43–76 years (median 55), while second generation 5 participants were 31–55 years (median 45). Diabetes duration: ND Setting: Community center	Perceived self-management	To explore the effects of T2DM on British-Pakistani women's identity and its relationship with self-management.	- Familiarity with ill health - Diagnosis improves social support - Perceived change in self - Supporting family is a barrier to self-management - Role re-alignment enables successful self-management
Marshall *et al*. (2020) USA [55]	Retrospective cohort study	Sample size: 9,923 women (8,235 women with T2DM, 1,688 women with T1DM) Age range (mean, SD): 18 – 44 years (ND) Diabetes duration: ND Setting: Inpatient and outpatient clinic	Self-management differed by race/ethnicity	To assess the quality of diabetes care in a diverse cohort of women of reproductive age in an integrated system and to examine the extent to which processes and outcomes of diabetes care differed by patient race/ethnicity.	- Of women with T2DM, approximately 31% had the HbA1c of greater than 9%, indicating suboptimal glycemic control. Non-Hispanic Black (15%) and Hispanic (19%) had more likely to have suboptimal glycemic control than Non-Hispanic White. - Fewer than 31% of women with T2DM had the HbA1c of less than 7%, indicating optimal glycemic control. - Among women with T2DM using oral medication, nearly one-third were non-adherent to these medications during the year. Non-Hispanic Black, Hispanic and Asian were more likely than non-Hispanic White women to be nonadherent.

(Table 1) contd....

Author/Year/ Country/Refs.	Study Design / Methods	Population and Setting	Study Focus	Aims	Main Results / Themes
Miller & Marolen (2012) USA [56]	Focus groups	Sample size: 11 African American females with T2DM Age range (mean, SD): 21–50 years old (ND) Diabetes duration: 9.1±7.3 years. Setting: Outpatient clinic	Physical activity-related experiences	To explore physical activity-related experiences, perceptions, and counselling expectations among urban, underactive, African American women with T2DM.	- General Physical Activity/Exercise perceptions - Barriers to Physical Activity - Enablers to Physical Activity - Comparison of Physical Activity - Counselling Expectations and Experiences - Physical activity-related health responsibility - Greater Concern for Healthcare-Related -Needs of Others
Muruoka (2015) USA [57]	Mix method (interviews and document analysis)	Sample size: 20 women with T2DM Age range (mean, SD): 35-49 years (43.35 (±3.6) years) Diabetes duration: 8.95 (±3.43) years Setting: Outpatient clinic	Physical activity-related experiences	To identify factors that may impact African American overweight/obese women with T2DM in their attempts to lose weight and engage in physical activity, and to identify the specific environmental conditions of 38106 and 38109 that may promote or inhibit weight loss and physical activity efforts.	- Factors identified as positively influencing health status and weight loss - Factors identified as negatively influencing health status and weight loss
Miller *et al.*, (2010) USA [58]	Focus groups	Sample size: 31 African American women with T2DM Age range (mean, SD): 21–50 years (ND) Diabetes duration: 10.2±4.9 years Setting: Community center	Physical activity-related experiences and emotional support	To evaluate motivational interviewing (MI) perceptions among rural African American women with T2DM before a physical activity intervention.	- Perceptions of physical activity/exercise - Readiness to exercise - Perceptions of non-MI consultation - Perceptions of MI consultation - Emotional support for negative emotions during focus groups
Miller (2011) USA [59]	A cross-sectional survey	Sample size: 160 African American females (135 completed all SDS-CA questions, 131 all PAID questions, and 108 all CES-D questions). Age range (mean, SD): 21 and 50 years of age (39.1±8.1) Diabetes Duration: 6.4±6.0 years Setting: Community health centre	Self-care and psychological well-being	To describe diabetes self-care behaviours, diabetes-related distress, depressive symptoms, and diabetes-related needs among rural African American women with T2DM.	- Women with T2DM were most likely to take diabetes medications among self-care components (5.5 days/week) and least likely to engage in exercise (3.0 days/week). - The average PAID score was 34.6±23.0, illustrating diabetes related distress. - Almost half of the participants (44%) reported that worrying about the future and complications. - Nearly one-third (31%) felt guilty about inconsistent self--care or fearful about living with diabetes. - Most diabetes-related concerns were about diet (34%) (*i.e.*, what to eat), exercise (30%), taking medications (10%), and finances (8%).
Alcozer, (2000) USA [60]	Interviews (a secondary analysis)	Sample size: 20 women with T2DM Age range (mean; SD): 27-45 years (33±2.8 years). Diabetes duration: 6 years (SD=4.2). Setting: Community centre	Diabetes and its meaning	To explore explanatory models of diabetes from the perspective of Mexican American women withT2DM.	- Defining diabetes - Getting diabetes - Having diabetes - Describing diabetes - Taking care of diabetes - Meaning of diabetes

(Table 1) contd....

Author/Year/ Country/Refs.	Study Design / Methods	Population and Setting	Study Focus	Aims	Main Results / Themes
Montague *et al*., (2005) USA [61]	A descriptive pilot cross-sectional study	Sample size: 75 women with T2DM. Age range (mean, SD): 3 age groups (25-44 years, 45-64 years, and 65-84 years); group 1 (reproductive age, 25-44 years) consisted of 22 women with a mean age of 31.59 years. Diabetes duration: 4.8±3.7 years Setting: Community health center	Self-management	To describe demographic and medical characteristics, self-efficacy, locus of control, self-management defined by functional status, hemoglobin HbA1c outcomes, and the relationships among these variables based on age group differences in African American women with T2DM.	- HbA1c value ranged from 5.5 to 16.6%, with a mean of 8.9% and SD of 2.7 for age group 1 (25-44 years, n = 22). - There were no significant differences among the groups in self-efficacy. - No significant differences were revealed for the 3 loci of control subscales among the 3 groups when analyzed separately.
Knowledge of Women about Pregnancy and their Contraception Use					
Osman *et al*., (2015) South Africa [62]	A prospective descriptive study	Sample size: 115 women (61 women T1DM, 54 women T2DM) Age range (mean, SD): 18 - 45 years (ND) Diabetes duration: ND Setting: Hospital clinic or community health center	Reproductive knowledge	To assess the reproductive knowledge of women with diabetes of reproductive age attending outpatient clinics for the management of diabetes, and their use of contraception, to elicit what counselling women with diabetes received on the implications of their condition with regard to pregnancy and reproductive health.	-Women with T2DM had knowledge with 22.2% in terms of how pregnancy affects diabetes. - There was no association between type of diabetes and knowledge of complications (p=0.082). - Women with T2DM did not differ from those with T1DM with regard to number of intended pregnancies and unintended pregnancies (p=0.248). - Women with T1DM reported a lower rate of contraception use than those with T2DM (P=0.082).
Pre-pregnancy Care					
Lavender *et al*., (2010) UK [63]	A hermeneutic phenomenological approach	Sample size: 22 women (15 women with T1DM and 7 women with T2DM) Age range (mean, SD): 21-42 years Diabetes duration: 2-28 years for T1DM;1-8 years for T2DM Setting: Diabetes clinic	Pre-pregnancy care experiences	To explore the experiences of White British and South East Asian women with T1DM and T2DM, and the perceived impact of diabetes on their reproductive health.	- Relinquishing personal control, - Pregnancy overshadowed by diabetes - Haphazard preconception care.
Murphy *et al*., (2010) UK [50]	Interviews	Sample size: 29 pregnant women (21 with T1DM, eight with T2DM) Age range (mean, SD): 16–45 years (30.0±7.51) Diabetes duration: 13.7±9.1 years Setting: Diabetes clinic	Pre-pregnancy care experiences	To explore the views of women who did not attend pre-pregnancy care, their accounts of contraception, previous pregnancies and the influence of healthcare advice.	- Women's views of pre-conception counselling - Contraceptive behaviours - Knowledge regarding the risks of diabetes during pregnancy - Past pregnancy experiences - Becoming pregnant - Attending pre-pregnancy care
Spence *et al*., (2010) UK [51]	Focus groups	Sample size: 24 women (18 with T1DM and six with T2DM). Age range (mean, SD): 16-40 years (30 (24–38)) Diabetes duration: 2 (1–6) years Setting: Outpatient clinic	Pre-pregnancy care experiences	To determine knowledge and attitudes of women with Type 1 and Type 2 diabetes of childbearing age towards pre-pregnancy care.	- Knowledge - Quality of relationships with healthcare professionals - Women's attitudes to pre-pregnancy care advice

(Table 1) contd....

Author/Year/ Country/Refs.	Study Design / Methods	Population and Setting	Study Focus	Aims	Main Results / Themes
Letherby *et al*., (2012) UK [64]	Interviews	Sample size: 12 women (8 women with T1DM, 4 women with T2DM) Age range (mean, SD): 18-40 years (ND) Diabetes duration: 2-30 years for type 1, 2-17 years for type 2 diabetes Setting: Diabetes clinic	Pre-pregnancy care experiences	To explore the experience of women with pregnancies complicated by diabetes.	- Planning for a baby? - Experience of pregnancy
Forde *et al*., (2019) UK [65]	Interviews	Sample size: 30 women with T2DM, 22 healthcare professionals Age range (mean, SD): 22-44 years (37 years) Diabetes duration: 5.5 (1–15) years Setting: Hospital clinic	Pre-pregnancy care experiences	To consider the experiences and views of women living with T2DM, together with those of their healthcare professionals, on pregnancy and the provision of reproductive healthcare.	- Lack of visibility of pre-pregnancy care in routine Type 2 diabetes care - Perceptions of T2DM - Reproductive intention/potential - Communication on reproductive issues - Accessing pre-pregnancy care - Previous pre-pregnancy care experiences
Earle *et al*., (2017) UK [66]	Interviews	Sample size: 12 women (3 with T2DM, 9 with T1DM) Age range (mean, SD): 18-45 years Diabetes duration: 1 (2) years Setting: Primary care	Pre-pregnancy care experiences	To identify views on the provision of, facilitators of and barriers to the uptake of pre-pregnancy care.	- Pregnancy choices and contraception - Enablers to pre-conceptual care - Barriers to preconception care - Communication with professional carers: patients or partners
Scavini *et al*., (2018) Italy [67]	Retrospective cross--sectional study	Sample size: 14,643 women (6341 women with T1DM and 8302 women with T2DM). Age range (mean, SD): 18–45 years (mean: ND) Diabetes duration: ND Setting: Outpatient clinic	Pre-pregnancy results	To describe selected characteristics, relevant in case of an unplanned pregnancy, of women of childbearing age (18–45 years) with a diagnosis of either T1D or T2D, attending the network of Italian diabetes clinics participating in the AMD-Annals initiative.	- 43.4% (95% CI 42.8–43.9%) women with T2DM had a HbA1c < 7.0% (53 mmol/mol), with increased rates of miscarriages, congenital malformations and perinatal mortality. - Almost half of the women with T2DM (48.1%) were treated with diabetes drugs or ACE inhibitors (15.8%) or stains (13.2%) not approved for use during pregnancy. - T2DM women were more likely to have hypertension (23.3% *vs*. 10.7%) or microalbuminuria (28.6% *vs*. 23.1%) than T1DM women. - 66.7% of women of childbearing age with T2DM had at least one unfavorable condition for starting a pregnancy.
Egan *et al*., (2017) Ireland [68]	Retrospective cohort study	Sample size: 384 women (n = 247 with T1DM and n = 137 with T2DM). Age range (mean, SD): ND (M=32.8 years). Diabetes duration: 14.5 years for type 1; 2.7 years for type 2 diabetes. Setting: Hospital clinic	Pre-pregnancy care	To compare metabolic variables of women with T1DM and T2DM preconception and 12 months post-partum, and to assess for any differences between those who did and those who did not attend structured pre-pregnancy care	- 27.7% (n=38) women with T2DM attended pre-pregnancy care. - Women who attended pre-pregnancy care had a lower preconception HbA1c [46 *vs.* 59 mmol/mol (6.4% *vs.* 7.5%), P = 0.04] compared to that of no pregnancy care. - There was no difference in HbA1c between groups in the third trimester of pregnancy [41 *vs.* 43 mmol/mol (5.9% *vs.* 6.1%), P = 0.29] or post-partum [53 *vs.* 52 mmol/mol (7.0% *vs.* 6.9%), P = 0.74)].

(Table 1) contd....

Author/Year/ Country/Refs.	Study Design / Methods	Population and Setting	Study Focus	Aims	Main Results / Themes
Murphy *et al.* (2010) UK [69]	A prospective cohort study	Sample size: 676 women (405 T1DM and 271 T2DM) Age range (mean, SD): ND (M=31 (25 – 38) T1DM, M=35 (27 – 39) years) Diabetes duration: ND Setting: Hospital setting	Pre-pregnancy care	To implement and evaluate a regional pre-pregnancy care program on pregnancy preparation, glycemic control, and pregnancy outcomes in women with T1DM and T2DM.	- In women with T2DM, the pre-pregnancy care attendance was lower (20%) than T1DM (31%), but pre-pregnancy attendees still achieved significantly better glycemic control before pregnancy ($p < 0.0001$) and the first two trimesters ($p = 0.007$, and $p = 0.03$). - Attendees were less likely to have potential harmful ACE inhibitors ($p<0.005$) and/or statins ($p<0.0003$). - Women with T2DM had less likely to have pre-conception care (29.8 *vs.* 59.8%), folic acid pre-conception (32.9 *vs.* 46%) than women with T1DM. - There were reductions in adverse outcomes (5.3%, $p = 0.0008$) and in malformation (4.5%, $p = 0.009$), and was an increase in metformin use in women with T2DM (54.7%, $p = 0.0003$) over the past decade.
Yamamoto *et al.* (2018) UK [70]	A prospective cohort study	Sample size: 494 women (308 T1DM, 186 T2DM) Age range (mean, SD): 16 – 45 years (ND) Diabetes duration: ND Setting: Primary care centers	Pre-pregnancy care	To develop and evaluate a community-based pre-pregnancy care program with the aim of improving pregnancy preparation in all women with pregestational diabetes (T1DM, T2DM, and others).	-During/after pre-pregnancy care, there was a nearly three-fold improvement in pregnancy preparation in women with T2DM; with almost 60% reaching target HbA1c at conception; and 50% taking preconception folic acid. -There was no change in taking potentially harmful medications (16% before, 12.2% during/after pre-pregnancy care implementation) in women with T2DM.
Sexual Dysfunction					
Bal *et al*., (2015) Turkey [71]	Cross-sectional	Sample size: 176 women (76 Women with T2DM, 100 control group) Age range (mean, SD): 24-47 years (study group 41.47 ± 5.5 years; control group 36.52 ± 8.13 years) Diabetes duration (mean, SD): 15.86 ± 3.35 Setting: Hospital clinic	Sexual dysfunction	To investigate female sexual dysfunction in women with T2DM.	- Significant reduction in the mean Index of Female Sexual Function (IFSF) score (18.94 ± 11.6 ($p < 0.05$)) was associated with increased sexual dysfunction for women with T2DM. - The prevalence of sexual dysfunction is 77.6%. - Increased HbA1c, body mass index, and duration of diabetes related to increased prevalence of sexual dysfunction ($p < 0.05$).
Elyasi *et al.*, (2015) Iran [72]	Cross-sectional	Sample size: 150 women with T2DM Age range (mean, SD): 18-65 years, (42±10.1 years) Diabetes duration (mean, SD): 7.57±5.5 years Setting: Outpatient clinic	Sexual dysfunction	To (i) determine the prevalence of sexual problems in Iranian women with T2DM, (ii) investigate the influences of diabetes-related factors on female sexuality, and (iii) assess the influences of depression and anxiety on sexual function.	- Significant reduction in the mean Female Sexual Function Index (FSFI) score (22) was associated with higher sexual dysfunction in women with T2DM. - Prevalence of sexual dysfunction in women with T2DM was 78.7% (CI: 71.4-84.4). - There were no differences between the presence of sexual dysfunction and age, BMI, HbA1c level, duration of DM and the presence of hypertension, age at

(Table 1) contd....

Author/Year/ Country/Refs.	Study Design / Methods	Population and Setting	Study Focus	Aims	Main Results / Themes
					onset of menopause, type of treatment, and type of oral diabetes medication (p>0.05). - Among the complications of diabetes, diabetic neuropathy was reported the most frequent (57.3%), followed by diabetic nephropathy (25.3%), and major cardiovascular problems (10.7%). - 58.7% of the women reported depressive symptoms and 96.7% reported anxiety.
Erol *et al*., (2002) Turkey [73]	Cross-sectional	Sample size: 132 women (72 women with T2DM; 60 control group) Age range (mean, SD): 25-47 years (38.8 ± 6.6 women with T2DM; 34.7 ± 7.1 control group) Diabetes duration: 6.2 ± 4.7 Setting: Outpatient clinic	Sexual dysfunction	To evaluate sexual dysfunction in women with T2DM and to compare the prevalence of sexual dysfunction symptoms using the IFSF (Index of Female Sexual Function) questionnaire with age-matched controls.	- Reduction in the mean IFSF score (29.3) was associated with increased sexual dysfunction in women with T2DM. - Prevalence of sexual dysfunction in women with T2DM was 51.3%. - There was no significant correlation among HbA1C levels, BMI, duration of diabetes, and presence of nephropathy in women with T2DM, with or without sexual dysfunction (p > 0.05).
Fatemi & Taghavi (2009) Iran [74]	Cross-sectional	Sample size: 90 women (50 women with T2DM; 40 women without diabetes) Age range (mean, SD): < 45 years of age (38.6+6.6 (34–45) and 42.1+5.3 (32–44) years, respectively.) Diabetes duration: ND Setting: Outpatient clinic	Sexual dysfunction	To assess the prevalence rate of sexual dysfunction in women with T2DM, comparing them with an age-matched control group.	- Reduction in the sexual function scores was associated with increased sexual dysfunction in women with T2DM (p < 0.05). - Duration of diabetes and age correlated negatively with all domains of sexual function. - There was no significant relationship between sexual function and body mass index (BMI), glycemic control, education or employment status.
Sharifiaghdas *et al*., (2012) Iran [75]	Case-control	Sample size: 136 women (45 women with T2DM, 91 women without diabetes). Age range (mean, SD): 20–55 years (42.17±5.91 for case group and 34.96±8.30 years for controls). Diabetes duration: 6.35±5.41 years. Setting: Hospital clinic	Sexual dysfunction	To evaluate female sexual dysfunction in T2DM non-menopausal women in comparison with age match non diabetes volunteers.	- There were statistically significant differences in the 3 domains of desire, arousal sensation and pain (p < 0.05), indicating a higher rate of sexual dysfunction in women with T2DM. - There was no significant relationship between sexual function, body mass index, job, smoking, and glycemic control.
Nowosielski *et al.*, (2011) Poland [76]	Cross-sectional	Sample size: 242 females (109 females with T1DM, 133 females with T2DM) Age range (mean, SD): 18–55 years of age (43.6±9.45 years). Diabetes duration: <5 years, 6–10 years, 11–20 years, >20 years. Setting: Outpatient clinic	Sexual dysfunction	To compare sexual behaviors between females with type 1 and T2DM, and to establish the mediators of sexual functions in the population of women with diabetes.	- Significant reduction in the domains of the female sexual function index (FSFI), with the exception of pain, was associated with increased sexual dysfunction in women with T2DM (p<0.05) - There was no relationship between sexual dysfunction and the presence of comorbidities, the duration of diabetes, the presence of diabetes complications, the glycemic control (p>0.05). - The strongest significant predictors of sexual dysfunction were: the presence of depressive symptoms, the importance of sex to the respondent, and satisfaction with the partner as a lover (p<0.05).

40 **(Table 1) contd....**

Author/Year/ Country/Refs.	Study Design / Methods	Population and Setting	Study Focus	Aims	Main Results / Themes
Ismail *et al.*, (2014) Malaysia [77]	Cross-sectional	Sample size: 347 women (173 women with T2DM, 174 women without diabetes) Age range (mean, SD): 42.32 (4.76) years Diabetes Duration: ND Setting: Hospital clinic	Sexual dysfunction	To assess the prevalence and associated factors of orgasmic dysfunction among Malay women with T2DM.	- The prevalence of sexual dysfunction was 13.3%. - Unemployment and lower academic status were associated with sexual orgasmic dysfunction.
Yacan & Erol (2019) Turkey [78]	Cross-sectional	Sample size: 60 women (30 women with T2DM, 30 women with T1DM) Age range (mean, SD): 18-45 years (41.10 ± 5.61 years for T2DM, 18.47 ± 8.12 years for T1DM) Diabetes duration: 4.30 ± 3.98 years for women T2DM. Setting: Hospital clinic	Sexual dysfunction	To determine the effects of diabetes on women sexuality and compare the sexual function of women with and without diabetes	- Reduction in the total score of FSFI (18.70 ± 4.77) was associated with increased sexual dysfunction for women with T2DM. - Women with T2DM experienced less arousal as the duration of their diabetes increased and less arousal and orgasm as their HbA1c value increased ($p < 0.05$). - Of the women with T2DM, 63% (n=19) had chronic complications and 50% (n=15) had retinopathy ($p < 0.05$). Women with T2DM also have more sexual concerns.
Yencilek *et al.*, (2010) Turkey [79]	Cross-sectional	Sample size: 112 women (62 with T2DM and 50 healthy) Age range (mean, SD): 39.2± 9.4 for women with T2DM, 37.6±8.2 for health women) Diabetes duration: (1–5; 6–10, and longer than 10 years) Setting: Hospital clinic	Sexual dysfunction	To compare the factors affecting sexual function in premenopausal women with T2DM using the female sexual function index (FSFI).	- Reduction in the overall FSFI score (23.95±9.42, $p < 0.01$) in women with T2DM was associated with higher sexual dysfunction. - Menstrual disturbance ($p < 0.001$), smoking ($p = 0.01$), and longer duration of diabetes (more than 10 years) ($p = 0.002$) impaired FSFI scores in women with T2DM.
Menopause					
Monterrosa-Castro *et al.*, (2013) 11 Latin American Countries [80]	Cross-sectional	Sample size: 1401 women (319 women with T2DM, 1082 women healthy) Age range (mean, SD): 40-44 years Diabetes duration: ND Setting: Outpatient clinic	Age at menopause	To assess the impact of T2DM on the age of menopause and on climacteric symptoms	-T2DM was associated with early menopause in women under 45 years of age.
Sekhar *et al.*, (2015) India [81]	A prospective cohort study	Sample size: 600 women (300 women with T2DM, 300 healthy) Age range (mean, SD): ND (44.65 years) Diabetes duration: 13.14 years Setting: Outpatient clinic	Age at menopause	To aim at understanding the age of menopause in Indian women with T2DM	-T2DM increased the risk of early menopause.

Abbreviations: BMI: Body Mass Index, CES-D: Centre for Epidemiological Studies Depression Scale, DALY: Disability-adjusted life years, FSFI: Female Sexual Function Index, FRS: Framingham Risk Score, IFSF: Index of Female Sexual Function, HbA1c: Haemoglobin A1c, LGA: Large for Gestational Age, ND: No define, PAID: Problem Areas in Diabetes Scale, T1DM: Type 1 Diabetes, T2DM: Type 2 Diabetes, SD: Standard deviation, SDSCA: Summary of Diabetes Self-care Activities, WCBA: Women of childbearing age.

3.4.1. Diabetes-related Modifiable Risk Factors

The studies reported findings related to the modifiable risk factors of diabetes in women of reproductive age. Four main sub-heading were identified from studies: blood glucose, cardiovascular risk, neuropathy/nephropathy/retinopathy, and diabetes self-management barriers.

3.4.1.1. Blood Glucose

In this review, fourteen studies reported HbA1c values for women with T2DM ranging from 5.2 to 16.6% [55, 61, 65, 68-74, 76, 82-84]. In a study of 50 women with T2DM on the menstrual cycle, Gugapria *et al.,* reported an increase in glucose levels during the luteal phase of menstrual cycle

Table 2. Six domains identified from the narrative analysis.

The impact of T2DM on women's health and well-being
1.Diabetes-related modifiable risk factors **• 1.1. Blood glucose** **• 1.2. Cardiovascular risk** **• 1.3. Neuropathy/nephropathy/retinopathy** **• 1.4. Diabetes self-management barriers**
2. Reproductive health **• 2.1. Diabetes care before pregnancy** **• 2.2 Pre-pregnancy care barriers of women** **• 2.3. Pre-pregnancy care expectations of women** **• 2.4. Contraceptive use**
3. Psychological wellbeing **• 3.1. Depression symptoms and diabetes distress** **• 3.2. Perceptions of T2DM** **• 3.3. Emotional concerns about pregnancy**
4. Sexual function
5. Menopause
6. Sociocultural factors **• 6.1. Social support** **• 6.2. Cultural norms**

mediated by hormones ($p<0.05$) [53], thus women with T2DM are more likely to have higher glucose levels. To address this issue, this study suggested specific adjustments in physical activity, glycaemic control, drug regime and lifestyle behaviour during the luteal phase of menstrual cycle [53]. A retrospective cohort study of Marshall *et al.,* reported racial and ethnic disparities in diabetes care of reproductive aged women with T2DM. 31% of women with T2DM (n=8,235) had suboptimal glucose control (HbA1c>9%), especially non-Hispanic Black women (15%) and Hispanic women (19%) compared to non-Hispanic White women [55].

3.4.1.2. Cardiovascular Risk

Three studies reported that cardiovascular problems were more prevalent among younger women with T2DM comparative to diabetes other populations [54, 67, 72]. A cross-sectional study by Garcia *et al.,* reported the prevalence of cardiovascular risk factors among premenopausal and postmenopausal women who were divided according to age (<40, 40-49, 50-59, >60 years). This study found that women of reproductive age (mid-30s) had 75% higher total plaque area (TPA), which is used in the measurement of atherosclerosis. This rate resulted in elevated acute myocardial infarction and stroke in the youngest women with T2DM. Further, 55.2% of the 36 younger women migrated to a higher risk category [54]. Elyasi *et al.,* reported 10.7% of 150 women with T2DM who experienced cardiovascular problems [72]. Moreover, younger women with T2DM had seven-fold higher rate of obesity (BMI>30 kg/m^2) than women with T1DM and also increased rates of hypertension or microalbuminuria associated with cardiovascular problems and diabetes [54, 67].

3.4.1.3. Neuropathy / Nephropathy / Retinopathy

Seven studies have been reported on micro-vascular complications [54, 59, 61, 67, 72, 76, 78]. The cross-sectional study by Yacan & Erol reported that 63.3% of 30 women with T2DM had chronic complications and 50% had retinopathy. Similarly, Nowosielski *et al.,* reported that 26.36% of 133 women had retinopathy, and 2.33% had diabetic foot syndrome. The most frequently reported complications in the study of 150 women by Elyasi *et al.* were found to be neuropathy (57.3%), followed by diabetic nephropathy (25.3%), and diabetic retinopathy (16%).

3.4.1.4. Diabetes Self-management Barriers

The diabetes self-management activities included concordance with taking medication, diet and exercise considerations, diabetes knowledge and attendance at diabetes self--care activities. In the seven studies, which include three quantitative, four qualitative and one mixed studies, women with T2DM felt confused about self-care in their life [52, 55-61].

In a survey of 160 women with T2DM, Miller (2011) reported taking medication (5.5±2.4 days/week), which was measured using The Summary of Diabetes Self-Care Activities (SDSCA) questionnaire (including the 5 key components of diabetes care: specific diet, general diet, exercise, medication, and blood glucose testing). Exercise was reported least frequently at 3.0±2.1 days/week compared to the other four self-care components. The common reason was reported as a lack of the motivation for maintaining a regimen [59]. This was associated with not seeing immediate results such as weight loss or "being lazy" despite having time to exercise or a general lack of the education concerning how to lose weight and maintain health adequately [56-59].

A cohort study reported ethnic differences in adherence to oral diabetes medication, which one-third of 8,235 women with T2DM exhibiting non-adherence to oral diabetes medication, practically non-Hispanic Black, Hispanic and Asian women compared to non-Hispanic White women [55]. A lack of understanding about how to take medicines was reported by 10% of 160 women in a survey [70]. The rate of eating high fat foods was 3.2 days/week and specific dietary issues were related to uncertainty about eating the right foods such as, what to eat [59]. The higher price of healthier foods was also considered a barrier [59]. In addition to this, competing priorities (*e.g.*, working a full-time job, home maintenance, spending time with family) were expressed a barrier to self-management due to putting the family needs before their own [56, 58].

Women expressed that attending diabetes management classes supported them to better understand how to manage their eating habits and lose weight more effectively [57]. In this case, women emphasised the importance of good communication in terms of the relaxed, comfortable environment, the openness of the consultation, and active patient involvement [58].

3.4.2. Reproductive Health

Four sub-headings emerged in relation to women's reproductive needs and T2DM: diabetes care before pregnancy, pre-pregnancy care barriers of women, pre-pregnancy expectations of women, and contraceptive use.

3.4.2.1. Diabetes Care Before Pregnancy

Nine studies reported that women with T2DM had some knowledge of the risks regarding diabetes during pregnancy, predominantly concerns such as optimizing blood glucose control (80%), the benefits of folic acid and/or possibility of malformations of nervous system (48%), and the risk of a large baby (35%) [50, 51, 62, 66-70, 85]. Some women believed that the baby would be born with diabetes unless diabetes was properly controlled during the pregnancy [66]. Being aware of the risks associated with pregnancy for women with T2DM was reported as an incentive to attend pre-pregnancy care and to follow the advice received [50, 66].

In a retrospective review of the impact of pre-pregnancy care on HbA1c, Egan *et al*., reported that of the thirty-eight women (38/137) with T2DM who attended pre-pregnancy care had a lower HbA1c during the first and second trimester (46 *vs.* 59 mmol/mol, p=0.04), compared to those who had not attended pre-pregnancy care [68]. Similarly, Murphy *et al*., reported that the attendance to pre-pregnancy care was suboptimal (20%), however pre-pregnancy attendees still achieved significantly better glycaemic control before pregnancy ($p < 0.0001$) and the first two trimester ($p = 0.007$, and $p = 0.03$) [69]. The studies identified a need to ensure all women have access to and attend pre-pregnancy care for lower HbA1c [68-70].

A prospective cohort study by Yamamoto *et al*., demonstrated a threefold improvement in 'optimal' pregnancy preparation during and after pre-pregnancy care implementation in women with T2DM (5.8% before, 15.1% during/after, $p = 0.021$) [70]. Of women with T2DM (186 women), 60% reached target HbA1c at conception, and 50% took preconception 5 mg folic acid daily (23.5% before, 41.8% after, $p = 0.001$) [70]. In contrast, Murphy *et al.,* indicated that women with T2DM had less likely to have pre-conception care (29.8 *vs.* 59.8%), folic acid pre-conception (32.9 *vs.* 46%) than women with T1DM [69]. Almost half of the women with T2DM (48.1%) were treated with diabetes drugs or ACE inhibitors (15.8%) or statins (13.2%) not approved for use during pregnancy [67]. T2DM women were more likely to have hypertension (23.3% *vs.* 10.7%) or microalbuminuria (28.6% *vs.* 23.1%) than T1DM women [67]. Similarly, Scavini *et al.,* reported that women with T2DM (66.7% of 8302 women) had a higher risk of unfavourable condition (*e.g.*, hypertension, BMI>30kg/m^2, microalbuminuria) at the start of their pregnancy than women with T1DM (51% of 6331 women) [67]. Therefore, the authors emphasised the need to improve women's awareness about pregnancy risks related to diabetes and how they may be minimised by optimal pregnancy preparation [69, 70].

3.4.2.2. Pre-pregnancy Care Barriers of Women

The barriers to attending pre-pregnancy care were reported in four studies [50, 63, 65, 66]. The main reasons for not attending were attributed to the pregnancy being not 'fully planned' (45%), fertility concerns (31%), negative relationship with HCPs (21%), more complex emotional reasons, including fear of disappointment and wanting conception (17%), or financial concerns (10%) [50]. As barriers to attending, three women who were interviewed also reported being unaware of pre-pregnancy care [50, 66], and disruption to everyday lives [63]. Additionally, women expressed that the information provided was uninformative and did not connect with their intentions for pregnancy or contraception use [65].

3.4.2.3. Pre-pregnancy Care Expectations of Women

The perceived approach of HCPs was reported as a major problem to seeking pre-pregnancy advice in three included studies [50, 65, 66]. Women reported that HCPs mostly focused on medical aspects of diabetes management such as blood glucose level, diet and exercise, rather than the issues to be addressed before pregnancy [50, 65, 66]. Women described that consultation with HCPs was like tick-box exercises as they focused on asking questions from a template that failed to include their reproductive needs [65]. Similarly, Earle *et al.,* reported that women experienced frustration because HCPs looked at the notes and gave general information and did not let women speak. Conversations about folic acid did not always communicate the importance of taking it to protect their baby's health [65]. Another study mentioned that women felt that HCPs did not take their care seriously because they neglected to pass on important information such as the change from tablets to insulin injections to manage their diabetes [51]. Even though HCPs addressed key elements of pre-pregnancy care, women did not feel they had either a clear understanding or correct interpretation of their advice and recommendations [65].

Two studies identified the women's views during diabetes consultations [56, 58]. Women reported their experiences that they expected to have good communication with HCPs in terms of the openness of the counselling, active patient involvement, and the relaxed, comfortable environment [58]. While the other study reported that the conservation between women and HCPs was one-sided and impersonal that HCPs were more responsible than patients for creating a positive communication environment [56, 58].

3.4.2.4. Contraceptive Use

The use of contraception to reduce unintended pregnancies was reported as sub-optimal in the included studies. Osman *et al.,* reported that 44.2% of women with diabetes had an unintended pregnancy, although women with T2DM had a higher rate of contraception use than women with T1DM [62]. Murphy *et al.,* found that women with diabetes used safe and effective methods of contraception, with 72.4% (n=21) reported using an oral contraceptive pill, progesterone injection or intrauterine device [50]. However, some women believed that contraception failure or interaction with intercurrent medications was the cause of their pregnancy [50, 66]. The unexpected effects of prescribed medications like antibiotics or the impact of weight loss on their fertility, resulting in a pregnancy, were also reported by women [50].

Some of the women were confused about their fertility, which suggests the need for clear guidance on women's fertility status [50, 66]. Perceptions ranged from the consequence of diabetes would diminish to the belief that pregnancies were a time when blood glucose came closer to normal because of intensified care [50].

3.4.3. Psychological Wellbeing

The impact of living with T2DM on psychological wellbeing was associated with depression symptoms, diabetes distress, and negative perceptions of living with T2DM, the complexity of T2DM and emotional concerns about pregnancy among pregnant women with T2DM. These feelings were reported by focus groups, survey, and cross-sectional participants [56-59, 61, 72].

3.4.3.1. Depression Symptoms and Diabetes Distress

The studies identified that depression and diabetes distress were frequently expressed by women with T2DM, thus associated with fewer self-care activities [56-59, 61, 72]. In a survey of 160 women, Miller (2011) reported 40% experienced elevated diabetes distress (34.6±23.0) that was assessed using the Problem Area in Diabetes Scale (PAID) [59]. Particularly, worrying about the future and complications (44%) were commonly reported as a serious problem characterized by stress, low mood and resignation to their present circumstances [57, 59]. 31% of women felt guilty and anxious unless they adhered to self-care goals or fearful about living with diabetes (31%) [59]. Denial of diabetes and frustration were prevalent (54%), followed by feeling alone with diabetes (54%) [58, 59].

Nearly half (46%) of the 108 women completing the Centre for Epidemiological Studies Depression Scale (CES-D) reported they "enjoyed life", and over a third as being "happy" (38%) [59]. However, the average CES-D score in women was 20.9±9.4, meaning that 30% had depression symptoms most of the time [59]. In the assessment using the Hospital Anxiety and Depression (HADS), 58.7% of women had depression symptoms and 96.7% expressed anxiety [72]. Some women expressed altruistic intentions that were more likely to put the needs of others above their own diabetes self-care management. These women felt greater concerns for the health-related needs of others with diabetes or other health conditions, and thus altruism for women with T2DM was a barrier to diabetes self-care [56].

3.4.3.2. Perception of T2DM

The perceptions of T2DM in five studies were associated with the feeling of shame, negative self-image, guilt, label, self-blame and psychological complexity in consequence of living with T2DM during their reproductive years [51, 52, 60, 63, 65]. Forde *et al.,* found that some women felt stigmatised and judged by family, friends and healthcare professionals (HCPs) for having T2DM during their reproductive years. As a result of these negative associations, many women reported non-disclosure of their diagnosis to others, including family and HCPs and showed a tendency toward disengagement when communicating with HCPs about their reproductive intentions [51, 65].

In an exploration of women's experiences of living with diabetes, Alcozer reported that the cause of diabetes was defined by women as 'when you are on insulin' or 'sugar in my urine' or 'when you are on renal dialysis' [60]. Taking insulin was also thought by women to be a cause of diabetes complications such as renal disease, blindness and amputations [60]. Having a family history of T2DM was an alert to the symptoms of diabetes, and this was a trigger to seeking diagnosis [52]. For women with T2DM, the studies reflected the psychological complexity of T2DM, the treatment regimens of this condition and the source of diabetes knowledge [52, 60].

3.4.3.3. Emotional Concerns about Pregnancy

In four studies, women felt confused by/about planning for a pregnancy, whether the time was right for themselves and whether they were ready for pregnancy in terms of diabetes [50, 63-65]. The experience of being pregnant could frequently be stressful for women and their families [50, 51, 63, 64]. Women were scared that diabetes can pass on to their babies, and thus decided not to breastfeed them in case they passed diabetes to the baby [63]. Some women were worried about the future of their babies, because they believed that their pregnancy would result in an unhealthy infant [63, 64].

3.4.4. Sexual (Dis) Function

Nine studies revealed the prevalence and mediators of sexual dysfunction, including arousal, lubrication, orgasm,

satisfaction and pain [71-79]. Among studies, the prevalence of sexual dysfunction ranged from 51.3% [73] to 78.7% [72]. Ismail *et al.,* reported the prevalence of orgasmic dysfunction (13.3% of 173 women with T2DM). Women with T2DM scored significantly lower in sexual function questionnaires, ranging from 18.70 [78] to 29.3 [73], which indicates sexual dysfunction. Based on the questionnaires of the female sexual function index (FSFI), Yencilek *et al.,* and Elyasi *et al.,* reported that the most common symptoms of sexual dysfunction were lack of arousal and desire, which were observed in 80.6% and 50%, respectively. According to Yencilek *et al.*, the other issues were lubrication (75.8%), orgasm (69.3%), pain (62.9%), satisfaction (61.3%), and desire (41.9%).

The majority of studies found a negative correlation between sexual dysfunction and some mediators, including longer diabetes duration, higher HbA1c, BMI, older age, those experiencing menstrual irregularity, those who smoke, are unemployed or have lower academic attainment. The decreased mean scores of sexual functions indicate higher sexual dysfunction [55, 58, 61-63]. Conversely, other studies found there was no correlation between sexual dysfunction and the mediators that were the important risk factors for sexual dysfunction (*e.g.*, age, HbA1c) [72-76]. Nowosielski & Skrzpulec-Plinta (2011) and Elyasi *et al.,* pointed out that the strongest statistical predictor of sexual dysfunction was the presence of depression symptoms rather than the other mediators [72, 76].

3.4.5. The Menopause

Two studies reported the association between T2DM and age at menopause [80, 81]. Monterrosa-Castro *et al.,* investigated the impact of diabetes and menopausal onset in 1082 women aged 40 to 44 years living with T2DM from 11 Latin American countries, and they found a statistically significant association between T2DM and early menopause in women under 45 years of age. Similarly, the study by Sekhar *et al.*, reported that 158 out of 300 women with T2DM had an early menopause (<45 years). The average age of menopause among women with T2DM was 44.65 years, compared to that of women without diabetes (48.2 years) [81]. This result indicated that T2DM increased the risk of early menopause [81].

3.4.6. Sociocultural Factors

Social and cultural factors had a significant impact on following a healthy lifestyle in women with T2DM, leading to better health outcomes [52, 56, 57].

3.4.6.1. Social Support

The social factors, including family, neighbours and friends, were reported to be key to increasing self-care in terms of consistency and motivation [52, 56, 57]. Having a supportive person in their life facilitated long-term physical activity and health maintenance [56]. Women who had greater social connections within their neighbourhoods expressed more engagement with physical activity, whereas those living in unsafe areas were less likely to be active [57].

Family support was expressed as an encouraging factor in engaging in self-care, most commonly in the completion of household chores [52, 57]. Women who shared the advice provided by healthcare professionals with their family members, partners and children were more supported with self--care behaviours, as they were offered reminders of the necessary changes to diet and exercise patterns [57]. However, Miller *et al.,* reported that 64% of 160 women in their study were not supported by their friends and family in their diabetes management efforts. Lack of family support was perceived as a discouraging factor in engaging healthy lifestyle [52, 57]. Also, some women obtained beneficial information from friends who shared diabetes information and self-care practices such as supporting healthy eating [52].

3.4.6.2. Cultural Norms

Only two qualitative studies conducted in the US and UK reported the value of traditional remedies [52, 60]. Women spoke of traditions that their grandmother followed to take care of their diabetes, such as the intake of garlic or Davila tea [52, 60]. Some women did not see these traditions or spiritual rituals as appropriate even though some may be helpful to them, while others emphasised the importance of sharing this knowledge [60].

Three Asian women in the qualitative study by Murphy *et al.,* reported that both their own religious beliefs and their husband's views influenced their contraception use. In this study, women expressed a range of views such as that contraception was not necessary as they would not conceive due to their diabetes, or that it was not safe for them to take oral contraception [50]. The beliefs of some women might have resulted in suboptimal contraception usage [50].

4. DISCUSSION

4.1. Main Findings

All the studies included in this systematic review have aimed to identify the impact of T2DM on the health of younger women aged 16-45 years. This synthesis, generated from the qualitative and quantitative studies, has provided a better understanding of the health issues encountered by women with T2DM, specifically reproductive, psychological, cardiovascular, sexual, and early menopause. The evidence shows that the followings need to be emphasised in the care of women of reproductive age: (1) the diabetes-related modifiable risk factors, including blood glucose, cardiovascular risk, self-management activities, diabetes complications; (2) reproductive health needs related to women's diabetes knowledge before pregnancy, pre-pregnancy care barriers and expectations, contraceptive use; (3) psychosocial impacts of T2DM, including depression symptoms, diabetes distress, the perceptions of T2DM, stigma, family and friend relationships; (4) sexual dysfunction; (5) menopause; (6) sociocultural factors.

In this systematic review, one of the major findings is the fluctuation in glycaemic control ranging from 5.2 to

16.6% among women of reproductive age. Especially, Gugapriya *et al.,* found an association between the menstrual cycle and HbA1c and concluded that HbA1c levels demonstrated a statistically increase in luteal phases of the menstrual cycle. This finding is consistent with the results of Barata *et al.,* who reported an increase in hyperglycaemia in the luteal phase among women with T1DM compared with the follicular phase [86], thus indicating that the menstrual cycle in women with T2DM should be taken into consideration in terms of careful monitoring, drug regime and lifestyle adjustment when planning self-care due to the fluctuation in glycaemic level.

This review showed that women of reproductive age with T2DM were likely to experience 75% higher cardiovascular problems and 6% greater likelihood of having coronary heart disease aged <40 years [54]. This result is consistent with the meta-analysis of Peters *et al.,*based on data from 64 studies, which reported that the relative risk of incident coronary heart disease was 44% greater in women with diabetes than men with diabetes [87]. Likewise, younger adults with diabetes, especially younger women, had a 14--fold hazard of myocardial infarcts compared to control groups without diabetes [88].

The literature suggests that diabetes self-care activities are the cornerstone of diabetes care to achieve optimal glycaemic control and to prevent complications [89, 90]. This review highlighted the lack of understanding of the components of diabetes care; general diet, exercise, medication and blood glucose testing [56-59, 61]. There is a need for a clear and motivational guideline to improve self-care activities of women of reproductive age.

Two quantitative studies in this review also emphasised that the attendance to pre-pregnancy care was suboptimal among women with T2DM [68, 69]. This finding of overall suboptimal pregnancy preparation was supported by a cohort study in the UK [85] which showed that only 37% of women with T2DM and 14.3% of women with type 1 diabetes achieved the National Institute for Health and Care Excellence (NICE) guidelines HbA1c target of <6.5% (48 mmol/mol) [85, 91]. Furthermore, women with T2DM were less likely to take the recommended 5 mg dose of folic acid before conception compared with women to those with T1DM (22.5% *vs.* 46.1%, p<0.001) [85]. In case of an unplanned pregnancy, it would be associated with an increase in the rate of congenital malformation, miscarriages, and perinatal mortality [92, 93]. As a result, this review highlighted the importance of pre-pregnancy care and the need to increase the level of preparation for pregnancy, which is essential not only to avoid the potential consequences of T2DM but also to assure the health of infants and mother.

While the literature suggests the use of contraception as a fundamental part of pre-pregnancy care in preventing or reducing some of the maternal and neonatal complications [94], not all women with T2DM in this review appeared to understand the importance of contraception and they had a lack of information about fertility status. Thus, women with T2DM need to use a reliable method of contraception to avoid a high-risk unintended pregnancy. Some women were also more likely to be influenced by family support, religious beliefs and their partner's desire for pregnancy. Interventions may need to consider not only the women's views but also their spouses, families, religions and ethnic communities, such approaches might enhance the awareness of pre-pregnancy care and the use of reliable contraception methods.

Miller *et al.,* in this review reported the rates of diabetes distress and depression symptoms (40% *vs.* 30%), and women with T2DM experienced a high level of emotional distress stemming from their worries about the future and the risk of complications and feelings of guilt when not engaging with self-care [59]. These findings concur with those of others in concluding that diabetes distress and depression symptoms were associated with female gender, increased HbA1c, T2DM duration, and so resulting in sub-optimal self--care [5, 95-97].

Women also felt stigmatized because of feelings of shame and blame and guilty in consequence of living with diabetes. Further, women demonstrated a tendency toward unwillingness to talk about their reproductive intentions when communicating with HCPs or others (*e.g.*, family, or friends). Previous studies identified that increased stigma perception was associated with being female, and they found that diabetes stigma adversely affected the emotional and diabetes management aspects of their lives [98-100]. Sturt *et al.,* suggested that motivational interviewing and psycho-educational interventions can reduce diabetes distress linked to blood glucose and diabetes-related behaviours [5].

The aggregated evidence in this review was the higher prevalence of sexual dysfunction ranging from 51.3% to 78.7% in this review. The most recent meta-analysis, in agreement with this finding, reported that the overall prevalence of sexual dysfunction in women with T2DM was 68.6% [101]. Sexual problems have been shown to be common in women, and thus sexual health is an important part of diabetes care, which is especially neglected in women [102].

The present review indicated that T2DM increased the risk of early menopause [80, 81]. However, the European Prospective Investigation into Cancer and Nutrition (EPIC) study by Brand *et al.,* found no statistically significant association between diabetes and menopausal onset [103]. The most recent systematic review showed that the quantitative association between T2DM and menopausal age was unclear [104].

The review has identified a notable absence of intervention studies for this population despite these wide-ranging and considerable health burden. Another relevant result to take into account when assessing the impact of diabetes in women is that eating disorders and urinary tract infection are the important factors to explore [105-107]; therefore, more research is needed to better understand the impact of T2DM and to develop more targeted and effective interventions.

4.2. Strengths and Limitations of the Review

This study is the first systematic review examining T2DM impacts on the health of women of reproductive age, using a comprehensive search strategy and PRISMA methods. The protocol of this review was published on Prospero. The findings represented a diverse population with T2DM across the different countries, ranging from Europe to Asia. Six databases were used to find relevant studies.

However, the review only included the studies written in English, so they may be subject to language bias. The moderate MMAT scores attributed to the majority of studies mean that the finding of this review should be treated with caution. Further, the generalisability of quantitative studies was restricted due to the issues with sampling across studies identified in MMAT. No grey literature was included; hence some relevant studies could have been missed.

CONCLUSION

Several recommendations are presented for research and clinical practice to facilitate the understanding of the impact of T2DM on women with T2DM during their reproductive years. More longitudinal studies, which link the severity of complications and quality of life associated with diabetes management, are needed to clarify the benefits, barriers and modifying factors. In addition to qualitative and quantitative studies aiming to illustrate women's educational, reproductive, psychological, sexual, and other health needs, it can be recommended that interventions are needed specifically for this population to improve and/or maintain health broadly.

Reproductive issues emphasised in this study highlight the need for improved pre-pregnancy care and contraception use. Women are affected by emotional and psychological problems associated with poor self-care activities. Treatment of emotional issues should include psycho-educational or motivational interventions, lifestyle changes, and appropriately selected medical therapy. Also, HCPs should be aware of the high prevalence of self-image problems in younger women with diabetes and need to demonstrate support and empathy.

There is a paucity of research in some likely important areas such as eating disorders, menstrual cycle on blood glucose regulation. Hence, further research is needed to explore the health needs, views, experiences of living with T2DM relating to the barriers, facilitators or needs that they face during reproductive years.

Further, due to differences in cultural norms, the studies should focus on the cultural differences that can affect self--care activities. Family members should be encouraged to attend diabetes management programs so that they can support women with T2DM effectively.

This study has also identified a higher level of sexual dysfunction among women, which is treatable and may improve quality of life and glycaemic control. Also, in women, T2DM can be linked to early menopause; thus HCPs should be aware of these issues to improve long-term conditions.

In conclusion, this review highlighted wide-ranging health issues affecting women of reproductive age with T2DM, which, due to the rising prevalence in this age group, represent an important focus for health services research and health care delivery. Future research needs to address these underlying issues to improve women's health and well-being living with T2DM.

CONSENT FOR PUBLICATION

Not applicable.

STANDARDS OF REPORTING

The review was conducted and is reported following the adopted Preferred Reporting Items for Systematic Review and Meta-analyses (PRISMA) of qualitative and quantitative evidence. For transparency, the protocol of this review was registered at the International Prospective Register of Systematic Reviews (PROSPERO) database (Registration number: CRD42019146535).

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CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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SUPPLEMENTARY MATERIAL

PRISMA checklist is available as supplementary material on the publisher's website along with the published article.

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2.5 A specific discussion on reproductive age ranges

In women, reproductive age is the time between menarche and menopause. There is no universally agreed, or absolute age range for this phase in a woman's life. A number of definitions have been proposed, such as that by the World health Organization (2006) which suggest the reproductive age for women is between 15 and 49 years of age. Gopalan et al. (2020), exploring initial glycaemic control and care in young adults diagnosed with T2DM, consider this period to range from 21 to 44 years of age. Furthermore, McCarthy et al. (2022) included women aged 16-50 years of age as the population of reproductive age in their study to identify recruitment strategies in a reproductive health survey through social media. Kieffer et al. (2006) when assessing health behaviours among women of reproductive age with or without a history of GDM, defined reproductive age as between 18-44 years. Consequently, there is not a clear definition of this of time period. For this PhD research, the reproductive age is considered as between 18 to 45 years of age, reflecting on the experiences of living with T2DM and diabetes care in this population during their reproductive years. However, for this systematic review, when running preliminary searches, it was apparent that including women aged 18-45 in the search criteria resulted in a significantly lower number of hits. Therefore, the decision was made not to include the 18-45 age range in the search criteria (see Appendix A.1.1). The studies assessing young women over the age of 16 years and with a mean age of 45 years old were chosen, as this is an age range where young women are likely to reflect their reproductive health experiences and start to self-manage their condition. Thus, a greater expansion of age ranges allowed the relevant studies to be retrieved (Papaioannou et al., 2009). These ages were agreed through the consensus of the researcher and supervisory team.

2.6 Implications of the systematic review for the thesis

The systematic review identified the specific known health issues affecting women of reproductive age with T2DM. These consist of modifiable risk factors, including high levels of cardiovascular risk; reproductive health issues, such as pre-pregnancy care and contraceptive use; phycological wellbeing, such as high levels of depression symptoms and distress; and sociocultural factors (e.g., cultural norms). The results of this review are used to

identify potential intervention targets to improve health and wellbeing among young women living with T2DM during their reproductive years.

However, the majority of the included studies consisted of cross-sectional studies that show the prevalence of health issues at one given point in time, and this creates an unclear picture as to why women experience such physical and psychosocial challenges and limits our understanding of their experiences of diabetes (e.g., in social relationships) and healthcare needs. The qualitative studies included in this review only focused on specific points in time during the reproductive lifespans of women, such as pre-pregnancy care. However, women's reproductive lifespan ranges from menstrual cycle to menopause. None of qualitative studies identified the experiences of living with T2DM and diabetes care among young women of reproductive age (18-45 years). Furthermore, this review reported a notable absence of intervention studies for this population, suggesting the development of more targeted and effective interventions may be needed. Therefore, this review has illustrated the need for further research to comprehensively explore the experiences of, and views on living with T2DM in their reproductive years, identifying their health needs to inform strategies or future interventions to improve their health and wellbeing.

From the systematic review findings, a qualitative study is needed first to explore the diabetes and diabetes care experiences of young women with T2DM to develop a better understanding of living with T2DM and facilitate the development of effective interventions. Afterwards, further investigation of the health issues identified from the qualitative study will broaden the understanding of living with T2DM at reproductive age, quantifying the health issues which could be targeted in any future interventions. To address these research gaps, an exploratory sequential design was proposed in this thesis, initially using a qualitative study to provide an in-depth understanding of women's experiences and views. This is then followed by a quantitative study to quantify the identified health issues. The following chapter will further discuss the rationale and challenges of a mixed methods approach, along with the methodological approaches of the thesis.

2.7 Chapter summary

The systematic review presented in this chapter was the first to synthesise findings on the impact of living with T2DM on young women's health and wellbeing, providing an insight into emotional, reproductive, and psychosocial health issues during their reproductive years. While this review represented a major step forward in this population, reviewing the known health issues encountered by young women with T2DM, a deeper understanding of living with T2DM among young women of reproductive age is still lacking, along with the paucity of intervention studies for this population. This review demonstrated the evidence gaps in this population. To address these gaps in knowledge, it suggested further research to comprehensively explore the experiences and health needs of women with T2DM during their reproductive years to inform the strategies or future interventions for this population to improve their health and diabetes outcomes. The following chapter will discuss the methodological approaches taken to achieve the overall aim of this PhD thesis, which is to develop a comprehensive understanding of how T2DM affects the lives of women during this period of their lives. It will critically present and justify the methodological approaches used for comprehensively exploring the health needs of young women with T2DM. It will also outline the rationale for choosing the frameworks, study designs, and methods used in this PhD project.

Chapter 3 – Methodology

3.1 Chapter Overview

This chapter details the methodology followed in this PhD project. It outlines and discusses methodological approaches to developing and evaluating complex interventions in health. It provides a rationale for application of the MRC Framework (Craig et al., 2008) for the development and evaluation of complex interventions in relation to this study. Each phase of the MRC framework is discussed, as is how the MRC framework will be applied at each stage of this PhD project. This doctoral study focuses on the development stage of the framework that includes "identifying evidence base, identifying theory, and modelling process" (Craig et al., 2008), which aims to inform the future development of complex interventions to improve health outcomes and wellbeing in women of reproductive age with T2DM. This chapter also outline three theoretical concepts that underpin this study. Corbin and Strauss' model of living with a long-term condition provides a holistic perspective on women's lives with T2DM during their reproductive age (Corbin & Strauss, 1988). The Capability, Opportunity, Motivation – Behaviour (COM-B) model (Michie et al., 2014) is used to understand the many different behaviours, and then help analyse the relevant behaviours for women. Finally, self-efficacy theory is used to interpret women's ability to conduct a specific activity and behaviour and to enhance self-efficacy (Bandura, 1977).

3.2 Complex intervention development in health

Complex interventions include a number of interacting components (Skivington et al., 2021b; Craig et al., 2008). Diabetes self-care interventions are complex interventions. An intervention for people with T2DM needs to have contextually tailored diabetes management approaches and various interconnected components, which include method of delivery – such as, is the intervention web-based, group-based, or one-to-one; content – this needs to be gender-specific, also the socially or culturally perceived needs of women with different socio-economic or ethnic backgrounds need to be considered; context – where will it be delivered/accessed, is the programme for use in primary or secondary care or home

use; intervention design and components – what would be involved, such as video-, tool-, text-based information provision. It also needs to be implemented by different HCPs who include nurses, doctors, and dietitians.

Developing and assessing complex interventions is challenging, and to optimise the effect much rigour is required in planning, decision-making processes, and the design and inception of an intervention (Hoddinot, 2015). By transparently reporting the intervention development phase, methodological rigour will be improved, and everyone may learn from the experiences of others (Hoddinot, 2015). However, an estimation of 85% of research activity has been attributed to 'research waste' in healthcare due to poor question selection, insufficient attention to previous research results, poor intervention description, and poor reporting (Bleijenberg et al., 2018; Ioannidis et al., 2014; Chalmers & Glasziou, 2009). Inadequate description of complex interventions results in an inability to replicate and to assess for transferability (Candy et al., 2018). Development of an effective intervention relies more on established guidance and evaluation to optimise the translation of research into practice (Craig et al., 2008; O'Cathain et al., 2019; Craig & Petticrew, 2013).

3.3 The use of theory in complex interventions

A theory provides a common description of what is known within an organisation and is defined as a systematic way of understanding situations and events. A theory is a set of definitions, propositions, and concepts that explain and predict these events and situations by illustrating the relationships between variables (Michie & Prestwich, 2010). Developing a complex intervention is challenging due to problems in assessing and identifying the effects of various components of the intervention (Blackwood, 2006). Thus, utilising a theory in developing and evaluating interventions has several benefits. Firstly, a theory can be used to inform an intervention by identifying key concepts in the theory (constructs), facilitating an understanding of what works across different contexts and population (Michie et al., 2008). This means that identifying key concepts in the theory can inform an intervention via appropriate target behaviour (Michie & Prestwich, 2010). Additionally, theory provides the means for selecting component intervention techniques by identifying theoretical constructs to target, and for tailoring or refining intervention techniques (Michie et al., 2008). Secondly,

conducting an empirical study with a theoretical framework facilitates the accumulation of evidence about effectiveness across a range of populations, contexts, and behaviours. Thirdly, theory-based intervention not only inform intervention development but can aid understanding of why interventions are effective or ineffective, thereby providing an understanding of mechanisms of change (Michie & Prestwich, 2010). In the absence of a theoretical underpinning, intervention design is subject to implicit bias, thus transferability can be limited due to poor understanding of intervention design and its effect (Michie & Abraham, 2004).

Despite the apparent advantages of using theory for intervention development, a substantial proportion of studies fail to make explicit reference to theory (Trifiletti et al., 2005; Dombrowski et al., 2007; Fishbein et al., 2007). This leads to inconsistent or unclear results in the literature. For example, some interviews report the greater effectiveness of interventions grounded in theories (Webb & Sheeran, 2006), while the others find a small or no association between theory and intervention effectiveness (Baban & Craciun, 2007; Michie & Prestwich, 2010). These result from the theory being used as a 'loose framework', such as a passing reference being made, rather than theory being an integral part of a rigorous scientific process with the details about how the theory informs the design or evaluation of the intervention (Michie & Prestwich, 2010; Rothman, 2004). To address this issue, adequate reporting of the specific intervention components and theory underpinning such interventions are needed to extend the evidence base and to facilitate evidence synthesis (Bobrow et al., 2018). Comprehensive reporting of theory may lead to a systematic approach to identification of theory and evidence, and to guide further intervention development and evaluation. Furthermore, following a systematic approach in the development and evaluation of complex interventions may provide insight to the process underlying any intervention effects, including which settings interventions work and for whom, to inform and improve the development, evaluation, and implementation of future interventions (Lakshman et al., 2014). In addition, Oakley et al. (1995) noted that providing an intervention description allows for the replication and external validity of intervention evaluation (e.g., the context of the intervention).

3.4 Intervention development frameworks

HCPs, patient groups, policy makers, or researchers develop interventions, innovations, or programmes to improve health and wellbeing (O'Cathain et al., 2019). Successful intervention development is characterised by being scientific and rigorous, resulting in feasible and effective interventions that can be implemented in real-word settings (Turner et al., 2019; Duncan et al., 2020). However, problems arise in the evaluation and implementation of complex interventions because how the intervention was actually developed is not explicitly detailed (Campbell et al., 2000; Duncan et al., 2020). In this process, the use of an intervention development framework can support the selection of a systematic, comprehensive, and transparent approach to intervention development, which is relevant to the intervention content (Duncan et al., 2020). Careful development of a complex intervention is necessary so that new interventions can be effective, and feasible when evaluated and adopted in real-world healthcare systems (O'Cathain et al., 2019). To enhance the effectiveness and feasibility of an intervention, as well as being able to replicate the success of the intervention, this thesis is guided by the use of a complex intervention framework. The rationale for the choice of framework is discussed in this chapter in section 3.5. Further description of its application to this PhD project is then described in section 3.6.

3.5 The Medical Research Council (MRC) Framework for complex interventions

The MRC framework was originally published in 2000 (Campbell et al., 2000), providing guidance for the development and evaluation of complex interventions (Campbell et al., 2000). The initial version of the MRC framework presented a stepwise approach, including a pre-clinical phase, and four subsequent phases focusing on the modelling of interventions, conducting exploratory trials, a definitive randomised control trial, and finally considering long-term implementation (Figure 1) (Campbell et al., 2000).

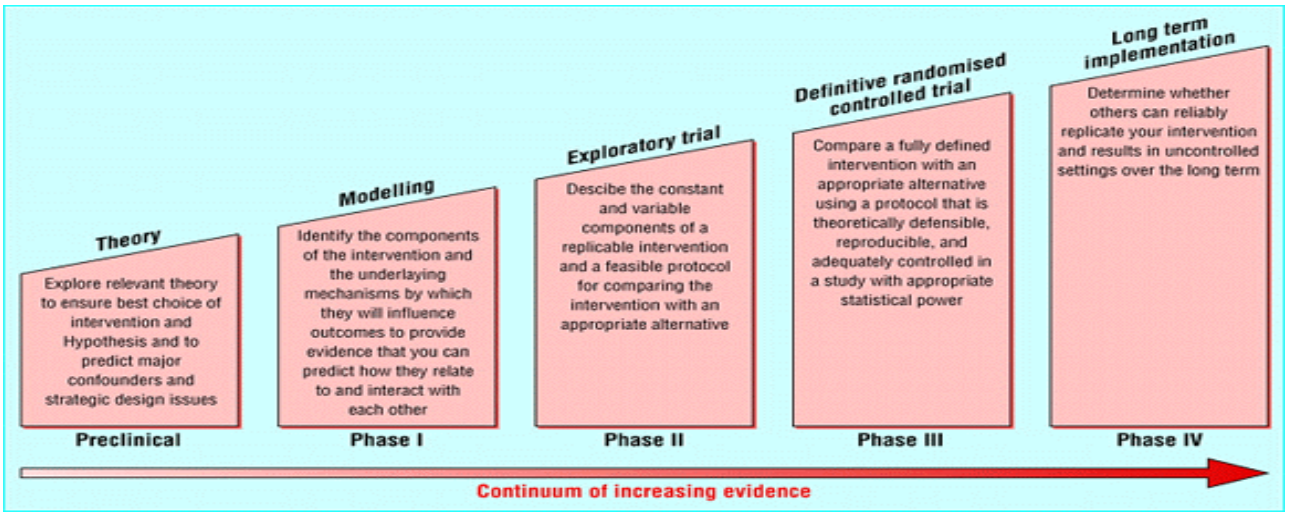


Figure 1 The original MRC Framework (Campbell et al., 2000)

Despite the impact of the original MRC framework on the research community, a number of limitations were identified such as how to deal with highly complex or non-healthcare sector interventions, and the limited guidance on how to approach the development and implementation phase of studies (Campbell et al., 2007). In addition, the diagram of the framework implied a linear stepwise approach which did not reflect the complexity of the multiple components of intervention development (Massoud et al., 2016, Campbell et al., 2007), and there was a lack of attention to the geographical, social, and political context in which interventions take place. When the intervention context is not clear, its scope is limited, and it is difficult to define whether it is applied to an appropriate context (Campbell et al., 2007). While this initial framework emphasised RCTs as the primary method of establishing intervention effectiveness, there was little consideration as to whether intervention outcomes would be effective or transferable to other contexts (Blackwood et al., 2010). Corry et al. (2013) reported that there was little attention given to modelling and testing for acceptability in the development phase of interventions, despite the emphasis on the importance of the development and modelling phases.

The subsequent version of the MRC framework (Craig et al., 2008) provided a more flexible and iterative process, which addressed the issue of linearity among the first three phases and to better understand the intervention components and the evaluation (Massoud et al., 2016). There was also a certain recognition that the evaluation of complex interventions that was not limited to RCTs is challenging, and the contributions of other types of experimental

or non-experimental studies were acknowledged for evaluation purposes (Craig et al., 2008, Blackwood et al., 2010). The 2008 MRC framework aimed to develop interventions systematically, using best available evidence and appropriate theory followed by testing with a series of pilot studies targeted at each of the key uncertainties of the intervention design, and progressing on to an exploratory and a definitive evaluation, and dissemination of the results (Craig et al., 2008). There was an emphasis on the intervention context, which recognised the social, political, geographical factors that may affect the development and evaluation of the intervention (Shahsavari et al., 2020; Craig et al., 2008).

This second version of the framework outlined four stages encompassing the development, feasibility and piloting testing, evaluation, and implementation of an intervention (Figure 2).

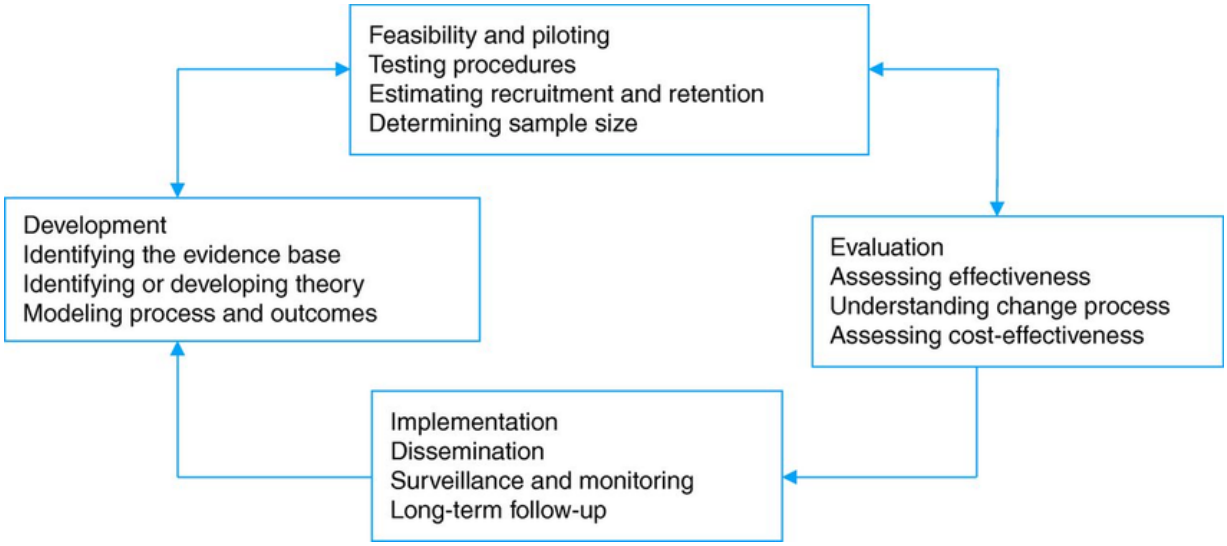


Figure 2 Revised and updated MRC framework for the development of an intervention (Craig et al., 2008).

Firstly, the development phase of the framework includes identifying the evidence base, identifying or developing theory, and modelling process and outcomes. It aims to identify the relevant evidence, ideally by carrying a systematic review and involving the development of the intervention's theoretical rationale, and further providing important information about the design of development and evaluation. Secondly, the feasibility and piloting phase aims to test the procedures for their acceptability, including the calculation of likely sample size, the rates of recruitment, and retention of subjects. Following this, evaluations of complex interventions aim to choose appropriate designs in terms of their suitability to

different questions and circumstances, including randomised or non-randomised experimental design. This phase includes understanding effectiveness, understanding the change process, and assessing cost-effectiveness. Finally, the implementation phase involves stakeholders in the choice of question and design of research to ensure relevance. It has a chance of getting the research findings translated into routine practice or policy, taking into account the context and identifying the element relevant to decision making such as harms, benefits, and costs. Thus, this phase includes dissemination, surveillance, and monitoring, and long-term follow-up to optimise the effectiveness of the intervention and its long-term efficacy (Blackwood et al., 2010).

Despite the broader approach of the updated framework (Craig et al., 2008), several studies identified that it still contained some limitations. First, there is little mention of the context of the intervention research. Moore and Evans (2017) reported that the MRC guidance for complex interventions did not consider context when explaining intervention development, and only provided limited discussion on the role of contextual factors (e.g., physical, socio-demographic features of the healthcare or health system in which interventions are implemented) in modifying intervention effects. The interventions specify mechanisms, linking actions to outcomes, however there is little attention to how those mechanisms function across time and space. Context is vitally important as it helps the researcher with regard to what 'works' in one time, thus it should be examined how interventions interact with context. Second, the MRC framework identifies three broad stages of intervention development: identifying the evidence-base, developing theory, and modelling process, but it does not break down these stages any further (Wight et al., 2015). Therefore, Bleijenberg et al. (2018) criticised the limited explanation provided for the development phase of the MRC framework, expressing a need for a comprehensive revision.

A more recent update of the MRC framework was published by Skivington and colleagues (2021a) to address some of the limitations of earlier iterations, drawing on previous guidance developed by O'Cathain and colleagues (2019). Skivington et al. (2021a) provided the framework about the adoption of an existing intervention for a new context or choosing an intervention that already exists (or is planned), either via policy or practice. They also referred to the guidance of O'Cathain and colleagues (2019) on a new intervention development, rather than replicating it. This guidance recommends actions for consideration

when developing interventions (O'Cathain et al., 2019). These include seeing the intervention development phase as an iterative process, involving stakeholders (e.g., public and patient involvement (PPI) members), reviewing published research evidence, drawing on existing theories, articulating programme theories, undertaking primary data collection, understanding context, paying attention to future implementation of the intervention in the real world, and designing and refining intervention. O'Cathain et al. (2019) suggested that each action should be considered by addressing its relevance to a specific intervention in a specific context. Thus, actions were incorporated in this thesis (Table 2) to enhance the consideration of the context, which may include individuals or population, geographical setting, and social, economic, cultural, and political influences such as funding or policies. Furthermore, Bleijenberg et al. (2018) suggested four additional approaches within the development phase of the MRC framework (Craig et al., 2008), to include problem identification and definition, determination of the needs, and examination of the practice and intervention design (Figure 3). These approaches provide in-depth understanding of the development phase of the MRC framework, including intervention context.

Problem identification and definition provides for the identification and operationalisation of the problem that is an essential part of research, and for insights into the current gaps in the specific context (Aranda, 2008). Thus, qualitative methods, including in-depth interviews or focus groups, are useful to analyse the specific nature of the problem.

Determine needs provides a thorough understanding of the needs, perceptions, preferences, and capacities of participants, which needs to be incorporated in the development process. Investigating the needs of participants provides those parts of an intervention that are most likely to be adopted, for example, how the proposed intervention can be tailored concerning content, intensity, and dose. The COM-B model is used to understand the many different behaviours to be targeted in possible interventions/care pathways (Michie et al., 2014). Qualitative methods are valuable in terms of being able to identify the needs, perceptions, and capacities required to better understand individual barriers and needs (Ludvigsen et al., 2013).

Examine practice aims to explore the context where the intervention will be implemented by exploring enablers and barriers concerning the proposed intervention among participants and providers to enhance the effect of the intervention that fits the current practice (Moore

et al., 2015). Considerations regarding how, what, when, where, and by whom with regard to the intervention are crucial to its delivering (Glaszious et al., 2010).

Finally, *intervention design* is closely related to the modelling process and a full prototype of the intervention. It is vital to be able to understand the success of the intervention and to enable replication (Bleijenberg et al., 2018).

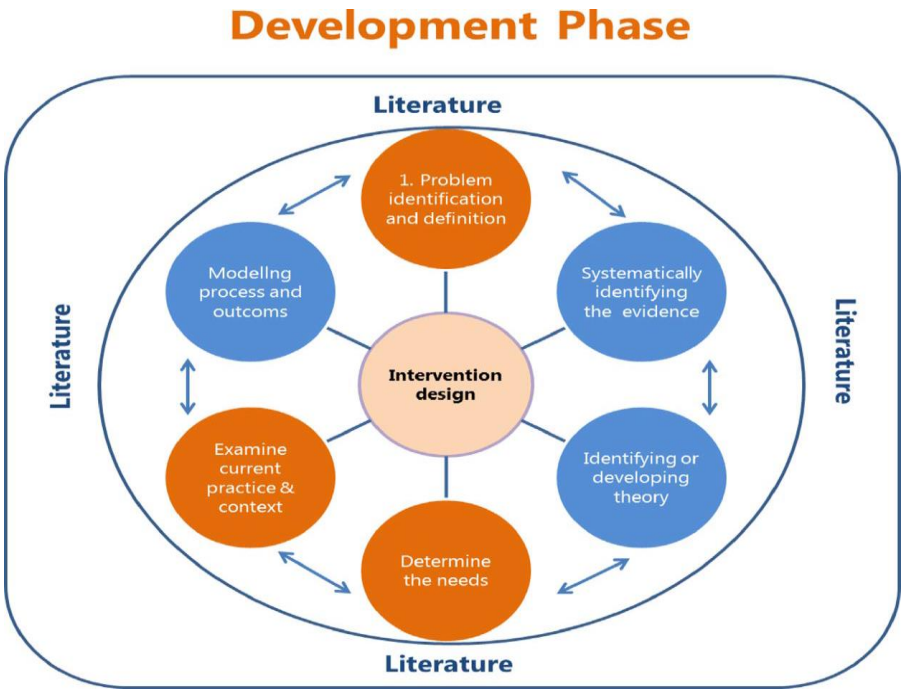


Figure 3 Adapted MRC Development phase. Blue elements are from the original MRC framework, and orange sections have been added to development phases (Bleijenberg et al., 2018, p.89).

3.6 Rationale for the choice of the Medical Research Council Framework

The main intervention development frameworks, alongside the MRC framework, include the Intervention Mapping framework (Bartholomew et al., 1998) and the RE-AIM framework (Glasgow et al., 1999). However, they provide little specific detail on intervention development, required highly technical skills and years, or otherwise tend to be orientated on individual behaviour change (e.g., only weight loss) (Wight et al., 2015).

Intervention mapping, for example, is a framework for health education intervention development and provides a system for the empirical findings from the literature, and the

integration of theory and information collected from a target population. It includes matrices and plans that guide the design, evaluation, and implementation of an intervention (Bartholomew et al., 1998). Intervention mapping consists of five interconnected stages, with each stage leading to a product required for the subsequent stages. The stages are defined as follows: i) creating a matrix of proximal programme objectives; ii) selecting theory-based intervention methods and practical strategies; iii) designing and organising a programme; iv) specifying adoption and implementation plans; and v) generating programme evaluation plans. However, the main focus of mapping interventions appears to be on primary care prevention and planning health promotion (Bartholomew et al., 2006) and ignores how implementation and causal pathways may vary by context. It tends to ignore the complexity of multi-component approaches to health improvement (Hawe, 2015). For these reasons, intervention mapping was not applicable to guide the development of the complex intervention addressing a multidimensional condition such as women living with T2DM during their reproductive years. Another framework is the Re-Aim framework, which is intended as an evaluation model rather than for intervention development (Glasgow et al., 1999). The Re-Aim framework focuses on the public health impact of interventions, and includes the efficacy, implementation, and maintenance that was considered in steps 3 to 5 of the MRC framework (Hardeman et al., 2005), but which go beyond the scope of this PhD study.

The MRC framework provides guidance on complex interventions to improve healthcare (Craig et al., 2008; Craig & Petticrew, 2013). Specifically, this lies in the emphasis it places on modelling of outcomes and theory to target active components and is tailored for a specific population. It is widely used to judge research proposals for intervention development (Corry et al., 2013; Craig & Petticrew, 2013; Hawkins et al., 2017). In a systematic review exploring the most comprehensive approaches to developing complex interventions for nursing practice, the MRC framework was the only approach reported for the development of a complex intervention in nine of the 14 studies included (Corry et al., 2013). A more recent scoping review by Levati et al. (2016) aimed to identify and synthesise the available evidence on the methods and strategies used to optimise the complex interventions at the pre-trial phase. This review reported that 17 of the 27 studies used the MRC framework (Levati et al., 2016). The MRC framework has likely become popular as its emphases is on the

modelling and piloting of complex interventions, and the iterative nature of the research process which is required in developing complex interventions. This framework makes the recommendations that can be supported by practical examples and draws attention to methods that are known to work, for example the use of a systematic review to facilitate the identification of an evidence base (Craig & Petticrew, 2013). Therefore, this thesis is informed by the MRC framework for the development and evaluation of complex interventions (Craig et al., 2008).

This study is positioned in the development phase of the MRC framework, where initial focus is on assessing the evidence base (this was the focus of the systematic review outlined in Chapter 2). It is also important in this phase to develop a deeper theoretical understanding of the study problem (outlined in Chapters 1, 4 and 5) that might elicit potential mechanism for future interventions. Therefore, the goal of the development phase which forms this PhD project is to inform the development of a future complex intervention to improve health outcomes and wellbeing in women of reproductive age with T2DM. This will provide a platform for the design of the intervention for the next phases of the MRC framework, which are modelling, piloting and feasibility testing. Such an approach should enhance the utility, applicability, acceptability and hopefully the efficacy of the intervention as well as elaborating its mechanism for action.

3.6.1 Application of the Medical Research Council Framework to this project

The MRC framework will guide each stage of this study, divided into steps, including the additional four phases described by Bleijenberg et al. (2018) and the actions recommended by O'Cathain et al. (2019). These have been detailed in Table 2 with a summary of findings of each stage related to this PhD study, and the implications for this thesis.

Table 2 Application of the development phase of the MRC framework, integrating the additional recommendations by Bleinjienberg et al. (2018) and the 11 "Actions" of intervention development by O'Cathain et al. (2019) and how they were incorporated in this study.

MRC Development phase (Craig et al. 2008)	Extended MRC framework recommended by Blejienberg et al. (2018)	Key Actions (number) (O'Cathain et al. 2019)	Findings	Implications for thesis	Chapters
Phase 1: identifying the evidence base	Problem identification and definition	(Action 1) Understanding the problem to be targeted	The prevalence of T2DM in women of reproductive age is dramatically increasing, however little research has been undertaken to explore their health needs.	Provides rationale for the thesis and highlights need of intervention development for young women to reach them and improve their health and wellbeing.	1 (introduction) 4 (Qualitative) 5 (Quantitative)
	Systematically identifying the evidence	(Action 4) Reviewing published research evidence	Evidence that T2DM negatively affects younger women's health and wellbeing. There is a paucity of research in some likely important areas such as reproductive health and emotional wellbeing.	Identification of known health needs of women associated with living with T2DM during their reproductive age, and the need for further research to provide a greater understanding of how T2DM affects the lives of women during this time of their lives.	2 (Systematic review)
Phase 2: identifying components of the intervention and identifying appropriate theory	Identifying and developing theory	(Action 5) Drawing on existing theories	Reviewing the theoretical approaches to living with T2DM and justification for use of the COM-B model, self-efficacy theory, and the Corbin and Strauss Model.	Provides the components of mechanisms to be targeted in possible interventions/care pathways. The COM-B model identifies the potential predictors of the behaviours, while the Corbin and Strauss Model provides a holistic perspective of living with chronic illness. Self-efficacy theory facilitates	3 (Methodology) 6 (Discussion)

				enhancement of self-efficacy and expands women's understanding concerning their health and wellbeing.	
	Determine the needs	(Action 7) undertaking primary data collection (Action 2) involving stakeholders, including those that will deliver, use, and benefit from the intervention	Qualitative study explored the diabetes and healthcare experiences and views of women with T2DM during reproductive years. Cross-sectional study investigated the relationship between the identified psychosocial factors and self-management behaviours.	The findings from qualitative study provided unique diabetes healthcare needs and views of women with T2DM during reproductive years. Afterwards, PPI activities provided the highest priority health topics faced by women, which could be examined in a larger group using a quantitative survey, thereby quantifying these health issues as well as assessing correlations between identified psychosocial health issues and self-management behaviours. Together, data facilitated the recommendations about more effective ways to improve diabetes outcomes and wellbeing in this group. The results guided the content of possible interventions/care pathways.	4 (Qualitative) 5 (Quantitative)
	Examine current practice and context		Reviewing previous interventions in T2DM (e.g., Women's Wellness with Type 2 Diabetes Programme).	Previous interventions and current evidence about young women with T2DM were discussed through theories.	1 (Introduction) 6 (Discussion)
Phase 3:	Modelling	(Action 8)	Systematic review and	Integrations and synthesis of all	2 (Systematic

Modelling process	process and outcomes	understanding context (Action 10) generating ideas about content about the intervention	qualitative studies provided an understanding about women's health needs and views. Cross-sectional studies confirmed the negative or positive relationship between psychosocial health issues and self-management behaviours.	phases of this thesis were conducted to suggest possible interventions.	review) 4 (Qualitative) 5 (Quantitative) 6 (Discussion)

3.7 Development phase

The MRC framework recommends that the intervention development phase should start with a systematic review to determine the scope and nature of the phenomenon of interest, and to specify what is already known from the current literature. The development phase of the MRC framework includes:

i) identifying the evidence base
ii) identifying/developing appropriate theory
iii) modelling process and outcomes.

Findings from this phase will generate the ideas that will inform possible intervention components. The following sections discuss each of these parts, including the additional four phases suggested by Bleijenberg et al. (2018), and how they relate to this project. Some chapter findings will be presented here in the context of their role; however, the full results of each study will be presented in the relevant subsequent chapters.

3.8 Step 1: Identifying the evidence base

3.8.1 Problem identification and definition

To identify the evidence-base for the intervention, the development phase commences with a clear understanding of the problem to be targeted or the identification of health issues to be addressed (Croot et al., 2019). Chapter 1 of this thesis identified that T2DM is a high prevalence, non-communicable condition and has the potential to lead to macrovascular and microvascular complications, and whose incidence is increasing among younger women of reproductive age, accounting for 60 million women worldwide. Further work is needed to identify the health needs, modifiable risk factors, and reproductive health needs associated with living with T2DM.

3.8.2 Systematically identifying the evidence

After gaining a clear understanding of the problem to be targeted, a thorough identification of the available evidence is required; ideally, a systematic review or meta-analysis must be conducted, as proposed by the MRC framework (Craig et al., 2008). Thus, a systematic

review was undertaken to combine all relevant studies which meet pre-defined eligibility criteria to answer a clearly formulated research question (Rudnicka & Owen, 2012; Higgins & Green, 2011; Khan et al., 2003). Details of the systematic review are presented in chapter 2 (Published Study 1).

3.9 Step 2: Identifying the evidence base and developing theory

3.9.1 Selecting theories to guide the development of the intervention

Using theories to develop the intervention can help to identify what components are influential in improving health outcomes (Tougas et al., 2015). Interventions based on theory are more likely to produce larger effects than those lacking a theoretical base (Zhao et al., 2016). Further, Craig et al. (2008) point out that the intervention must be developed systematically using the best available evidence and appropriate theory. The incorporation of a theory is particularly recommended by the MRC framework in order to choose appropriate theory and methods (Craig et al., 2008). Further description of chosen theories and models are discussed in the following sections.

3.9.2 Corbin and Strauss's model of living with a chronic illness

The MRC framework provides guidance to help define the main stages of the research, but other theories may be needed to help the possible mechanisms and actions of the intervention (Bleijenberg et al., 2018). To help define the scope of this PhD intervention, one of the key theoretical models is Corbin and Strauss's model that describes the overall impact of a long-term condition on people's lives (Corbin & Strauss, 1988). There are a number of reasons to use this particular model. First, it provides a holistic perspective of living with chronic illness that includes medical management tasks, and emotional work that affects diabetes-related distress. It is also explicitly mentioned that the role management focuses on how the people with chronic illness view their roles, such as within the family. Second, this model is one of the most cited pieces of work in the literature on living with a chronic condition (Dack et al., 2019). Finally, the constructs of the Corbin and Strauss model are

inherently patient-centred as this model focuses on the patients' perspectives of their chronic illness concerns, experiences, and problems associated with their chronic illness, rather than starting with a health professional's defined list of actions that are likely to place medical management as the highest priority.

Corbin and Strauss's model describes three types of work when living with a chronic condition – medical management (e.g., managing interactions with healthcare professionals, remembering to take medications regularly, exercising more, eating healthy); emotional management (e.g., managing many emotions and cognitions such as fear, anxiety, guilt, denial); and role management (e.g., managing the changes to identities and biological disruption, and the roles required when living with a long-term condition) (Schulman-Green et al., 2012) (Figure 4). Overall, this model provides a holistic perspective of intervention and focuses on patient-centred constructs.

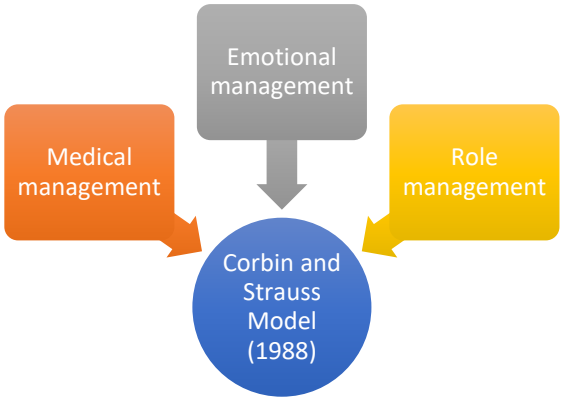


Figure 4 The Corbin and Strauss model (1988)

The model will inform the development of evidence in the following ways. This model focuses on living with a chronic illness to understand the needs of patients. Thus, the main constructs of the model were used to encourage a holistic perspective to explore (i) the impact of T2DM on women's relationships, and day-to-day activities (medical management), (ii) the burden of making lifestyle changes for the medical management of the condition (emotional management), and (iii) the changes to the roles which young women played within their families or at work (role management). This model informs the research questions and interpretation of the findings to understand the health needs of young women with T2DM.

3.9.3 Self-efficacy theory

Self-efficacy is concerned with one's judgment and beliefs in their capacities to organise and conduct the events that affect their lives (Bandura, 2010; Lenz et al., 2002). Thus, the self-efficacy theory of Bandura (1997) was also used to enhance four main sources of information: mastery experiences (practising and earlier experiences), vicarious learning (observation of others), verbal persuasion (encouraging or discouraging feedback), and psychological state (self-evaluation of psychological and emotional states) (Bandura, 1997) (Figure 5). Bandura proposed that an individual's persistence and efforts concerning specific behaviour is closely linked to their level of self-efficacy. A key part of self-efficacy theory is that the stronger the individual's confidence or belief to conduct a set of actions, the more likely they will be to persist in the given activity. Therefore, the intervention related to diabetes needs to address the factors of self-efficacy theory (Lee et al., 2008). Successful examples of interventions using this theory include the Pink Women's Wellness Programme (Anderson et al., 2015), the Diabetes Manual (Sturt et al., 2008), and the Women's Wellness with Type 2 Programme (Anderson et al., 2021). These interventions have demonstrated that participants exposed to a lifestyle intervention and self-care programmes showed clinically significant improvements in self-efficacy and behaviour change (Anderson et al., 2015; Sturt et al., 2008). This study will use self-efficacy theory to explore the role of self-efficacy and its enhancement concerning younger women health and wellbeing.

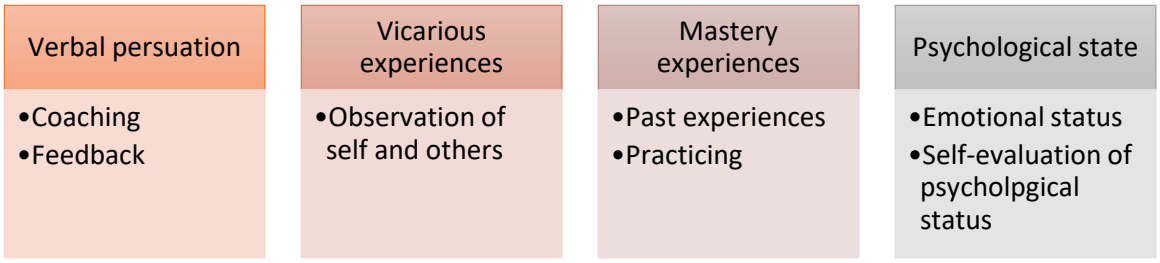


Figure 5 Components of Self-efficacy theory

Self-efficacy theory will inform the development of the evidence in the following ways. This theory reflects an individual's belief and confidence in their ability to exert control over their own motivations, behaviours or social environments. Thus, it enabled an exploration of the

experiences and health needs of women through mastery and vicarious experiences, verbal encouragement, and (re)appraisal of emotional responses. This theory informs the design of research questions, analysis, and interpretations of the study findings to facilitate understanding of women's physical and emotional needs related to diabetes in terms of initiation and maintenance of health-promoting behaviours.

3.9.4 The COM-B Model

Tackling the challenges posed by chronic disease will require initiatives associated with individual behaviour change (Mars et al., 2013). Behaviour change has been reported to be more effective if interventions are based on the theories of behaviour and behaviour change (Craig et al., 2008; Richardson et al., 2019). However, there are a range of behaviour change theories (e.g., the Transtheoretical Model (Prochaska & DiClemente, 1983)). These behaviour change theories have many similar or overlapping constructs, meaning it can be difficult to identify key determinants of change (Michie et al., 2011). While the MRC framework recommends the use of theory through intervention development, the actual description of how to do this is somewhat sparse (Loft et al., 2017). To address this challenge, Michie et al. (2014) proposed that a person needs capability (C), opportunity (O), and motivation (M) to perform a behaviour, and accordingly developed the COM-B model to guide complex intervention design via understanding of behaviour in context and developing behaviour targets. This model is a theoretical guide to analysis the behaviour and helps researchers and policymakers design complex interventions to change behaviours. It helps researchers identify the potential predictors of behaviours and is based on the assumptions that the interactions between an individual's capability, opportunity, and motivation can explain why a particular behaviour (B) is, or is not, performed (COM-B) (Michie et al., 2014) (Figure 6). The capability component refers to one's psychological and physical capacity to engage in the activity concerned and includes having the necessary knowledge and skills to do so. Motivation is defined as all those brain processes that direct and energise behaviour, not just conscious decision making and goals, and includes emotional responding, habitual process, and analytical decision making. The opportunity component is concerned with all the factors that lie outside the individuals that make the behaviour possible to achieve (Michie et al., 2011).

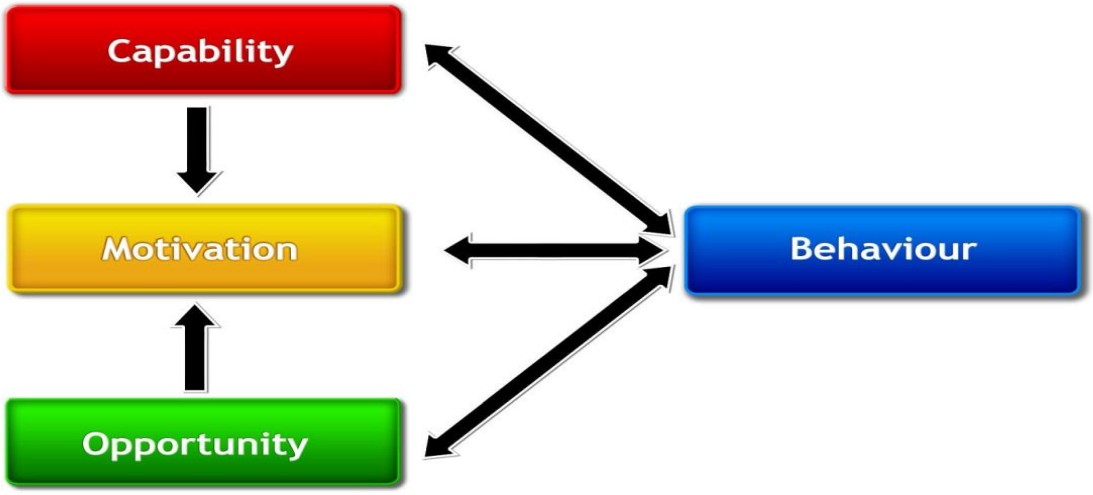


Figure 6 The COM-B system – a framework for understanding behaviour

In line with the MRC framework, the application of the COM-B model facilitates a systematic and explicit process to the design and reporting of the development of a complex intervention. According to Michie et al. (2011), this structured approach helps with the transparency of the process of intervention development and facilitates further evaluation and implementation. The COM-B model has been used in different settings within healthcare. For example, Goff et al. (2021) developed the culturally tailored diabetes self-management programme for UK African-Caribbean communities and found that this intervention was suitable for the participants (Goff et al., 2021). To the best of my knowledge, the COM-B model has not been used in this population and will inform the design of research questions and analysis and interpretation of findings to understand the barriers to, and opportunities for promoting capability, opportunity, and motivations in these women's healthcare experiences and self-care behaviours.

3.9.5 Determine the needs

A thorough and comprehensive understanding of the needs, preferences, and perceptions of the participants is a fundamental element of any intervention development process. In relation to this study, understanding what women with T2DM need from an intervention in terms of content and delivery are essential so as to include aspects that are likely to be adopted (O'Cathain et al., 2019). A mixed-methods systematic review (study 1) informs

evidence gaps by searching what is known about women living with T2DM from the current literature. A justification of how the part of the results of this systematic review informed the next steps of this PhD project is presented in *section* 2.6, *Implications of the systematic review for thesis,* along with section 3.9.6 *Rationale and challenges for a mixed methods approach*. Details of the methods and results of qualitative and quantitative studies are presented in Chapters 4 (study 2) and 5 (study 3) of this thesis.

3.9.6 Rationale and challenges to a mixed methods approach

A mixed methods study is a research approach whereby qualitative and quantitative data-collection methods are combined within the same study (Shorten & Smith, 2017) and is a methodological approach recommended by the MRC framework (Craig et al., 2008). It allows a research question to be studied from fundamentally different perspectives (Regnault et al., 2018) by integrating quantitative and qualitative data to generate new insights, resulting in an enriched understanding of complex health research (Tariq & Woodman, 2013). The process of mixing the methods, however, can lead to a certain complexity to conducting research, and epidemiological challenges to producing "knowledge" (Yardley & Bishop, 2015). Quantitative research is rooted in a realist or positivist perspective and associated with a belief that reality can be measured and observed objectively. The strengths of a quantitative study include its potential to generate generalisable findings if based on samples that are both representative and sufficiently large. In health research, it remains a dominant paradigm (Tariq & Woodman, 2013). Yet a quantitative research approach is less suited to generating a hypothesis about how or why things are happening or elucidating the complex nature of a social and cultural phenomena (Tariq & Woodman, 2013).

In contrast, qualitative research represents an interpretive or constructivist framework, which values research as a way of generating a multifaced, novel, and rich understanding of worlds, as based on a socio-cultural context and meaning-making activities (Yardley & Bishop, 2015). In-depth qualitative research aims to provide comprehensive insights into views, beliefs, and meaning, and tends to acknowledge the role of the researcher in shaping and interpreting the data. Qualitative research can generate a theoretical understanding that is applicable, or transferable, to other contexts such as helping to guide HCPs and

policymakers (Murphy et al., 1998; Tariq & Woodman, 2013). For the research that purposes to impact on practice or policy, the findings of a qualitative study can be limited by the sample sizes that are required for exploratory study. The findings of a qualitative study can be transferable, yet they are not typically generalisable.

In the context of developing a complex intervention, a mixed methods approach has the potential to counterbalance limitations and harness the strengths of both research approaches, particularly when addressing complex, broad, and multifaced research questions (Tariq & Woodman, 2013) such as living with a chronic condition (Nicca et al., 2012) and intervention development (Raven et al., 2011). Both research approaches used together generate the more complete knowledge necessary to inform practice and theory (Tashakkori & Tedlie, 2010). A mixed method approach also provides strong evidence for a conclusion through collaboration of the findings and an increased understanding of social phenomena (Morgan, 2007; Johnson & Onwuegbuzie, 2004). For instance, a qualitative study can provide an in-depth understanding of the health needs and experiences of people living with chronic conditions, while a quantitative study can quantify these health issues in a larger population and test the relationship between them. With the advantages of using both research approaches, a mixed methods approach is innovative and an increasingly popular way of addressing complex research questions. However, combining these paradigms can create a philosophical tension. To address this tension, philosophical approaches such as pragmatism or Critical Realism have been used (Creswell, 2015). Critical Realism can support the development of a deep level of understanding and explanation rather than identifying generalisable law, beliefs, or lived experiences (McEvoy & Richards, 2006). It promotes the use of several approaches to examining phenomena in a holistic manner, researching it from different perspectives, such as the views of HCPs (Walsh & Evans, 2014), which are beyond the aim of the research questions addressed by this thesis.

This thesis draws on the pragmatist approach as a philosophical foundation (Yardley & Bishop, 2015; Morgan, 2014; Cornish & Gillepsia, 2009) as pragmatism is all about “what works”, meaning that the research should be designed and conducted in the best way to serve answering the research questions, regardless of its underlying philosophy (Creswell, 2015; Maarouf, 2019). This means that pragmatism offers an outcome-orientated method of inquiry based on actions and can be understood as simply choosing the appropriate method

for the research questions (Yardley & Bishop, 2015; Johnson & Onwuegbuzie, 2004). It is simply orientated towards solving research questions in the real world. Therefore, this approach facilitates the use of mixed methods, different assumptions, and different worldviews stemming from different forms of data collection and data analysis (Creswell, 2009). Within this study, pragmatism enabled the researcher to initially consider the research questions to be explored both within qualitative and quantitative study approaches. There are a range of techniques of integrating mixed methods, including convergent, exploratory, or explanatory sequential mixed method approaches (Tariq & Woodman, 2013; Creswell & Plano Clark, 2011).

For this study, an exploratory sequential design was implemented, initially using a qualitative study to better understand the experiences and health needs of young women with T2DM. This was then followed by a quantitative study to quantify the health issues that were identified from the qualitative findings, to provide greater clarity into age- and gender-based support in their reproductive lifespan, with a final phase of integration of the data through narrative from the two separate strands of data (Figure 7). This then led to the use of a number of data collection methods to gain a broad understanding of the research issue being explored. Additionally, this approach can enhance the workability of an intervention and add insights into its generalisability to a larger population (Zheng, 2015). The exploratory sequential design in this study featured a dominant qualitative aspect to fulfil the purpose of the study and answer the research question investigating how living with T2DM affects women's experiences and health needs during their reproductive years.

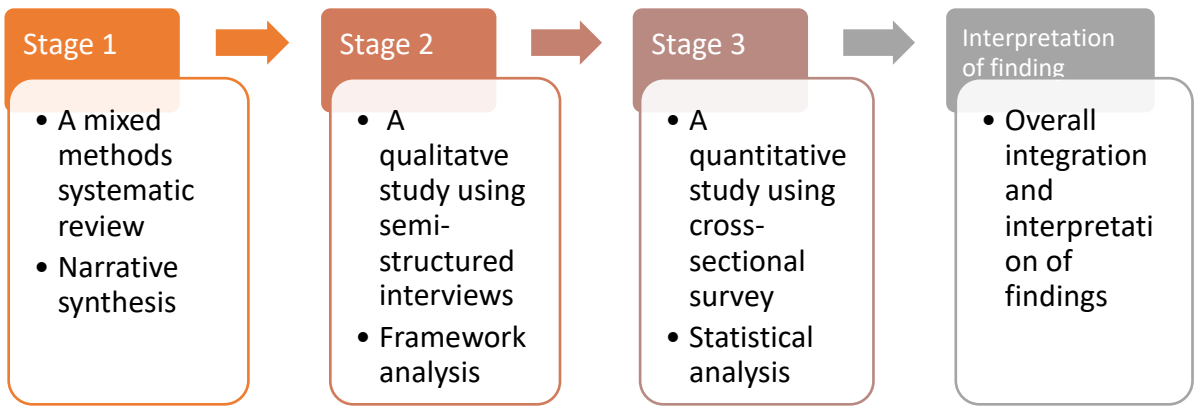


Figure 7 Exploratory sequential mixed methods approach

To improve the quality in the reporting of mixed methods approaches, O'Cathain et al. (2008) described the guideline entitled Good Reporting of A Mixed Methods Study (GRAMMS), which was used to increase transparency in reporting the mixed methods studies in this thesis (Table 3).

Table 3 Good Reporting of A Mixed Methods Study (GRAMMS) checklist (O'Cathain et al., 2008)

1	Describe the justification for using a mixed methods approach to the research question
2	Describe the design in terms of the purpose, priority, and sequency of methods
3	Describe each method in terms of sampling, data collection, and analysis
4	Describe where integration has occurred, how it has occurred, and who has participated in it.
5	Describe any limitations of one method associated with the presence of the other method
6	Describe any insights gained from mixing or integration methods

3.9.7 Examine practice

To optimise the successful delivery of intervention, identifying the existing practice within its context is extremely important when developing an intervention (Meijel et al., 2004). Intervention development aims to explore the context where the intervention will be implemented or delivered to determine enablers and barriers to it among participants and providers in order to increase the workability of the intervention into current practice (Moore et al., 2015). Identifying the evidence, including national registries, or guidelines can provide important information to understand the context. Considerations concerning how, what, when, and by whom the intervention will be used by or for, is vital (Glasziou et al., 2010).

3.10 Step 3: Modelling process and outcomes

The modelling stage of the development phase of the MRC framework aims to understand what may be feasible in practice through an iterative process of experimentation (Craig et al., 2008). It can provide important information about the design of the intervention. Thus, a series of studies might be required to progressively refine the design before starting a full-scale evaluation. As recommended by the MRC framework, the findings from the systematic review (study 1) and qualitative interviews (study 2) with women living with T2DM during their reproductive years, along with guidance from the COM-B model, have identified components to be modelled and tested in a cross-sectional study (study 3). The qualitative study can allow for a greater exploration of the experiences in living with diabetes as well as allowing the needs of women to be explored and understood for the development of an intervention. Then, a cross-sectional study assesses the relationship between identified psychosocial health issues and their self-management behaviours. All the findings provide an understanding of components to be targeted in the intervention. The findings of studies 1, 2, and 3 will be integrated and synthesised in the discussion chapter to inform future interventions and components for improved care.

3.11 Methodological conclusions

This chapter has discussed the methodological approaches and procedures utilised in this PhD research, which aims to comprehensively explore the experiences and health needs of young women with T2DM. The MRC Framework has been discussed in the context of this thesis and how the phases of this framework have been mapped onto the undertaking and the outputs of this PhD project. This framework is a widely used and well-regarded intervention development framework which provides a comprehensive set of guidelines on the use of the systematic review of the evidence and a mixed methods approach (Craig et al., 2008). Corbin and Strauss's model (1988), the COM-B model (Michie et al., 2014), and self-efficacy theory (Bandura, 1997) were used to understand the experiences, behaviours, and health needs of young women with T2DM. This PhD project will therefore be based on a strong evidence base, robust theoretical underpinnings, and appropriate methodology.

Chapter 4 – Women's experiences of living with type 2 diabetes and diabetes care during their reproductive years: A qualitative study

4.1 Chapter overview

This chapter reports the detailed results of the qualitative study addressing the research question, 'What are the diabetes and diabetes care experiences of young women with T2DM during their reproductive years?'. This chapter presents the second publication from this PhD study entitled: 'No one ever asks about something that actually is relevant to my life': A qualitative study of diabetes and diabetes care experiences of young women with type 2 diabetes during their reproductive years (Published article: Diabetic Medicine). The chapter will describe additional study details and discussions beyond the published manuscript. These include the rationale of the research methods used to conduct the study, the ethical considerations, identification of the research participants, data collection and analysis, together with the steps taken to ensure trustworthiness of the findings. This chapter also provides the implications of the qualitative study for the thesis.

4.2 Rationale for the qualitative study

To answer the research question, individual in-depth, semi-structured interviews were conducted. Interviews are the most frequent qualitative data source in healthcare research, and this method of data collection is commonly used in qualitative research (Kallio et al., 2016; Alshenqeeti, 2014). The overall purpose of semi-structured interviews is to gather information from a target population who have experiences, perceptions, attitudes, and beliefs related to a particular research topic (Gill et al., 2008; Stuckey, 2003, Nyumba et al., 2018). Researchers can use semi-structured interviews to collect new exploratory data related to the topic of interest, and to delve deeply into personal and sometimes sensitive issues (DeJonckheere & Vaughn, 2019). On the other hand, it is recognised that data about sensitive topics, such as sexual function, are likely to be absent in focus groups (Nyumba et al., 2018). Furthermore, as people with T2DM experience and perceive diabetes-related

social stigma, they may consequently be reluctant to disclose their condition to others (e.g., friends, family members) (Browne et al., 2013; Forde et al., 2021; Schabert et al., 2013). In-depth semi-structured interviews are both versatile and flexible and found to be successful in enabling reciprocity between participant and interviewer (Gallette, 2013), enabling the researcher to develop follow-up questions based on participants' responses (Polit & Beck, 2010; Rubin & Rubin, 2005; Hardon et al., 2004). Individual interviews allow in-depth exploration of the existing needs of women with T2DM (Stuckey, 2013). Thus, in-depth semi-structured interviews were conducted to explore the experiences of young women with T2DM.

4.3 Study design and setting

The published paper described below focuses on exploring the experiences and health needs of women with T2DM during their reproductive years. This qualitative study was conducted using individual, in-depth semi-structured interviews with women living with T2DM using online methods via video/phone or email. As discussed in Chapter 2, the reproductive age in this qualitative study is considered to be between 18 to 45 years of age, reflecting on their experiences of living with T2DM and diabetes care in this population during their reproductive years. This definition was agreed through consensus on such between the researcher and supervisory team. To widen the perspective in relation to exploring the experiences and health needs of women with T2DM, the participants were recruited from the UK and Türkiye. They were fluent in English or Turkish to enable the in-depth and clear understanding of their experiences and views during their reproductive years. The study population was diverse from the ethnicity and cultural perspectives and varying reproductive health experience from both the UK and Türkiye. The researcher was able to gain an understanding of the experiences from both perspectives, widening the insight in relation to exploring the health needs of women with T2DM, and thus to develop scientifically robust research.

4.4 Recruitment and selection of participants

In light of the COVID-19 pandemic, all primary data collection involving face-to-face participant interactions was suspended. Therefore, potential participants were recruited through online methods such as social media, online forums, diabetes charities, women's membership organisations, and employers. Social media sites – Instagram, Facebook, Twitter, and LinkedIn – offer various platforms for connecting and sharing information and interests, while allowing users to maintain physical separation and a degree of anonymity (Gelinas et al., 2017). Social media is an attractive medium through which to recruit potential participants because it may enable researchers to reach a wider segment of the accessible population and allow them to infer their eligibility for a particular study. A poster was disseminated through social media platforms to advertise the study with contact details for further information (see Appendix B.1.1). However, the response rate was quite low (10 participants) during the first five months of starting the recruitment. To enhance recruitment, an animation and study website were created by the researcher. This animation contained the aim of the study, eligibility criteria, incentives, and contact details. A strategy to promote the study via social media was devised to support dissemination. Drawing on a network of diabetes researchers, and clinicians the animation was shared via Twitter in an organised manner over a period of four weeks. For this, the researcher created a doodle poll for those with an account and who were willing to support the Twitter campaign. A schedule was created so that the tweet was disseminated by a variety of people over a prolonged period. Those who agreed were sent a reminder along with the text for the tweet and the links to include.

A study website, called **R**eproductive **A**ge women with **DIA**be**TE**s (RADIATE), included information about the study, facts about diabetes and reproductive health, a study overview, the study animation, and information on how to protect the data provided by participants, how to get involved in the study, a direct link to participant information sheet (see Appendix B.1.2), a consent form (see Appendix B.1.3), and a demographic questionnaire (see Appendix B.1.4). This website is available at https://sites.google.com/view/radiate-study/home?pli=1. Alternatively, the participants who were interested in learning more about the study or otherwise getting involved were asked to submit their contact details

using the form on the website and were then contacted directly to discuss participation. This revised approach generated considerably more interest in the study.

With the gatekeeper permission (see Appendix B.1.5), an advertisement for the study was also shared via the Diabetes UK website, their online forum, and Twitter accounts. They have a large membership and social media following which would be expected to have contact with wide range of women with T2DM. Specific Diabetes UK support groups (e.g., Luton, Haringey) were also contacted to post our research on their website. To ensure the inclusion of diverse participants, the researchers attempted to reach women from diverse ethnic backgrounds. Challenges of recruiting to studies from South Asian population have been reported in several studies (Lloyd et al., 2008; Waheed et al., 2015). Many studies (Prinjha et al., 2020; Ekezie et al., 2021) suggested that while approaching potential participants from Black, Asian, and Minority Ethnic (BAME) groups, it is significant that any research strategies are culturally adapted to the needs of target populations and collaborative working was integral throughout the research process. Thus, to capture the broad range of ethnic minorities, the researchers (AC, AT) contacted the ethnic minority community coordinators who could easily gain access to potential participants via online methods. They advertised the study in their community platforms, website, and diabetes support groups, and some churches.

In addition to advertising on social media the university community was also targeted in the recruitment strategy utilising internal email for research volunteers. This yielded both expressions of interest and volunteers to participate in the study.

4.5 Transcription and translation of interviews

Once the participants were interviewed, the researcher transcribed each of the interviews verbatim in the original language (Turkish or English) as this helps to achieve greater familiarity with the data (Flick, 2014). Following this, the audio recordings were again listened to, and the transcriptions were read simultaneously to check for accuracy. To ensure anonymity all transcriptions were coded with pseudonyms to ensure confidentiality (Silverman, 2010; Malterud, 2001). In addition, all the personal information (e.g., the names of locations and hospitals) were pseudonymised before anyone else read

transcriptions. Afterwards, most of the transcripts of the interviews conducted in English were read by a native English speaking research student while simultaneously listening to the audio recordings to check for accuracy of the transcript in terms of grammar, typographical accuracy, and readability. This KCL research student was informed about all ethical information (e.g., confidentiality of participants) by the researcher before reading the transcriptions.

The interviews that were conducted with Turkish participants were translated by the researcher who is a bilingual researcher (Turkish – English) in diabetes after each audio-video interview recording. Another two bilingual (Turkish – English) researchers in the UK reviewed the pseudonymised transcriptions in terms of translation for accuracy and credibility and then discussed two texts with the researcher for readability comprehension and consistency of meaning (Regmi et al., 2010). The entire transcriptions from both countries were read by the supervisors who are fluent in English. This provided an insight and a sense of the data and thus improving the rigour of data analysis process.

4.6 Rationale for Framework Analysis

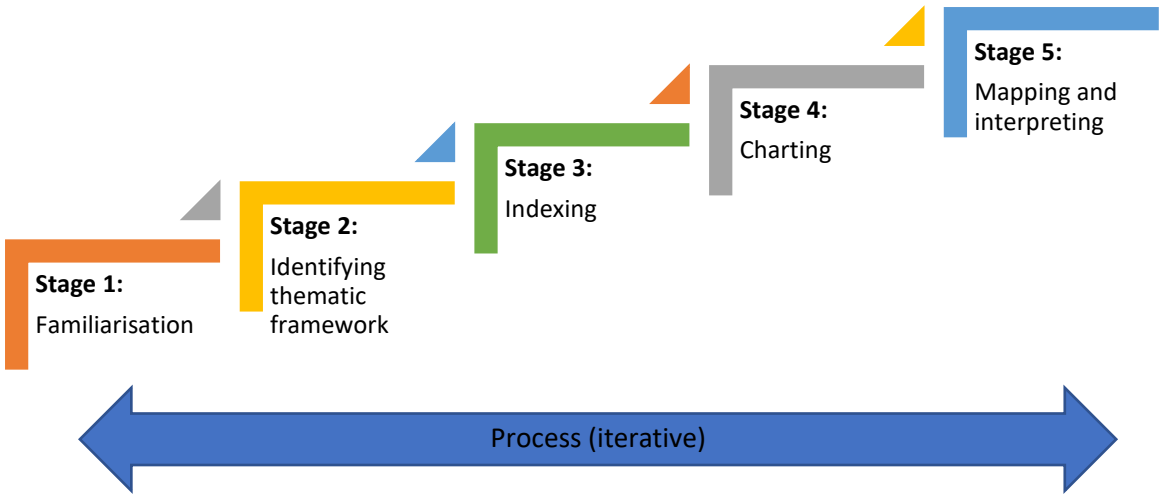
Framework Analysis was chosen because it provides flexibility across a range of theoretical perspectives to generate a rich dataset or a detailed account of a particular aspect. This flexibility allows for inductive themes to be generated from the data that identified how a woman lives with diabetes or the creation of deductive themes stemming from Self-efficacy theory (e.g., exploring the emotional management of living with T2DM) as well as a mixed methods systematic review (Study 1). It has become a commonly used approach to the management and analysis of qualitative data in health research (Flemming et al., 2019; Gale et al., 2013) because it provides clear steps to follow to ensure highly structured outputs of summarised data. Thus, a framework approach allows for a degree of transparency so that readers are able to see how the interpretations and findings are derived from the data (Furber, 2010; Ritchie & Spencer, 1995). This simultaneously enhances the rigour of the study. Framework Analysis involves a matrix-based approach of data display that allows for

retrieval of data from the original data set (Ritchie et al., 2014) and it is appropriate for early career researchers because of the explicitly described processes (Gale et al., 2013).

To address the research question, Framework Analysis holds advantages over grounded theory (Noble & Mitchell, 2016) and Interpretive Phenomenological Approach (IPA) (Smith & Osborn, 2009) because it is less focused on theory or specific phenomena as outcomes of interest. The research question benefits from greater heterogeneity in participants' ethnicity, age, and diabetes duration than would be considered appropriate in grounded theory or IPA and thus, a Framework Analysis was considered to be more closely aligned with the aims of the study.

Framework Analysis follows the five interconnected stages, as set out below (Figure 8).

Figure 8 Stages of Framework Analysis



A detailed explanation of five stages will be given the following sections.

4.6.1 Stage 1: Familiarisation

Stage one of Framework Analysis involves familiarisation with the transcriptions. A verbatim transcription of each interview was obtained and then the researcher listened to the recordings while reading the transcriptions. This allowed the researcher to maintain a certain closeness with the original research data and to become familiar with and immersed in the data and to develop an overview of the main ideas it contained. During this process, all the transcripts were anonymised.

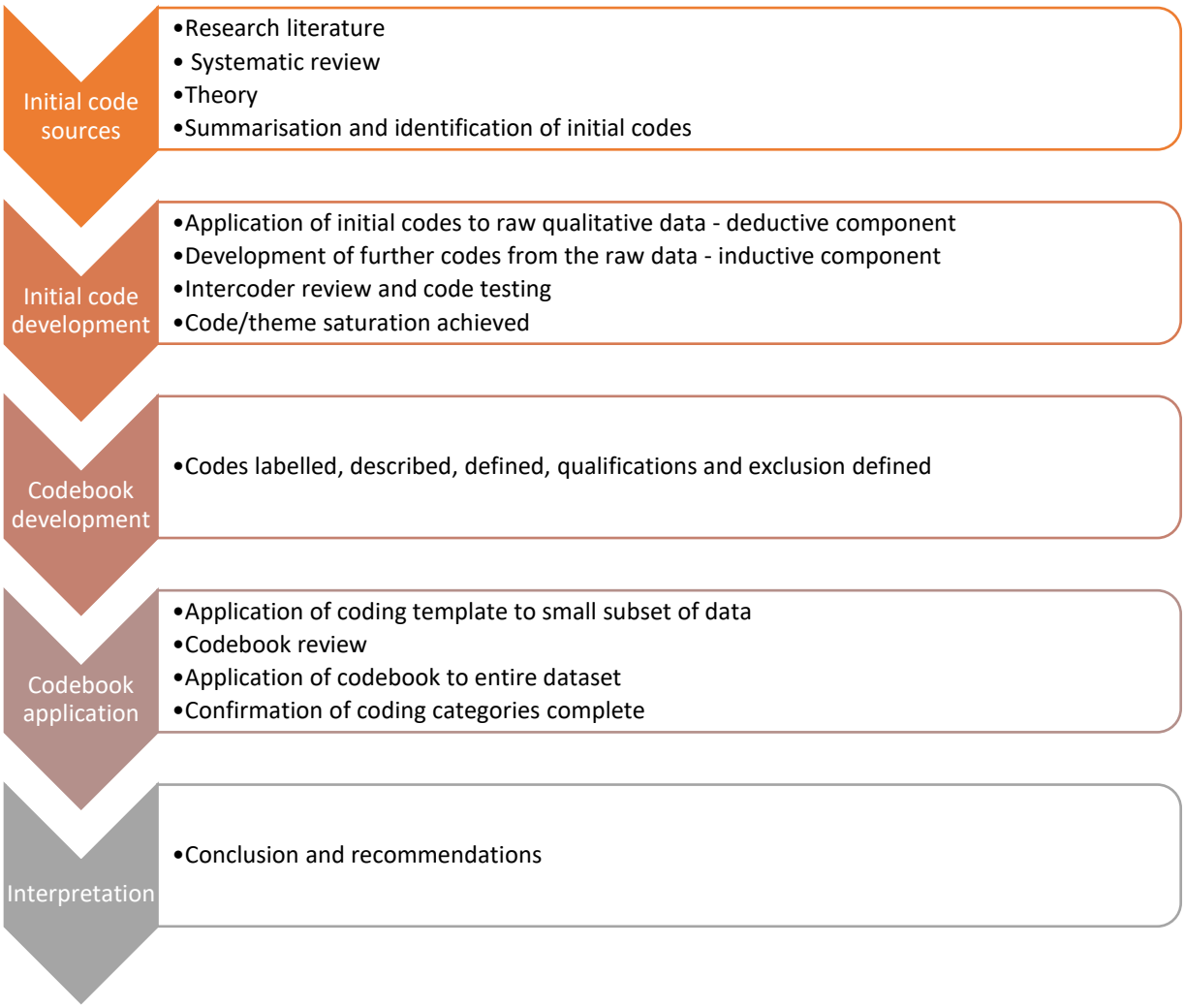
4.6.2 Stage 2: Identification of Initial Thematic Framework

Following the familiarisation process, the initial thematic framework was developed iteratively to organise the data using a deductive approach from *a priori* data derived from a synthesis of previous systematic review and theories utilised. In the inductive approach, four transcriptions were chosen as they represented the diverse experiences of women with T2DM. These transcriptions included a wide range of experiences of women from mixed ethnic backgrounds and diabetes durations. Each transcript was read line by line, and codes were developed from phrases, key words, lines, and sentences in the transcripts. This process was carried out by the researcher and reviewed independently by two supervisors. The researcher and supervisory team discussed the inductive and deductive codes to reach a consensus on the codebook (Figure 9) before being applied to the complete dataset.

4.6.3 Stage 3: Coding index

After the codebook creation, the researcher coded all the remaining transcripts using the codebook, which was continuously revised in an inductive manner until the data from all transcriptions were captured. The supervisory team then moderated the codes and addressed any uncertainties and ambiguities. This activity was carried out systematically as coding aims to classify all of the data so that it could be compared with other parts of the dataset. An example of the coding index is presented in Appendix B.1.6.

Figure 9 Process of code creation (Adapted from Roberts et al., 2019, p.3)



4.6.4 Stage 4: Charting (Collecting codes into Framework Matrix)

Charting involves summarising the data by category from each transcript and developing them into the themes, and which includes references to interesting or illustrative quotations (Ritchie et al., 2014; Gale et al., 2013). The researcher conducted this process with NVivo 12, which facilitated the development of a matrix. The codes were charted into a framework matrix, which means that summaries of the data were entered into the matrices, and these were linked to the data from the transcript which helped to maintain the context of the data extract. Summarising the data during charting, as well as being practical way to organise the

data, means that all the researchers can engage with the data and offer their own perspectives during the analysis process without being involved in its more technical part (Gale et al., 2013). When summarising, the researcher used words from the data to keep it close to the interview transcript.

4.6.5 Stage 5: Mapping and interpretation

The final phase of the Framework Analysis involves mapping and interpretation of the data (Ritchie et al., 2014; Pope et al., 2000). In this stage, key elements of the data were found in order to group data into categories and identify key dimensions. These key dimensions became the subthemes and themes of the findings. The themes were reviewed and refined so as to make sure of the sense of the entire dataset to elaborate upon and answer the research questions. Developing of the themes and sub-themes is an iterative process and changes as the analysis progresses. Mapping and interpretation were discussed with the supervisory team to ensure that the themes captured all the information from all the codes, and a final consensus was reached with the researcher and supervisory team. Please see Appendix B.1.6 for a summary of mapping and interpretation process of Framework Analysis.

4.7 Trustworthiness

Trustworthiness, or rigour of a study shows how thorough and consistent the process of a study has been, meaning the degree of confidence in data, interpretations of findings, and methods used to ensure the quality of the study (Pilot & Beck, 2014). Trustworthiness and transparency of the conduct of the study or truth value of qualitative research are significant to the utility and integrity of the findings (Cope, 2014). However, there are debates in the literature as to what actually constitutes trustworthiness (Leung, 2015). While Tracy (2010) has presented a model which includes quite expansive and flexible markers for quality in qualitative research, many researchers (Connelly, 2016; Norris et al., 2017) have accepted the criteria outlined by Lincoln and Guba (1985), which focus on the credibility, transferability, dependability, and confirmability of a study. To illustrate trustworthiness of

this study, the criteria introduced by Lincoln and Guba (1985) were chosen; these trustworthiness criteria have been briefly defined and then presented in a description of the efforts that were made to conduct a trustworthy study.

Credibility: According to Lincoln and Guba (1985), the credibility of the study shows whether its findings are correct and accurate. It is crucial to ensure credibility, which is one of the most important factors in establishing trustworthiness and refers to the confidence in the truth of the study and is determined by experienced researchers and readers. Although there are no universally established criteria used to evaluate qualitative research (Noble & Smith, 2015), the researcher has undertaken the following strategies to increase the credibility of this study:

- Semi-structured and recorded interviews were conducted to allow for repeated revisiting of the data to check developing themes and remain consistent to participants' accounts.
- Framework Analysis was undertaken to allow the researchers to manage the large datasets where obtaining a holistic descriptive perspective of the entire dataset is desirable.
- Verbatim extracts from participants' accounts were used to assist the reader to make judgments about whether the final themes and sub-themes are true to the participants accounts.
- Analytical and peer debriefing with other researchers and the supervisory team was undertaken to minimise the researcher's biases and assumptions and to discuss interpretations of the raw data and the development of the final themes.
- The themes and sub-themes were discussed with the supervisory team and a consensus reached.

Dependability: This is similar to what is considered reliability in quantitative research and refers to data stability over time. Data should be consistent, repeatable, and clearly documented. The procedure for dependability includes peer debriefing.

- This study involved discussing all the data with other research students who were not involved in this study. They examined the research process and reviewed preliminary findings in order to establish dependability.

Confirmability: This is analogous to objectivity in quantitative research and refers to neutrality or level of confidence that the research findings are based on the participants' accounts and words rather than potential researcher biases.

- In order to increase confirmability, the researcher detailed the process of data collection (e.g., field notes (Appendix B.1.7)), data analysis, and interpretation, and recorded what health topics were unique to the study population, provided a rationale for why certain codes were merged together, and explained what the themes and subthemes mean. All analytical stages were discussed with supervisors to reduce researcher biases.
- All transcripts were reviewed by two other research students who were not involved in this study. They reviewed nearly all the transcriptions and compared them with data interpreted by the researcher, followed by a discussion about interpretation of data and then a consensus reached. This process supported the final data interpretation with representing the participants' accounts.
- The researcher undertook reflexivity during the research process, including the collecting and analysing the data.

Transferability: This refers to the extent to which findings can be transferred to other settings, times, situations, or contexts with other populations. The researcher should provide evidence that the findings of the study could be applicable.

- Transparent and clear description of the research process were defined through the development of research methods and the reporting of findings.
- Purposive sampling was used to recruit a diverse range of experiences of participants, enabling a more inclusive and overall picture to be gained.
- The participants' anonymised accounts have been detailed, considering the baseline understanding with which the results of further study could be compared.

4.8 Ethical considerations

Prior to commencing the study, ethical approval was obtained from the Psychiatry, Nursing, and Midwifery (PNM) research ethics sub-committee at KCL in June 2020 (Reference Number: HR-19/20-18146). Confirmation of this is included in Appendix B.1.8. Advice was sought from a diabetes research expert (SC) who is a clinical academic at the University of Health Science in Türkiye about obtaining ethical approval there however this was not required as KCL ethical approval was in place and the recruitment was online via social media.

Ethical issues are of paramount importance in all stages of the study, from designing the study to reporting the findings. Ethical issues include the potential study benefits and risks, anonymity, confidentiality, informed consent, and respect for human dignity and justice (Sanjari et al., 2014; Polit & Beck, 2012). In this study, the participants would not personally benefit from the research findings, however, learning from this study can be used to enhance the understanding and care needs for women of reproductive age who may benefit from future health innovations that could be developed from the findings of this study. While participation in this study posed no direct risks through the process of conducting the interviews, there was potential for the women to become emotional as they reflected on their life with diabetes, especially those who had had previous unpleasant experiences. If they feel uncomfortable with the any of the questions or topics, the interview is paused or stopped immediately, and the participant may feel free to talk the researcher. There was one participant who did become upset during the interview. In this case, she had had the negative experiences with her diabetes diagnosis and family relationships. The researcher spoke with her about possible sources of support, such as GP, or a family member and also signposted her to sources of support such as a national diabetes association.

Another ethical issue is the informed participant information sheet as an integrated part of ethics in research. It is of the utmost importance to specify in advance, using language that allows the potential participants to understand what the research is about, and how taking part may affect them, how the data will be collected, and how it will be used (Hoeyer et al., 2005). Additionally, informed consent aims to clarify the following issues: the research objectives, the participants' potential role(s), the identity of the researcher, and how the

results will be used (Sanjari et al., 2014). All the participants were provided the participant information sheet (see Appendix B.1.2) and were given time to decide whether to take part in the study. Further, it was clearly stated that there was no obligation to take part in the study, meaning that participation was voluntary. Participants were invited to ask questions prior to participating and were informed of their right to withdraw at any point of the study without having to give a reason. All participants provided verbal and written consent before starting the interview (see Appendix B.1.3).

Confidentiality is another important ethical issue while conducting a study. Potential participants were informed that all data collected would be kept confidential, and any identifiable or personal data were removed. Actual names were replaced with pseudonyms and only unidentifiable data were used in the study and in the dissemination of the study findings. Confidentiality was maintained throughout, and after completion of the study. The interview transcripts and other information related to the study were stored in password-protected computer files and securely locked in a filing cabinet in accordance with university and national guidance.

The qualitative study presented in this chapter is presented in the following article:

Citation: Celik, A., Sturt, J., Temple, A., Forbes, A., & Forde, R. (2022) 'No one ever asks about something that actually is relevant to my life': A qualitative study of diabetes and diabetes care experiences of young women with type 2 diabetes during their reproductive years. *Diabetic Medicine*, e15017.

All study documents, including ethical approval, participant information sheet, and consent forms are included in Appendix B.

4.9 Published article

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DIABETIC Medicine

RESEARCH ARTICLE

'No one ever asks about something that actually is relevant to my life': A qualitative study of diabetes and diabetes care experiences of young women with type 2 diabetes during their reproductive years

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Abstract

Aim: To understand the health needs, experiences, and views of women with type 2 diabetes in relation to diabetes, reproductive health experiences, and general wellbeing.

Method: A qualitative study using semi-structured interviews. Thirty-six women with type 2 diabetes (median age 37 years; age ranges 20–45 years; median diabetes duration 4.5 years), recruited through social media and charities in the UK ($n = 23$) and Turkey ($n = 13$). Video interviews ($n = 28$) were audio recorded and transcribed verbatim. Email interviews ($n = 8$) and transcribed video interviews were analysed using Framework Analysis.

Results: Two overarching themes were identified: (1) Perception of self and identity, (2) type 2 diabetes care is not orientated to women's needs. These themes highlight that living with type 2 diabetes was negatively perceived by the women in terms of their self-identity and reproductive health. Women reported that the diabetes care provided was often not appropriate or relevant to their health needs, and neglected issues of relevance to them. The women voiced ideas for enhancing current care to reflect their health needs, in particular the need for more emotional and peer-based support.

Conclusion: Living with type 2 diabetes may negatively impact how women view themselves and how they relate to the roles they identify with such as, as a partner, mother, colleague. Current healthcare systems are not orientated to the specific needs of younger women with type 2 diabetes with limited opportunities to target their diabetes care around their health and wellbeing concerns and interests.

KEYWORDS

care experience, emotional stress, qualitative research, reproductive health, self-identity, type 2 diabetes, women

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1 | INTRODUCTION

The increasing prevalence of type 2 diabetes (T2DM) is accompanied with shift towards a younger age of onset.[1–3] Among younger people, the incidence of T2DM is higher in girls compared with boys.[1,3–5] During their reproductive years T2DM can be challenging.[5,6] Women with T2DM can experience problems related to the menstrual cycle, menopause, sexual dysfunction and infertility.[5–7] The neonatal death rate is significantly higher among the infants of women with T2DM compared with those of women with type 1 diabetes.[8] Diabetes distress,[9] stigma[10] and cardiovascular diseases[11] have all been reported at higher levels in women with T2DM during this time of life compared with men with T2DM.

Over two decade ago, an Australian study reported relatively common binge eating behaviours among women with T2DM; still, there has been little focus on disordered eating among this group since.[12] Although it is recognised that diabetes-related health issues are burdensome,[2,4,9] there is little understanding of the diabetes experiences and healthcare needs of women with T2DM during their reproductive years.[5,7,9,13] To address this gap, the impact of diabetes must be explored to better understand challenges women with T2DM experience during this time of life.[2,5,14]

Previous studies focussed on either specific time points during the reproductive lifespan of women with T2DM such as, pre-pregnancy care,[15] menopause[7] or have used heterogeneous study samples rather than women of reproductive age.[9–12] However, the reproductive years span several life transitions from adolescents through to early mid-life.[5,6] Therefore, the needs of women with T2DM may vary during these life stages, which have not been previously studied. Furthermore, diabetes care is not tailored to the specific healthcare needs of this population, with a lack of dedicated care-pathways,[2] limited research[2,4] and they do not feature in national diabetes guidelines[16,17] apart from pregnancy-specific guidelines. Therefore, this study aimed to understand the experiences, views and the health needs of women with T2DM during their reproductive years. These data may inform the future development of strategies to improve healthcare delivery and health outcomes for this population.

Novelty statement

- This novel qualitative study explored the diabetes experiences and health needs among younger women with type 2 diabetes during their reproductive life course.
- Living with type 2 diabetes during their reproductive years generated a major disruption to women's perception of themselves and their identity.
- Women seek age and gender-specific diabetes care to improve their overall health and wellbeing and that of their children.

2 | RESEARCH DESIGN AND METHODS

This qualitative study used individual in-depth interviews to identify and explore the health needs, experiences and views of women with T2DM. Data were analysed using Framework Analysis which enables the inclusion of a priori data from previous literature and theory to support the development of an analytical framework that can then be inductively refined reflecting new insights from the data.[18] Self-efficacy theory provided a theoretical underpinning of this study. It enabled an exploration of the experiences and health needs of women through mastery and vicarious experiences, verbal encouragement and (re) appraisal of emotional responses, which are the components of self-efficacy theory.[19]

3 | ETHICAL APPROVAL

Ethical approval was received from King's College London (Reference Number: HR-19/20–18,146). All participants provided informed consent and the study was conducted in accordance with the guidelines of the Declaration of Helsinki.

4 | SAMPLE AND RECRUITMENT

Participants were recruited online via social media, diabetes charities, employers and women's membership organizations. A study advertisement including the aim of the study, eligibility criteria and researcher's contact details (email and phone) was posted in social media platforms, diabetes charity websites and diabetes online forums with the gatekeeper's permission. Prospective participants contacted the researcher directly to participate or learn more about the study. Participants were recruited from the UK and Turkey. These countries have a high prevalence of young adults with T2DM and have publicly funded healthcare systems.[2,4,20] Participants were purposively sampled to include women with T2DM, aged 18–45 years, living in either the UK or Turkey who were able to speak and understand English or Turkish. Excluded were those with any

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other form of diabetes, those not able to provide informed consent or if they self-reported cognitive impairment, untreated or current symptoms of a psychiatric illness. To recruit a maximum variation sample, there were no restrictions on ethnicity, diabetes duration, diabetes management methods or other co-existing medical conditions.

To enhance the representativeness, a sampling-frame based on the characteristics of the target population was used targeting the country of residence, age and duration of diabetes (File S1). Sample size was determined using the concept of information power.[21] Based on the criteria described by Malterud et al.[21] a sample size of 36 women was decided upon, with the aim of recruiting at least 15 participants in each country to provide breadth of data and be sufficient to accommodate the selection criteria.

5 | DATA COLLECTION

Data were collected via semi-structured individual interviews. Due to Covid-19 restrictions, interviews were conducted remotely using video-conferencing ($n = 27$), phone ($n = 1$) and email ($n = 8$), which are all valid and trustworthy alternatives to face-to-face interviews.[22] All participants were contacted via email or phone to arrange the interview and identify which mode was convenient for them (video, phone or email). The interview topic guide (File S2) was iteratively developed and refined drawing on the literature including a recent systematic review,[7] input from the research team and patient and public involvement (PPI) groups from both countries. This guide included open-ended questions reflecting the research purpose, and additional probing questions were used to elicit in-depth accounts of women's views and experiences. The interview topic guide was also pilot tested to ensure relevance and test implementation. Prior to each interview, participants completed a short demographic questionnaire including age and diabetes duration to help contextualise the interview. The interviews were conducted in either English or Turkish according to linguistic choice of participants and transcribed by the researcher (Aycan Celik). Turkish interviews were translated into English by a bilingual researcher (Aycan Celik) and checked with other bilingual researchers (BK, NC) for translation accuracy.[23]

The interviews conducted via videoconferencing lasted between 30 and 80 minutes and were also audio recorded. E-mail interviews were conducted over a series of between 5 and 20 contacts, ranging from 1 day to 3 weeks, which provides participants with time for reflection before answering, along with enabling researcher time for follow-up questions.[22] Interviews were conducted by two researchers (Aycan Celik, Aya Temple), both women with a professional nursing and dietetic background and no prior relationship with the participants. To capture relevant details such as, nonverbal behaviours or emotions, field notes were written at the end of each interview.

6 | DATA ANALYSIS

Data were transcribed verbatim and analysed thematically using Framework Analysis including both inductive and deductive methods.[18] All transcriptions were reviewed for accuracy and imported to NVivo version 12 for data management to support qualitative analysis. The first author analysed the data, with members of the researcher team cross-checking the codes and themes. Disagreements were resolved through discussion. The analysis followed a five-step process[18] commencing with (1) familiarisation—the first author repeatedly read and re-read each transcript; (2) a thematic framework was developed iteratively to organise the data using a deductive approach from a priori data and inductively reflecting new insights from the interviews. A consensus was reached on the meaning of each code through discussion between the research team; (3) indexing—the remaining transcripts were then coded using the framework which was continuously revised inductively until the data from all transcriptions were captured; (4) charting the data into the framework matrices in NVivo 12 ensured the coded data were linked to the individual transcripts. Finally, (5) mapping and interpretation of the data—key elements of the data were detected to group data into categories and identify key dimensions, as described by Ritchie et al.[18] These key dimensions became the subthemes and themes of the findings presented below.

7 | FINDINGS

7.1 | Participants

From a total of 48 interested participants, 12 did not participate for the following reasons: did not meet inclusion criteria ($n = 5$), requested more information, but were later non-contactable ($n = 5$), were too busy ($n = 2$). Overall, 36 women with T2DM participated from the UK ($n = 23$) and Turkey ($n = 13$). The participants age ranged between 20 and 45 years with a median age of 37 years. The median diabetes duration was 4.5 years (range 1–21 years). Most women were of white ($n = 20$) and Asian ($n = 13$) ethnicity and had family history of diabetes ($n = 29$), were married ($n = 23$) and had at least one child ($n = 27$). Twenty-eight of the participants had completed some education following secondary school (Table 1).

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TABLE 1 Participant characteristics

	All ($n = 36$)	UK ($n = 23$)	Turkey ($n = 13$)
Age, years			
Median (Range)	37 (20–45)	37 (20–45)	37 (27–44)
IQR (lower quartile -upper quartile)	10.25 (33–43.25)	10 (30–40)	10.5 (33.5–44)
Ethnicity, *n* (%)			
White	20 (55)	7 (35)	13 (65)
Asian	13 (36)	13 (100)	0
Black	2 (6)	2 (100)	0
Mixed	1 (3)	1 (100)	0
Family History, *n* (%)			
Yes	29 (81)	16 (55)	13 (45)
No	7 (19)	7 (100)	0
Duration of diabetes, years			
Median (Range)	4.5 (1–21)	4 (1–20)	10 (1–21)
IQR (lower quartile -upper quartile)	8 (2–10)	10 (2–12)	4.5 (1.5–6)
Number of children, *n* (%)			
No Child	9 (25)	9 (100)	0
1 Child	10 (28)	7 (70)	3 (30)
More than 2 children	17 (47)	7 (41)	10 (59)
Education, *n* (%)			
Primary school	7 (19)	1 (14)	6 (86)
Secondary school	1 (3)	0	1 (100)
College degree/Diploma	10 (28)	6 (60)	4 (40)
University/Degree	11 (30)	10 (91)	1 (9)
Postgraduate degree	6 (17)	6 (100)	0
Other(s)	1 (3)	1 (100)	0
Relationship status, *n* (%)			
Single	7 (19)	7 (100)	0
Married	23 (64)	11 (48)	12 (52)
In a relationship	3 (8)	3 (100)	0
Divorced	1 (3)	1 (100)	0
Widowed	1 (3)	0	1 (100)
Other	1 (3)	1 (100)	0
Employment status, *n* (%)			
Employed full-time	10 (28)	9 (90)	1 (10)
Employed part-time	11 (30)	7 (64)	4 (36)
Home duties	9 (25)	1 (11)	8 (89)
Student	1[a]	1 (100)	0
Unable to work	2 (6)	2 (100)	0
Other(s)	4 (11)	4 (100)	0
Diabetes management, *n* (%)			
No treatment	3 (8)	2 (67)	1 (33)
Diet and/or exercise	6 (17)	1 (17)	5 (83)
Tablets	11 (30)	8 (73)	3 (27)
Insulin	1 (3)	0	1 (100)

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TABLE 1 (Continued)

	All ($n = 36$)	UK ($n = 23$)	Turkey ($n = 13$)
Diet + tablets	6 (17)	6 (100)	0
Diet + tablets + insulin	3 (8)	2 (67)	1 (33)
Tablets + Insulin	6 (17)	1 (17)	5 (83)

[a]One participant reported her employment status as employed part-time and student.

7.2 | Themes

The findings are presented below in relation to the identified themes. Each theme includes several sub-themes representing a range of experiences and health needs of women with T2DM and is supported with relevant extracts from the interviews (Tables 2–4).

Theme 1: **Perception of self and identity as a young woman with type 2 diabetes.**

The perceptions of T2DM related to self and identity represent a range of emotions and attitudes towards diabetes management. This theme comprising of four subthemes reflect how women generated a sense of identity disruption, negative self-perception, concerns about fertility and future pregnancy plans, and the emotional burden of diabetes management, are described below, with supporting data in Table 2.

7.2.1 | Identity disruption

After their diagnosis, most young women expressed how their role identity such as, a parent, partner, friend, or work colleague were disrupted, in comparison to life before T2DM. The disruption was expressed as a change in how women viewed themselves and related to their roles, for example, as a partner and experiencing sexual health issues related to diabetes. Others reported concerns about not being able to fulfil the needs of their children despite being a young parent. The inability to perform routine activities was considered a critical part of their identity, such as socialising with friends. Women reported severe tiredness and weakness creating difficulty with work performance and concerns for their future careers or employment, which they attributed to the burden of diabetes.

Most women described being judged by others due to their diagnosis of T2DM at a younger age. They described stigma associated with T2DM, due to their '*wrong*' lifestyle, being overweight, or through their own failings, bringing the condition upon themself. Others reported stereotyping assumptions with the perceptions that T2DM is not '*real diabetes*' or due to '*laziness*' which was frustrating and upsetting for them.

7.2.2 | Negative self-perception

Living with T2DM was reported by women as sense of negative self-perception. They compared themselves to others in terms of age with statements such as, '*my age is much younger*', '*why is it happing to me*', and in terms of weight, particularly with those who are overweight and yet did not have diabetes. They reported that these negative thoughts affected their behaviours over time.

Women also expressed a perception of self-blame for bringing T2DM on themselves through their unhealthy lifestyle. They expressed that other forms of diabetes would be preferable, such as type 1 which they did not associate with '*poor lifestyle behaviours*' or '*older age*'. These negative perceptions were often the catalyst for women not disclosing their diagnosis to their friends or family members. Women described key reasons for concealing their diagnosis as being ashamed, and a fear of social monitoring such as, people watching or commenting on what they ate. For many women their diagnosis generated a loss of self-value, resulting in feelings of isolation and loneliness.

7.2.3 | Fear surrounding fertility and pregnancy

Women were concerned that T2DM would impact their fertility with some expressing a fear that they were at risk of early menopause, resulting in worry and uncertainty about future pregnancy plans. Several women believed that they would not get pregnant due to diabetes, while others thought their chances of conceiving would increase if they followed a diet plan. A belief that diabetes could harm a future baby during pregnancy was reported by several women; however, they were not quite sure how. Women who had previously been pregnant with T2DM described that the burden of diabetes management during and after pregnancy caused emotional distress. They indicated that more attention to diabetes is needed for the future health of their children. One woman reported that the distress of not knowing how diabetes could impact her pregnancy resulted in her having a termination. Women reported that the opinion of their partner was influential in their pregnancy planning behaviours, particularly if they had a previous adverse pregnancy experience. Cultural perceptions were also expressed with a South Asian woman

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TABLE 2 THEME—Perception of self and identity as a young woman with type 2 diabetes

Subtheme	Subtheme definition	Supporting data (Participant ID)
1.1 Identity disruption	Role disruption: The roles, including partner, parent, friend, and future career/work, were disrupted in their life.	Partner: "*When I had cracks and itches [in my genital area], it was even more irritated during intercourse and it hurts me, of course, it causes reluctance.*" (P03, TR) Parent: "*It is stressful, think about it, you are a young adult, with children, but you cannot take care of your children like you used to.*" (P35, TR) Friends: "*I went out with a group of friends, and I ate before I went out because where we were going didn't really have diabetes friendly food.*" (P02, UK) Work: "*With the diabetes making you feel tired... When I'm having a bad day, I'm thinking, sometimes, thinking [to] myself [about] going back to work. I think it's all overwhelming. I think it was like "I'm not gone cope to back to work." So, I want to go back less hours than previously.*" (P25, UK) Career plans: *"It [diabetes] affects my energy levels and makes me very tired... Because I get tired quickly. I think it might affect my career at work because I see other people that [are] fit and healthier, and they don't seem to have that problem."* (P29, UK)
	Identity judged due to type 2 diabetes: How perceived by others as a woman with type 2 diabetes? Feeling stigmatised by others, including friends, family, and healthcare professionals.	Weight related stigma: *"If I say to people, 'oh, I've also got type 2 diabetes now', I feel that I'd be judged because they would feel that 'well it's obvious because you can see that she gained weight'..."* (P33, TR) Blame: "*People just think, well, you know...You must have done something wrong; but you think yourself, I've done everything right and I've still got it, then is there some other factor that contributed towards it? That's what it is.*" (P18, UK) Label: "*There is almost a label attached to the diagnosis, that you don't look after yourself and eat the wrong things, which really is not the case.*" (P30, UK). Discrimination: "*You know, if you ever say to people, you've got it [type 2 diabetes], there's this kind of, um... we talk about all the sort of stigmas and the discrimination that's out there. I think there's an unspoken discrimination of people that are obese.*" (P31, UK) Stereotype assumptions: *"Another impact is dealing with the stereotypical assumptions people make once they find out you're not a "real diabetic" this makes me feel so annoyed. I didn't set out to give myself diabetes, unfortunately it chooses me."* (P14, UK)
1.2 Negative self-perception	Self-perception of developing type 2 diabetes: How each woman viewed their condition. Feelings of being "too young" for type 2 diabetes, feelings of self-blame, ashamed by having it at younger age, compared with that of people without diabetes.	Existential questions – "Why me": "*There were many times when I rebelled. I said, my age is much younger, why is it happening to me.*" (P26, TR) *"When I had the GP's receptionist called me and she just tells me over the phone. "You are diabetic" and that came to a shock because I don't have a sweet tooth. I generally do exercise...It was just like out of the blue for me."* (P18, UK) Comparison with others: *"I said to my husband, 'the thing that really upset me was I have friends and people that I know that are much larger in size to me, but they don't have diabetes'."* (P02, UK) Self-blame: "*Well, I had a blood test for 1.5 and it didn't come up with the antibodies..... but I want to have it [type 1.5] because that means it's not my fault.*" (P11, UK) *"There's also the day to day, sort of, 'you've done this to yourself...because it's one of those- 'it's your own fault'..."* (P04, UK) Shame: "*I think I told a couple of close friends, but I was really ashamed because there is that whole sort of 'you're very young to be getting this,' so I didn't tell many people.* (P04, UK)

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TABLE 2 (Continued)

Subtheme	Subtheme definition	Supporting data (Participant ID)
	Consequences: Feeling unable to participate in social activities, unwillingness to disclosure their condition to others, then feeling lonely	Isolation: "*Isolation is an issue as I feel unable to engage in the same social activities as my friends.*" (P15, UK) Non-disclosing diabetes—Exclusion: "*I wouldn't go anywhere. I couldn't go, I wouldn't go to my friends or my family's house because I didn't want to tell them that I had diabetes.*" (P18, UK) Loneliness: "*I have struggled to value myself in the same way after being diagnosed with this condition [type 2 diabetes]. I have not been able to find a secure relationship since and feel lonely.*" (P36, UK)
1.3 Fear surrounding fertility and pregnancy	Fertility ability and pregnancy related anxiety and fear of future baby health.	Fertility concerns: "*Fertility has been my main concern as I worry about being able to conceive...*" (P15, UK) Fear of early menopause: "*They tried to speak to me about it [menopause], but I didn't want to hear it was really upsetting. Because I think they said you could get early menopause, but I don't want to think about it.*" (P29, UK) Misconception: "*I think it's much harder for people with diabetes to have babies because of the trying to control it [diabetes].*" (P22, UK) "*I am afraid that high blood sugar level may poison the baby*. (P13, TR)" Termination of pregnancy: "*Due to my diabetes, I feared that the baby might be affected by something during pregnancy and be born disabled. That's why I aborted my third baby. If I deliver a healthy baby, how long will I live? How can I take care of the baby?*" (P03, TR) Partner views: "*If it is up to me, I want a second child, but my husband does not want it because of my diabetes... My husband says "you have diabetes, what if our second child becomes like our first child who was born too early [36 weeks of pregnancy]," he is afraid too, I am frankly scared.*" (P13, TR) Cultural beliefs: "*I don't know, lots of things associated with diabetes, like especially in my country, Pakistan, they think if you are more than 35 years...Yes, it's difficult to have children. If you are diabetic, you are not to conceive.*" (P17, UK)
1.4 Emotional burden of diabetes management	Diabetes management: The emotional impact of diabetes management (including insulin, optimising blood glucose level) was present throughout most women.	Diabetes management perception at time of the diagnosis: "*The reason I don't use medications is because I don't think I'm sick.*" (P12, TR) "*When I was first diagnosed, I'm not going to lie - I didn't take it seriously, I was on metformin only. I thought I would loose some weight and the diabetes would go away!! Looking back now I think wow, how stupid was I. It's had a massive impact on my life. Now I inject four times a day and take three different types of insulin.*" (P14, UK) Burden of diabetes management: "*I was crying my lungs out, only to realize that 'Oh my God, I have to take medicines like my whole life'... It was difficult because I've seen my father living with diabetes, but that was like in the late 50s or 40s. But for me, it was too early...*" (P17, UK) Emotional impact of blood sugar level fluctuations: "*Anxiety was quite a lot around it [diabetes] because it was the unknown. I think with depression... She [therapist] did say that sometimes your sugar level, if it's not controlled you can be more prone to having depression.*" (P18, UK) "*Living with diabetes is difficult. Of course, it impairs mental health... but is it going to stop my heart in a moment? Will my blood sugar rise at night and stop my heart?*" (P34, TR)
	Disordered eating: Emotional concerns seemed to cause emotional deep relationship with eating.	Eating to cope with emotions: "*I mean all of us eat for reasons beyond our hunger and eat because of relations, because of things to do with how we're feeling...when I say damaging myself, I mean literally, like there are points in my mental health where I eat things that I know will hurt me.*" (P19, UK)

Abbreviations: TR, Turkey; UK, the United Kingdom.

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TABLE 3 THEME—Type 2 diabetes is not orientated to women's needs

Subtheme	Subtheme definition	Supporting data (Participant ID)
2.1 Authoritarian approach	Healthcare professionals' interactions are process driven rather than driven by women's personal needs	Feeling "*patronised*": "*My practice nurse I found her patronising. She keeps saying "No you have to do it this way! to do it this way!" not understanding that you know, the way I am eating. I've been doing it for my life, and it [diabetes] changed all what I do, the way I function. She just thinks it's easy to stop eating. If I try and explain she doesn't want to listen to me.*" (P25, UK) "*If your sugar goes high, they won't say: "Yeah, I'll work with you. Let's see why it's high. Because it was low last time." They will say to you, here you go have an extra tablet.*" (*P18, UK*) Listening to younger women's preferences: "*It didn't matter how many times I said "this doesn't help, this doesn't work for me". It was sort of ignored... So, listening. Because every time I went, they would tell me, you know, "oh, just carry on taking it [medication], it's good, it's fine", and nobody listened, and I ended up just not taking it.*" (P31, UK) Missed care on diabetes and its management: "*All I've been told was to check my blood sugars, nothing about diet, nothing about exercise.*" (P33, TR) "*I was feeling quite rubbish and it was just because it turns out I had really high blood sugar. So yeah, no, I didn't know, nobody, there was no advice on it or how to prevent it.*" (P27, UK)
2.2 Conflicting agenda	A conflict between the agendas of women, such as their reproductive issues, or emotional support needs and the consultation topics of healthcare professionals.	Lack of reproductive age and gender-specific diabetes care: "*HCP have mostly talked about general health issues, such as diabetes impacts on kidneys, heart, eyes, feet and toes/nails, nerve damage* etc. *Those are usually the topics they cover but they have not specifically advised about fertility, menopause, or sexual health.*" (P30, UK) "*We talked about medication, we talked about lifestyle changes, but he [doctor] didn't even mention the fact that this was an incredibly significant life change for someone who was, at the time, not even 30...No one ever asks about something that actually is relevant to my life, so that would be interesting. I'm aware that it could affect my sexual health in the future.*" (P19, UK) Lack for individual psychological support: "*My diabetes nurse and diabetes midwife were too focused on my diabetes rather than my mental well-being and did not offer much support.*" (P24, UK) "*I feel like doctors are a little dismissive in, like, you know, it's a question in my mind, like, 'how did this happen? When did this start happening, and what went wrong first?' But doctors are not interested in answering the question because they're mainly interested in managing your condition now. So, they basically just want to discuss what dosage of medicine I need right now rather than discuss what's causing what.*" (P16, UK)
2.3 Lack of empathetic approach	A strong view on the lack of empathy in the diabetes care as well as experiences of feeling guilty due to healthcare professional's attitude.	Perceived direct or blunt approach: "*I think the way the doctor told me—it wasn't even like, 'sit down, we need to have a chat about your latest results'. It was almost like, 'oh, by the way, you know you're diabetic now, right?' I don't think it was very sensitively handled.*" (P04, UK) "*So just, with sensitivity...Like with gentleness, and with an understanding that the person you're telling is probably going to find that quite distressing. Whereas I think a lot of the doctors I've spoken to have been very blunt, and have not really taken into account that, you know, it's scary for people.*" (P04, UK) Triggering negative feelings: "*So from my first appointment at the GP, it was very much... compassionate, you know, and saying, "look, do you believe you can do this? I believe you can do this. Let's do this together. Let's see how we are and, you know, I know you're trying." And it was just lovely. I almost cried because she was just like really, you know. And then I felt guilty that I hadn't done enough.*" (P31, UK) Tick boxes approach: "*Maybe have a slig-htly more open conversation, so by that I mean it's just not productive to year on, year on, year on, year, to ask me questions that, if we're honest, just allow you to tick the boxes on the screen, and it's even worse when I can see you doing it.*" (P19, UK)

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TABLE 4 Components of improved care

Suggested Components	Component definition	Supporting data (Participant ID)
Information and awareness	A need for raising awareness and information about type 2 diabetes among younger women, family members and public.	Information from a younger age: "*I think education is a key aspect in reducing the risk of diabetes, at an earlier stage. So, I would not even wait until my age [35 years], but, as I'm here and many people are, and even older, it's not too late to be educated.*" (P07, UK) "*I think the best way to help young women with diabetes would be to introduce more education regarding the condition. Not only this, but the effects it has emotionally too…This education could be achieved through charities attending school assemblies or awareness days at universities which are dedicated to type two diabetes.*" (P24, UK) Information for others (family members and public and culture based): "*I really think people need education of diabetes before they start judging.*" (P14, UK) "*With regards to education, it's everyone! Especially family who do not understand the ins and outs of diabetes.*" (P14, UK) "*They need to look at the individual and you look at the culture because all your life you have always had a carb diet and suddenly you say to you cut yourself down. They do not have education, so that's the one thing they do not have. They do not have these.*" (P18, UK) Visibility in healthcare setting: "*It's important they also know diabetes doesn't just happen to older people, many young women and even children get diabetes. These facts could be given on the NHS website or leaflets or even given out routinely at GP appointments or stuck on notice boards* e.g., *a poster saying, "Did you know…*" (P09, UK) Media campaigns (newsletter, TV): "*It would be better if more information [about diabetes] is given in newspapers. In this way, it would be better if they see that it is not a shame… If they are broadcasted in televisions, for example.*" (P23, TR)
Tailored approach	Need therapeutic approach: suggestions of specialist and psychological therapies to manage diabetes better.	"*That kind of the complicated relationship between emotions, eating, diabetes and shame, and that spiral. And I'll just say it again, that it is probably out of the scope of most practice nurses and requires a more therapeutic approach.*" (P19, UK) "*If I'd accessed therapy at the point of diagnosis or soon after, that may have actually been really helpful… in an ideal world, I think that, um, therapy has this enormously important role in understanding why we behave the way we behave, why we feel the way we feel.*" (P19, UK)
	Age and gender awareness in diabetes care: interest in getting information on diabetes specific to age and gender.	"*I think that the first line of advice is to sort of you know, lose weight and, look at your diet, and I didn't feel that applied to me. So, I turned it down on that basis. I think it would have to be really interesting, actually. If it was something specific to women and about how, you know, you're sort of, your hormones and your monthly cycle, pregnancy, menopause, all of those aspects.*" (P27, UK) "*[Healthcare professionals] have not specifically advised about fertility, menopause or sexual health…these topics do need to be discussed more prominently when a diagnosis is made.*" (P30, UK)
	Need follow up in diabetes care: Highlighted the continuity of care	"*You have this initial program, Desmond, for two sessions, and then they send you on your way. Then they never look round to have another follow up…I think you should have something like a three-month review or a six-month review and then try to do, you know, try to get back in the for appointments to make sure that you stay on track.*" (P18, UK)

(Continues)

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TABLE 4 (Continued)

Suggested Components	Component definition	Supporting data (Participant ID)
Supportive connection with other people	Highlighted the importance of the support of healthcare professionals, social, peer and at work.	Healthcare professionals support: *"I feel more relaxed because it's like they are sharing some of my burdens, they're helping."* (P05, UK) *"Actually, the nurse I talked about, she's brilliant... It was reassuring that the care is there... so that makes you feel a bit less anxious about it and... yeah, just have to carry on doing what I can do."* (P27, UK) *"Another way young women could get help would be if they were provided some sort of information leaflet or booklet from their GP with meal ideas, tips, contact numbers and useful links, so that instead of looking on google or on an app, everything is in one booklet that's easily accessible."* (P24, UK) Social support (family, friends, and neighbours): "*My daughter is very aware of my diagnosis and monitors/tells me off if I eat something that is full of sugar. She constantly tells me off for eating rice."* (P30, UK) "*My housemates eat very healthy consciously—it sort of encourages me too."* (P04, UK) "*We would see them [neighbour] running everywhere, and even on Christmas Day and we were like, "do these people have no bloody shame? What is wrong with you?", like, you've just got to, 'Oh, I've just got to go for a quick run', and we laughed at ourselves when we started joining them... I just thought 'We're starting to be those people.'...*" (P31, UK) Peer support: *"You're all in the same boat, you want to lose weight, but you are doing it for the longer-term health benefits, so you will choose the right way and you share ideas from each other."* (P02, UK) "*It's like there's a lot to learn about diabetes with people with my age group would really, really, really need to get informed about what they're dealing with. The best way to manage it...So talking about it with other people makes you feel like you're not the only one struggling with it, but other people got it as well.*" (P25, UK) *"I did feel if I were to go to one those courses, it would, like, be focused on older people and it would be a room full of older people, and I didn't really feel like that applied to me."* (P27, UK) Support at work: "*I think that's a massive thing. If we're going to encourage other people to do this, we should be able to say to bosses— like if you had a doctor's appointment in the morning, you would be able to come in late and have some time."* (P31, UK) *"Workplaces need to be a little more understanding."* (P23, TR) *"It certainly encourages me to have exercise daily instead of delaying or cancelling some of the exercise because of work...in terms of exercise and work, I try to, I changed my job."* (P05, UK) Social media (Facebook-WhatsApp groups): "*I think also there's so much, like, informal support online. So, for example, I'm a member of a couple of groups, Health At Any Size, like, Facebook groups where members might have diabetes. And that's, yeah, the kind of nuance that's missing from NHS talks. And that's really helpful."* (P04, UK) "*Because I have sugar friends, we have a WhatsApp group to communicate...to support each other. We're not alone at least."* (P23, TR) Application suggestions: "*Maybe an App that would tell me If I am eating out what I can eat, that is healthy."* (P29, UK) *"Just more details about maybe an App or something that you could just record how your eyes are feeling and how your feet are feeling and whether you should get them checked quicker."* (P29, UK)

Abbreviations: GP, general practitioner; HCPs, healthcare professionals; TR, Turkey; UK, the United Kingdom.

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describing that T2DM would lead to fewer pregnancies and therefore would negatively impact their marriage prospects.

7.2.4 | Emotional burden of diabetes management

The participants expressed that living with diabetes at a young age may negatively affect how they emotionally relate to diabetes management. Some reported a sense of denial about their diagnosis, particularly surrounding what they perceived as restrictions. Crucially they believed that they were somehow immune to diabetes complications as '*nothing happens*' at younger age, resulting in suboptimal self-management and medication adherence. While several women made statements about '*feeling it was too early*' for them to have diabetes, they were also concerned about the need for prescribed medications for their lifetime. Women also expressed their fear for their future, fear of developing diabetes complications and how these might impact them.

Women also described how the emotional burden of their diabetes management impacted their eating behaviours and relationship with food. They shared that they coped with life stressors, or difficult emotions such as sadness, or anger with eating whenever they felt like, irrespective if they were hungry or not. Eating was considered beyond women's individual control, reporting that despite knowing that '*addictive eating*' could negatively impact their health, they would continue, but then feel guilty later.

Theme 2: **Type 2 diabetes care is not orientated to women's needs.**

This theme identified that women's health needs were not attended to in routine diabetes care that comprises of three subthemes: authoritarian approach, conflicting agenda and lack of an empathetic approach (Table 3).

7.2.5 | Authoritarian approach

Women described a process-driven approach by healthcare professionals during consultations. They expressed feeling '*patronised*' by healthcare professionals and not involved in decision-making about their diabetes care, such as the insistence on prescribing more medication rather than listening to their preference. Many women identified how this authoritarian approach contributed to reduced trust in their healthcare professionals, resulting in suboptimal adherence to prescribed medications. While women wanted to be involved in their diabetes management and emphasised the importance of being listened to in relation to their concerns, they also reported not feeling enabled to do so due to their lack of information about diabetes and its management.

7.2.6 | Conflicting agenda

Women highlighted a conflict between their expectations of what they wanted to address in a consultation and what the healthcare professionals spoke about. Women reported that conversations focused on general aspects of diabetes rather than reproductive issues such as fertility or sexual health, therefore their age and gender-related health concerns were not discussed. Most participants reported that their pregnancy intentions were not elicited during their annual diabetes reviews.

The women reported that for them emotional support was as significant as their clinical care. Many expressed strong opinions about not being afforded the opportunity to discuss their concerns and emotions with healthcare professionals during consultations, who they believed placed no attention on the emotional burden of diabetes.

7.2.7 | Lack of empathetic approach

Many women had an expectation that healthcare professionals would be more empathetic and supportive in terms of the emotional aspects of living with diabetes. However, they reported a lack of empathy during consultations. They felt healthcare professionals were often very negative which was distressing for them. Women also reported that the language used by healthcare professionals often triggered negative feelings such as guilt or a sense of failure. For some, consultations with healthcare professionals were like tick boxes exercises, which were not beneficial.

7.3 | Components of improved care

Women made a number of suggestions about what would be helpful to improve their health and wellbeing when living with diabetes during their reproductive years. Three subthemes were identified, information and awareness, a tailored approach to care and supportive connection with other people. The supporting data are presented in Table 4.

7.3.1 | Information and awareness

Most women expressed a desire for more age-specific information and awareness about diabetes and its management. They reported that knowing more about diabetes could improve their health and wellbeing and support them

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to optimise their diabetes management. However, women reported feeling judged by family members and the public. They attributed this to a general lack of diabetes information and awareness and suggested that this could be mitigated by public messaging and education. They also proposed culturally tailored education systems noting that cultural differences might be a barrier to optimal diabetes management.

For some women, their experiences of shame proved a big obstacle to optimising their self-management. Women indicated that greater public awareness may help, including a greater visibility of T2DM for example, on public websites, leaflets, newsletters, or television documentaries.

7.3.2 | Tailored approach

Most young women proposed greater continuity of care that was tailored to their emotional needs, age and gender. Women were vocal about the lack of emotional support in diabetes management and suggested incorporating psychological screening and management at every level of diabetes care.

Women indicated that as access to reproductive healthcare was limited in the context of their diabetes, they required support related to fertility, pregnancy planning, contraception, menopause and sexual healthcare. They identified general practice as being where this care could be situated ideally; however, currently their reproductive wellbeing was not considered in these consultations. Recognising that reproductive health topics were not always easy to discuss, women highlighted the importance of providing them with relevant information while also fostering openness during consultations, and a relaxed, comfortable environment. In addition, women emphasised the need for access to follow-up care, to ensure that *'they stay on track'* and would help them to build trust and confidence with their healthcare professionals.

7.3.3 | Supportive connection with other people

Women reported that they needed to feel connected to family, friends, work colleagues and healthcare professionals. They spoke about the importance of social support as well as peer support, particularly with those who have similar lived experiences. Women shared their experiences of speaking with other women made them feel relieved, confident and not alone. They also suggested that peer support could be accessed through technology, particularly apps that are interactive or that send supportive and motivational messages. Women suggested that for many of them there is a need for support within the workplace as there is a general lack of awareness about diabetes among their managers or employers.

8 | DISCUSSION

This study has provided novel insights into the health needs, experiences and views of women with T2DM of reproductive age. Women's perception of self and disrupted identity expressed gender and age-related health issues, fear surrounding fertility and pregnancy, and the emotional burden of diabetes management at younger age. Their experiences that healthcare was not orientated to younger women meant that the focus of diabetes care did not align with their needs, but rather that consultations were process driven. Women wanted their diabetes care to acknowledge and provide for their reproductive health needs, including their emotional needs. Reflecting their health needs, participants also provided suggestions about how to enhance care.

Related to their perception of self and identify, women expressed feelings of shame and stigma following a diagnosis of T2DM. This contributed to them to concealing their diabetes in their personal relationships, which has been previously reported.[7,13,15] The wider literature suggests that these negative emotions can impact negatively on self-management and patient activation.[10,13,14] This study highlighted that psychosocial health needs are not adequately addressed, contributing to women expressing a sense of low self-value, feeling isolated, and lonely. While stigma has been reported in older people with T2DM (median age 61 years),[24] it has not been reported in relation to younger women living with T2DM. Further research is needed to explore the relationships between diabetes stigma and self-management, and to develop strategies to reduce the impact of stigma.

Women with T2DM subjectively perceived themselves to have a low level of awareness, knowledge or understanding of the potential impacts of their diabetes on fertility and pregnancy.[15] This study presents the concerns younger women expressed regarding fear of future diabetes complications, shorter life expectancy, feeling overwhelmed by diabetes demands; however these feeling can be barriers to their self-care, thereby increasing their risk of long-term complications.[9,25] These data align with the concerns expressed about younger people living with T2DM.[2,13] The women's accounts also concur with the findings of previous meta-analysis showing a high level of emotional burden and the importance of psychological support.[9,25]

There is little understanding about how women with T2DM develop disordered eating and how it is effectively treated.[26] This present study reports that disordered

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eating among women with T2DM was used as a coping mechanism when managing emotional responses, either positive or negative. This novel understanding among younger women with T2DM has the potential to perpetuate negative impacts on the health and wellbeing among this population as women reported feelings of guilt and shame that created a cycle of disordered eating patterns. These experiences are mirrored in the disordered eating experiences of individuals who are overweight or obese, for whom psychosocial interventions were reported as effective in improving health outcomes.[27] This study that suggests further research is needed to better understand how disordered eating arises in young women with T2DM and how to treat them effectively.

Healthcare professionals providing emotional support during a consultation has been related to improve engagement in self-care, patient–healthcare professionals relationships and diabetes outcomes.[28] This study reported that a lack of attention to specific health needs was attributed to participants reduced confidence and trust in the healthcare professionals and their ability to provide effective care.

To enhance care during their reproductive years, women living with T2DM suggested the need for psychological support and peer support, which may help reduce feelings of isolation and loneliness. These corroborate a position statement outlining recommendations to address the unmet needs related to health and well-being of people living with diabetes.[26] Furthermore, the report of the women's health strategies for England highlighted women's health needs generally across their life course, such as pregnancy and mental health.[29] These align with the health needs and views of women with T2DM reported in this study. However, currently reproductive health is not routinely addressed in the consultations for women with T2DM, nor is it included in structured education programmes.[15,17,30] Therefore, there is a need for a greater awareness and recognition of this aspect of healthcare from a healthcare system perspective so that it can be incorporated into routine diabetes care for all women of reproductive age.[8]

8.1 | Study strengths and limitations

It was not possible to recruit women in their younger reproductive years who may have presented alternative perspectives. Nevertheless, it was possible to illustrate the experiences of women across three decades, with women aged in their twenties, thirties and forties from both the UK and Turkey represented in the study.

While information power is achieved at the level of women's reproductive age and diabetes diagnosis, there is much diversity contained within the study population such as culture, duration of diabetes, country of residence and specific reproductive health experiences (e.g., pregnancy; pregnancy intentions) that have not achieved information power. Framework analysis supported synthesis within this diversity, allowing for inductive themes to be generated from the data that identified how a woman lives with diabetes or the creation of deductive themes stemming from the self-efficacy theory. Despite some differences in socio-cultural context, the experiences expressed by women across both the UK and Turkey were remarkably similar. These similarities were apparent in their descriptions of their experiences, thus the study data presented were convergent between the accounts of women from each country and data from women from both countries have been presented in Tables 2–4.

While this study focused on women living with T2DM during their reproductive years, there are however potentially unrepresented groups, for example, none of the participants identified being from the LGBTQ community.

Online strategies were used to recruit study participants, which automatically excludes those without access or ability to use technology. Using different data collection techniques resulted in varying levels of depth to the data. However, combining data from different sources (video/phone and email) in a single study can provide trustworthy findings.[22]

9 | CONCLUSIONS

This study presents the experiences and views of women living with T2DM during their reproductive years from the UK and Turkey. The data from participants from both countries are convergent and presented together. These data illustrate that women's perceptions of themself and how they identify can lead to negative emotional consequences. Women had emotional concerns often related to their reproductive health; however, these did not feature during consultations with healthcare professionals. These data highlight the need for strategies targeting care for this group.

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CONFLICT OF INTEREST

The authors declare that they no conflicts of interest.

DATA AVAILABILITY STATEMENT

I confirm that my Data Availability Statement (pasted below) complies with the Expects Data Policy. The data that support the findings of this study are available from the corresponding author upon reasonable request.

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diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised controlled trial. *BMJ*. 2008;336(7642):491-495.

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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4.10 Reflexivity

Reflexivity refers to sensitivity to the ways in which the research process and researcher might shape the data collected, including researcher's prior knowledge, experiences, and assumptions (Dodgson, 2019). It is an ongoing process that involves reflection by researchers on their values and entails self-awareness, which means being actively involved in the research process. It is about the recognition that a researcher is part of social world that is being studied (Palaganas et al., 2017). To reflect on my own personal background, I have been involved in diabetes research since 2018, with a specific interest in T2DM and diabetes management at younger ages. To address any potential bias due to my own background, other clinical and academic researchers have been involved in different stages of this qualitative study (supervisory team comprising Professor Jackie Sturt (Academic researcher), Dr Rita Forde (Academic and clinical researcher), and Professor Angus Forbes (Academic and clinical researcher); and for the qualitative data collection support, Aya Temple (Visiting researcher).

The researcher does not have clinical diabetes experiences and were not familiar with the research population (younger women with T2DM), resulting in reducing assumptions about the participants. Additionally, my supervisors reviewed the initial transcriptions of the interviews, in particular to look for the quality of dialogue and identify any interviewer bias that would need to be eliminated in subsequent interviews. To decrease bias in data interpretation, nearly all the transcriptions were re-read by two different research students (research elective student) to check any missing important health issues before finalising the final themes and sub-themes generated by the researcher. Then, final themes were created after discussions within the wider research team. This process helped reduce my personal presumptions and biases.

4.11 Implications of qualitative study for this thesis

This study has provided a novel insight into the reproductive age health needs, experiences, and views of young women with T2DM. For example, this qualitative study highlighted that women with T2DM experienced disordered eating behaviours to cope with emotional management, which is a novel health issue to this population that could negatively impact their health and wellbeing. The findings also emphasised that they feel overwhelmed by the diabetes demands at a younger age (e.g., daily insulin injections); feeling tired created considerable difficulty maintaining their work performance; feelings of being ashamed due to having developed T2DM at younger age; and a feeling of being judged by others about having developed diabetes at younger age. A consequence of these feelings resulted in sub-optimal diabetes management among the participants, increasing their risk of long-term complications. To address the health issues reported by women, interventions tailored for the experiences of young women with T2DM are needed. Overall, this study identified a wide variety of relevant health topics to target in any future intervention, thus contributing to the literature. Specifically, diabetes-related psychosocial health issues and suboptimal diabetes management activities were identified. However, further research is needed to explore the prevalence of these health issues associated with living with diabetes and its consequences in younger women with T2DM, to be targeted in future interventions.

With the number of younger women with T2DM increasing, HCPs need to be aware of their needs to navigate reproductive health and diabetes concerns across their lifespans. This research may provide a stepping-stone to inform health policy about how reproductive age health issues can be effectively addressed in planning and delivering diabetes care with and for women with T2DM. For example, with the findings of this qualitative study, the researcher has contributed to the development of the UK Government's Women's Health Strategy of June 2021. The UK Government made the call for evidence to collect the views on women's health issues and women's experiences of the healthcare system in order to support improvements in women's health. This call for evidence was intended to inform the priorities, content, and actions within the Women's Health Strategy, ensuring that the strategy was evidence-based and reflected what women identify as priorities. The strategy focuses on the women's health and care needs across their life courses to support women in terms of improving their health and preventing or reducing the risk of ill health later in life

(Department of Health and Social Care, 2021). For this call, they requested written submissions from individuals or organisations with expertise in women's health. Therefore, we responded to the call for evidence and provided evidence of the health and healthcare needs of the women of reproductive age living with diabetes from a synthesis of eight studies, including a systematic review (Study 1) and qualitative study (Study 2) of this thesis. We highlighted the lack of age- and gender-based diabetes care (e.g., lack of discussion about fertility during the consultations); and there is a need to acknowledge the psychosocial health issues (e.g., stigma, shame) experienced by young women of reproductive age living with T2DM. Afterwards, we presented an action and specific recommendations to improve the health and healthcare of women with T2DM. Details of the report we submitted is presented in Appendix B.1.9.

In August 2022, the government published a report summarising all the evidence submitted by the expertise in women's health or individuals who responded to the 'Women's Health – Let's talk about it' survey components of the consultation. This report highlighted priority areas to improve women's health across their life courses, for example the early menopause, pregnancy, fertility, and mental health were reported as the highest priority health needs. They also published the actions to meet women's reproductive health needs across their life courses (e.g., understanding the changing health and care needs of women throughout their lives; and how to embed changes in clinical practice). As a result of this report, this thesis has produced a contribution to the body of evidence on women's health and healthcare needs to improve their health and wellbeing.

4.12 Chapter Summary

This chapter presents a qualitative study exploring the experiences and health needs of young women with T2DM during their reproductive years. It also outlines the rationale for the design of the study, including why in-depth semi-structured online interviews were chosen. The sampling strategy, recruitment, and the research methods of the data analysis were outlined in the chapter. The data analysis has been outlined in detail, including the components of Framework Analysis, and examples of data management. Trustworthiness, reflexivity, and ethical issues in relation to the conduct of the study were addressed. The

findings further highlight psychosocial factors including anxiety, distress, stigma, and fatigue that have a significant impact on the health and wellbeing of women with T2DM during their reproductive years, resulting in suboptimal diabetes management. Thus, this study suggests further research to explore the correlations between psychosocial factors and self-management behaviours among young women with T2DM. With recommendations of mixed methods research in the MRC framework (Craig et al., 2008), this provides a rationale for a cross-sectional study, which is presented in the next chapter.

Chapter 5 – Relationships between psychosocial health factors and self-management behaviours among young women of reproductive age living type 2 diabetes: A cross-sectional study

5.1 Chapter overview

The published manuscripts (Studies 1 and 2) have identified the particular and unmet healthcare needs of younger women with T2DM. These studies have provided certain insights into how a number of psychosocial factors have mediated women's health needs, including diabetes distress, anxiety, diabetes-related stigma, fatigue, and disordered eating regulation. However, there is a paucity of evidence addressing the prevalence of psychosocial factors related to living with T2DM and quantifying its consequences in young women with T2DM. Therefore, this chapter presents the rationale behind, and results of a cross-sectional study to assess the prevalence and correlates of psychosocial factors and self-management behaviours in this population. The chapter also outlines the study methods, including design and recruitment, and provides a rationale for the measures used, including the selection of psychosocial outcomes to be measured, along with the study strengths, limitations and implications.

5.2 Rationale for cross-sectional studies

The psychosocial health issues experienced by this population of women and identified in the previous chapter include diabetes distress, anxiety, diabetes-related stigma, along with fatigue, and disordered eating. These psychological morbidities have known associations with suboptimal glycaemic control, an increased risk of diabetes complications, and reduced quality of life (Yang et al., 2020; Hu et al., 2020; Preis et al., 2009). Therefore, it may be important to consider and potentially prioritise addressing psychological morbidities and other psychosocial factors when supporting young women with T2DM early in order to reduce hyperglycaemia and risk of future diabetes complications (Fritschi et al., 2012; Thomsen et al., 2016). The qualitative study identified their existence and the depth of their

impact in a small sample of women, but the prevalence of these experiences across a wider population is unknown. A cross-sectional study offers a first opportunity to understand this prevalence at a moment in time.

Cross-sectional studies are a form of observational study in which the investigator does not alter exposure status, but rather assess or observe the outcome and exposure(s) in the population and may further study their associations. The three main types of observational studies include cohort studies, case-control studies, and cross-sectional studies (Vandenbroucke et al., 2007; Mann, 2003). Unlike in cohort studies where participants are selected based on the exposure status, or case-control studies where participants are selected based on outcome status, the investigators in cross-sectional studies assess all the measurements for each person in a sample at one particular moment in time, or over a short time period, so as to provide a "snapshot" of the outcome and the characteristics associated with it (Levin, 2006). A cross-sectional study design is utilised to either estimate the prevalence of the outcome of interest for a given population or to consider possible associations between exposure and outcome (Vandenbroucke et al., 2007; Levin, 2006). This design allows for the testing of multiple hypotheses, with the inclusion of multiple dependent and independent variables. Therefore, it is a valid way to determine the prevalence of a problem, or set of problems, in a given population or as means of identifying associations between variables that can subsequently be used to inform an intervention model. The advantages of cross-sectional studies are that they are generally quick, easy, and cheap to perform, and as there is no follow-up, less resources are required to run the study (Mann, 2003). Therefore, a cross-sectional study design is used to estimate the association between variables, in this case diabetes distress, anxiety, diabetes-related stigma, fatigue, and disordered eating with diabetes self-management activities.

5.3 Determining Patient-Reported Outcome Measures (PROMs)

Public and patient involvement (PPI) can make a number of valuable contributions to every stage of the research activities. These include defining and refining the research scope and questions, applying for funding and ethical approval, carrying out the research, and disseminating the research findings (Involve, 2021). Involving PPI contributors in the process

of identifying and prioritising research question is a powerful way of ensuring that the research priorities align with those of people with lived experiences. The aim of the PPI activities in the present study is to ensure which health topics are a priority for women with T2DM to undertake the research that is relevant to women with T2DM.

Women who were involved in the ranking priority areas for the survey were participants in the original qualitative interviews (Study 2) rather than a separate PPI group. PPI activities were carried out to determine the topics of greatest priority from those identified previously by younger women with T2DM. This enabled the researcher to identify relevant research topics for the cross-sectional study. To do this, the researcher firstly created a newsletter to inform the women with T2DM recruited to study 2 about the research progress following analysis of the qualitative data (Appendix C.1.6). An invitation to participate in future aspects of the study as a PPI member was included. The newsletter was sent by email and the participants were reassured that their involvement in the PPI activities was entirely voluntary and would take place online via MS Teams, Zoom, phone or email, according to their preferences. One reminder email was sent to improve recruitment.

Eight women expressed an interest in contributing to the study. The research document, including the aim of the PPI activity and health topics supported by quotes from the interviews to be prioritised, were sent to these women (Appendix C.1.7). Six women preferred to send their responses via email, whereas others preferred to speak with the researcher via phone calls that lasted 10-15 minutes for each woman. During the phone calls, the lay summary of the research was explained again to the women. Each woman was invited to decide which health topics are the greatest priority for her. The PPI members had a mixture in age, ethnic backgrounds, and duration of diabetes.

The researcher used metrics-based approach that involves the individual rankings of research topics (Viergever et al., 2010). It means that all the health topics identified in the qualitative study were individually prioritised by eight members of the PPI group and their individual rankings were then pooled identifying the research topics of relevance to them. The majority of women (five out of eight) reported the topics of diabetes distress, anxiety, fatigue, stigma, disordered eating and self-management activities. While many of the studies in the previous systematic review (Celik et al., 2022, study 1) focused on reproductive health care outcomes, the health topics prioritised by PPI members for the survey (study 3)

reflected a finding of the review which identified a lack of evidence related to the psychosocial needs of women with T2DM during this time of life. Following feedback from the PPI, a consensus for the health topics was achieved through discussion with the research team. These health topics included (i) disordered eating behaviours which stem from an unhealthy relationship with eating; (ii) diabetes distress reflecting a range of emotional responses to the patient's perceptions of diabetes related health threats; (iii) anxiety indicated by frequent, intense and excessive worry about living with diabetes; (iv) diabetes-related stigma which are defined as negative attitudes, discrimination, and judgment against someone due to their diabetes; (v) fatigue which is defined as a subjective perception of a decreased capacity to perform mental and/or physical tasks because of one or a combination of psychological, physical, and/or lifestyle phenomena; and (vi) diabetes self-management activities, including eating, physical activity, and medication intake.

The researcher reviewed the literature on validated PROMs to assess the identified health issues and determined the reliable and valid PROMs that are fit for the purposes of this study. Peer-reviewed validation of both the English and Turkish versions of each PROM was assessed, and those published in both languages were selected. Details about the PROMs are presented in section 5.7.

Study aims

The aims of this cross-sectional study are twofold:

i) To identify the prevalence of diabetes distress, anxiety, diabetes-related stigma, fatigue, disordered eating in women of reproductive age (18-45 years) with T2DM

ii) To investigate the relationship between the identified psychosocial factors and self-management behaviours in women of reproductive age with T2DM (adjusting for age, duration of diabetes and sociodemographic characteristics). The objective is to identify initial targets for subsequent intervention.

Hypotheses

The relationships between psychological variables and self-management behaviours will be examined in the following hypotheses:

- *Diabetes-related stigma will negatively affect disordered eating, diabetes distress, anxiety, and self-care activities.*
- *Both anxiety and diabetes distress will negatively affect disordered eating, fatigue level, and self-care behaviours.*
- *Diabetes-related fatigue is hypothesised to negatively affect self-care behaviours.*
- *Disordered eating negatively affects self-care behaviours.*

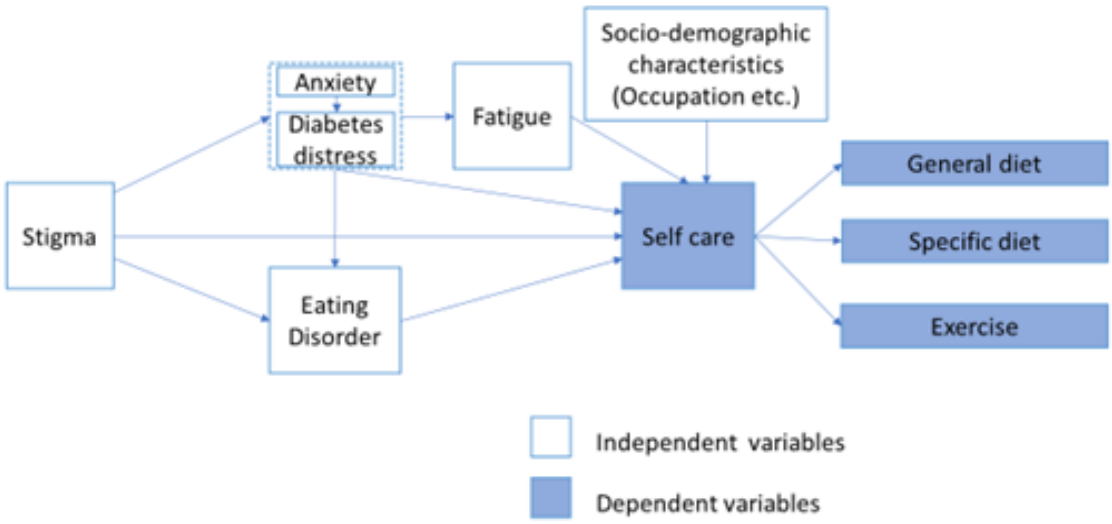


Figure 10: Hypothetical model of factors contributing to the self-care subscales (based on Studies 1 and 2)

5.4 Study design and setting

This was a cross-sectional study that examined the relationships between psychosocial health factors and self-management activities. It was conducted in two countries, the UK and Türkiye and carried out between March 2022 and October 2022. This cross-sectional study

was reported in accordance with the 'strengthening the reporting of observational studies in epidemiology (STROBE) checklist – cross-sectional studies' (Appendix C.1.8).

5.5 Participant recruitment

Social media platforms and communities

Participants were recruited through online study advertised (Appendix C.1.1) via social media platforms and patient diabetes organisations. An advertisement for the study was shared via the Diabetes UK website, their online forum, and social media accounts. Recruitment also was through social media groups in which women with T2DM participate. The recruitment proceeded via both public calls (e.g., Twitter) and accessing and posting the advertisement in private groups (e.g., Facebook groups). After ethical approval had been granted, the researcher approached the administrators of groups by sending gatekeeper permission letters (see Appendix C.1.2), including a brief introduction to the researcher and the research study. The role of the gatekeepers was to advertise the research study among their communities. Permission was obtained to post the research advert in their groups. If the gatekeeper organisations needed any further explanations about the study, this was provided by the researcher.

In addition to advertising on social media, the participants who both participated in the previous qualitative study (study 2) and provided the consent for further research were sent an email requesting them to complete the survey. This email included a lay summary of the study and a link to the survey if interested, and the researcher's contact details. Along this, the university community was also targeted in the recruitment strategy utilising an internal emailing for research volunteers. This yielded both expressions of interest and volunteers to participate in the study.

Interested participants were directed to a webpage providing additional information (plain language description) about the research. If eligible participants requested further clarification or had any questions about the study, this was provided as needed by the researcher. Participants were required to provide their consent before proceeding to the survey. To do this, they were asked to indicate that they had read and understood the

information provided and that they consented to their data being used for the purposes explained.

Health research recruitment service

A funded and targeted social media campaign using an approved KCL provider (called a Nativve service, https://www.healthresearch.study) was also utilised. This health research recruitment service used social media advertising to find eligible participants for surveys and clinical studies. They help research professionals by recruiting participants on time and to target via social media ads. This service kept our survey live for four weeks (from May 20 to June 20, 2022) and used advertisements on Google and Facebook/Instagram to promote our study both in the UK and Türkiye. At the end of the four weeks, approximately 52 participants had completed the survey fully.

Sample size

The sample size was estimated using Cochran's sample size formula with self-care activities as the dependent variable (Kotrlik et al., 2001) and its use was presented along with explanations as to how these decisions were made. Wang and Ji (2020) developed an online calculator to assist the researchers in performing sample size calculations based on study design. The online calculator is available at http://riskcalc.org:3838/samplesize/. Advice was sought from a statistician to ensure adequate power for a regression model using self-care activities as a continuous dependent variable. This is a descriptive cross-sectional study exploring a continuous dependent outcome; thus, the level of acceptable error is 3% for continuous data (acceptable margin of error for mean being estimated, d = 0.21), estimated standard deviation of the scale as 1.167 (SD = 1.167 calculating a seven-point scale and six standard deviations, three to each side of the mean), at the 5% Type I error rate ($\alpha = 0.05$), sample size of the survey is 119. Assuming a response rate of 65%, a minimum drawn sample size of 183 should be used. This calculation is based on the following (Kotrlik et al., 2001): anticipated response rate = 65%; minimum sample size = 119; sample size adjusted for response rate: 119/0.65 = 183. As a result, the sample was inflated to 183 participants, allowing for a response rate of 65%.

5.6 Participants

This study aimed to recruit 183 women with T2DM aged 18-45 years from the UK and Türkiye. Purposive sampling was used with the aim of recruiting the participants from both countries to widen the perspective in relation to exploring the psychosocial health issues and self-management behaviours among women with T2DM (Taherdoost, 2016). The following eligibility criteria were applied for this study.

Inclusion criteria:

- Women aged between 18-45 years old and living with T2DM and living in the UK or Türkiye.
- Eligible participants should be able to read and understand in English and/or Turkish.
- They should be able to provide their consent before answering the questionnaires.

Exclusion criteria

- Women living with type 1 diabetes, gestational diabetes, or other types of diabetes because they have different diabetes experiences, resulting in different research outcomes.
- Individuals who do not understand and read English or Turkish.
- Individuals who do not provide their consent, as it is legally required to take part to the study.
- Individuals who are currently having any investigation, treatment, or therapy for a psychiatric illness.
- There are no exclusions based on ethnicity, other medical conditions, diabetes management methods, or diabetes duration in order to recruit a maximum variation sample.

5.7 Study questionnaires

The questionnaire consisted of six measures: Diabetes Distress Scale (DDS), the Generalised Anxiety Disorder (GAD-7), the Type 2 Diabetes Stigma Assessment Scale (DSAS-2), Fatigue

Severity Scale (FSS), Sick, Control, One stone, Fat, Food Scale (SCOFF-5), and the Summary of Diabetes Self-care Activities (SDSCA). We also asked questions relating to sociodemographic and clinical characteristics to obtain insights into the background of the target population (Table 4).

Table 4 Concepts and measures

Concept	Measure or variable	Number of items
Socio-demographics	Age, residence of country, country of nationality, sex assigned at birth, ethnicity, marital status, education, income status, employment status	9
Clinical characteristics	Duration of diabetes diagnosis, diabetes therapy, family history, diabetes complications, attendance diabetes education, last HbA1c	6
Diabetes self-care activities	Summary of Diabetes Self-care Activities (SDSCA)	11
Fatigue	Fatigue Severity Scale (FSS-9)	9
Disordered eating	SCOFF (sick, control, one stone, fat, food)	5
Diabetes distress	Diabetes Distress Scale (DDS)	17
Diabetes related stigma	The Type 2 Diabetes Stigma Assessment Scale (DSAS-2)	19
Anxiety	Generalised Anxiety Disorder Scale (GAD-7)	7

5.7.1 Sociodemographic and clinical data collection

Demographic characteristics include age, country of origin, country of nationality, family history, sex assigned at birth, ethnicity, education level, marital status, household income status, and employment status, whereas clinical characteristics include data about duration of diabetes, diabetes-related complications, comorbidity (other health conditions), and injection therapy (oral or insulin or other than insulin or lifestyle), HbA1c.

5.7.2 The Summary of Diabetes Self-Care Activities (SDSCA)

Data on women's performance of diabetes self-care activities was obtained by administrating the SDSCA. The SDSCA was chosen for this study because it is the most commonly used research tool to assess diabetes self-care and it is a well-validated instrument (Schmitt et al., 2016; Lu et al., 2016). It was developed by Toobert et al. (2000) to assess the recommended T2DM self-management. This is an 11-item self-report instrument requiring people with T2DM to answer questions about self-care activities over the past week. The SDSCA is a comprehensive instrument of self-care behaviours compared to the Diabetes Care Profile (DCP), assessing social and psychological factors related to diabetes and its treatment (Fitzgerald et al., 1996), and the Medication Adherence Scale (MARS) focusing on medication intake (Horne & Weinman, 1999; Lu et al., 2016). It has also been compared to other self-care measures to examine concurrent validity, resulting in high correlations for exercise, and modest correlations for diet and blood glucose monitoring (Weinger et al., 2005).

The original SDSCA measures included five different aspects of diabetes management, including general diet, specific diet, medication taking and blood glucose testing (Toobert & Glasgow, 1994). This scale was refined and further analysed using the results of seven empirical research studies, resulting in two additional subscales (two items on foot self-care, one item dichotomous question on smoking) along with removal and revisions of certain self-care subscales (Toobert et al., 2000). The subscale of medication self-administration was removed as a result of low test-retest reliability ($p > 0.005$). The subscales of general and specific diet were combined into one subscale called diet, as specific diet lacked internal consistency (Toobert et al., 2000). The revised self-reported instrument includes the questions that assesses the frequency of the following diabetes activities: diet, exercise, blood glucose monitoring, medication adherence, foot care, and smoking, as well as additional items related to self-care activities from HCPs (example item: On how many of the last seven days did you participate in at least 30 minutes of physical activity (total minutes of continuous activity including walking?).

The SDSCA subscales items are relatively short, ranging from two to four items. The SDSCA is a continuous, multidimensional instrument and it is recommended that subscales be scores

independently (Tooberg & Glasgow, 1994) which subscales are independent from each other, and a composite score could potentially lead to the omission of valuable information and analysis (Mapi Research Trust, 2022). Answer options are presented on an ordinal scale and ranges from 0 (= no adherence in the past week) to 7 (= full adherence for the particular behaviour). Total score is calculated as the mean score for each domain separately. This scale has also been translated into Turkish and validated by Kav et al. (2010), with an internal consistency of 0.72.

5.7.3 The Diabetes Distress Scale (DDS)

This scale, developed by Polonsky et al. (2005), is used to assess diabetes distress. The DDS is a 17-item instrument representing the distress experienced over the previous months using a Likert scale. Each item score is scored from 1 (no distress) to 6 (serious distress) and it has four subscales addressing different kinds of distress: emotional burden (five items) – for example, 'feeling that diabetes is taking up too much of my mental and physical energy everyday'; physician-related distress (four items) – for example, 'feeling that my doctor does not know enough about diabetes and diabetes care'; regimen-related distress (five items) – for example, 'I am not testing my blood sugars frequently enough'; and diabetes-related interpersonal distress (three items) – for example, 'feeling that friends or family do not give me the emotional support that I would like'. Subscale scores are obtained by calculating the mean of responses to the component items of that scale. A mean item score < 2 demonstrates no distress, 2-3 demonstrates moderate distress, > 3 demonstrates severe distress. A total score can be obtained by finding the mean of all responses (Polonsky et al., 2005).

The DDS displays good internal consistency, demonstrating that the component questions are measuring a similar construct. High scores – that is scores above 3 on the DDS – show higher level of diabetes distress and have been found to correlate significantly with suboptimal lifestyle and higher HbA1c (Polonsky et al., 2005; Hessler et al., 2014). The Problem Area in Diabetes (PAID-5) scale (Polonsky et al., 1995), and DDS are widely accepted as statistically sound measures of diabetes distress. Compared to the DDS, the PAID scale is a more comprehensive psychometric tool to measure the emotional difficulties experienced

by people with diabetes; however, it does not contain any questions including perceptions about health professionals and the care received. Further, the PAID does not distinguish the various elements of diabetes distress, meaning that it may be difficult for people with diabetes to understand and interpret (Polonsky et al., 2005). Additionally, it has a stronger emphasis on eating behaviours and diabetes complications associated with more depressive symptoms, health-related quality of life and maladaptive coping behaviours. Conversely, the DDS scale includes items concerning self-care issues and physician-related issues that are strongly associated with self-management behaviours and metabolic variables (Schmitt et al., 2016). As the DDS scale was utilised as a more comprehensive measure, this study used this scale to measure diabetes distress. The scale has also been translated and validated in Turkish by Caklili et al. (2019) with a Cronbach's alpha of 0.874, indicating internal consistency.

5.7.4 The Generalised Anxiety Disorder (GAD-7)

GAD-7, a self-report seven-item scale developed by Spitzer et al. (2006), is used to measure anxiety. It is a valid and reliable measure to screen and measure generalised anxiety disorder and has been used in both research and clinical settings for other anxiety disorders, including social anxiety, post-traumatic stress disorder and panic disorder (Spitzer et al., 2006). GAD-7 has also been used in diabetes research (Sharma et al., 2021; Huang et al., 2020; Thour et al., 2016). The scale measures anxiety symptoms in the past two weeks and the items includes the feelings "nervous, anxious, irritable". All items are answered on a four-point scale (0 = not at all, 1 = several days, 2 = more than half of the days, 3 = nearly every day) from which a total score ranging from 0 to 21 is obtained, with higher scores indicating people's increased self-report of anxiety severity. Total scores of 5, 10, and 15 refer to ratings of minimal, moderate, and severe anxiety, respectively. The recommended screening cut-off was 10 or more, corresponding to at least a moderate level of anxiety (Plummer et al., 2016). The GAD-7 has a sensitivity value of 0.89 and a specificity value of 0.82 for identifying GAD (Spitzer et al., 2006). The scale was translated and validated in Turkish by Konkan (2011). The Turkish version of GAD-7 was found to be reliable with a Cronbach's alpha score of 0.85.

5.7.5 The Fatigue Severity Scale (FSS)

FSS is a reliable scale for detecting the presence and severity of fatigue in terms of different domains, including motivation, exercise, and interference with work, family, or social life (example item: 'My motivation is lower when I am fatigued', 'I am easily fatigued'). It highlights the impact of fatigue on people's daily activities in terms of the effects of functional fatigue, which appears to detect the presence and severity of fatigue. The FSS consists of nine items and each item is rated on a seven-point Likert scale (ranging from 1 = completely disagree, to 7 = completely agree). A total score of less than 4 is measured as having no fatigue, scores of 4 to 4.9 are measured as having moderate fatigue and scores of 5 or more are measured as having severe fatigue (Krupp, 1989). The FSS was compared with other fatigue scales, including the Fatigue Assessment Scale (FAS), focusing on the physical and mental domains of fatigue (Michielsen et al., 2003), and the Visual Analog Fatigue Scale (VAFS), assessing acute or transient fatigue at the moment (Tseng et al., 2010), to determine which would be most appropriate tool to measure fatigue in people with T2DM. The FSS has been recommended for measuring fatigue in this population. Additionally, it demonstrates good validity and strong concurrent validity with other scales, including the Visual Analog Scale (Singh & Kluding, 2013). The scale was translated into Turkish, and the validity and reliability of the scale were established in people with chronic conditions, with a Cronbach's alpha score of 0.94 (Armutlu et al., 2007).

5.7.6 The Type 2 Diabetes Stigma Assessment Scale (DSAS-2)

This is a self-report measure of perceived and experienced stigma related to living with T2DM. It is a valid and reliable measure of T2DM stigma (Browne et al., 2016). The scale includes 19 items and has three subscales: Treated differently, blame and judgment and self-stigma (Browne et al., 2016). The 'treated differently' subscale includes six items (e.g., ''some people see me as a lesser person because I have type 2 diabetes''); the 'blame and judgment' includes seven items (e.g., ''I have been told that I brought my type 2 diabetes on myself''); the 'self-stigma scale' includes six items based on the application T2DM stereotypes to oneself and its emotional consequences (e.g., ''having T2DM makes me feel like a failure''). Each statement is rated on a five-point scale ranging from strongly disagree

to strongly agree. Items within each subscale are summed, with a higher score indicating greater diabetes-related stigma. Compared to the DSAS-2, the Diabetes Self Stigma Scale (Seo & Song, 2020) focuses on only self-stigma with domains of comparative inability, social withdrawal, self-devaluation, and apprehensive feelings in people with diabetes; however, the DSAS-2 is a more comprehensive scale, assessing self-stigma along with T2DM-related social stigma in people with T2DM (Browne et al., 2016). The scale was translated and validated in Turkish by Inkaya and Karadag (2021), and the Turkish version of the DSAS-2 was also found to be quite reliable, with a Cronbach's alpha coefficient of 0.92.

5.7.7 The sick, control, one stone, fat, food (SCOFF)

SCOFF is a 5-item self-report screening questionnaire created in 1999 by Morgan et al. for detecting eating disorders. In fact, this questionnaire was modified and adapted for people with diabetes in clinical practice as the modified SCOFF (mSCOFF). Another questionnaire for screening of people with diabetes and eating problems is the Diabetes Eating Problem Survey – Revised (DEPS-R). However, both the mSCOFF and DEPS-R have items about insulin and thus these are not suitable for people with T2DM who are not managing their diabetes with insulin (Hendrieckx et al., 2019). The SCOFF was chosen for the present study as it has been used to screen eating problems for people with T2DM (Chevinsky et al., 2020). Items in the SCOFF require yes (= 1) or no (= 0) answers and total score ranges from 0-5 with a cut-off > 2 indicating a possible eating problem (example item: 'Do you worry you have lost control over how much you eat?'). It was translated and validated in Turkish by Aydemir et al. (2015), with a Cronbach's alpha score of 0.74.

5.8 Ethical considerations

Ethical approval was obtained from the Health Faculties Research Ethics Sub-committee at King's College London in February 2022 (Reference number: *HR/DP-21/22-26924*) (see Appendix C.1.3).

Research safety protocol

In this study, participants were informed of what taking part in the research would involve and were provided with a participant information sheet about the study (see Appendix C.1.4). The participants were given time to read the participant information sheet; detailed on the sheet were the researcher's contact details, thus a potential participant could contact them to ask further questions or discuss any concerns they may have about participating in the research. Participants completed the psychosocial surveys, which have the potential to cause distress to some women, and it is also possible that some women might score very highly on these measures to indicate a significant health need. To ensure that participants remain as safe as possible following their participation in the survey, all participants were required to provide their contact details once they confirmed meeting the eligibility criteria. This enabled the research team to make contact with them to say that we have noted their answers and indicate that they may need further help, and ask them if they are currently seeking help for this health need. If they are currently receiving help, we encouraged them to discuss their answer(s) with their care provider and reiterate the signposting of additional services to receive support. If the participants said that they were not receiving help in relation to this issue, we recommended that they contact their GP because this could pose a risk to their diabetes and general health. In addition, we asked their permission for our clinical academic research team member, Dr Rita Forde, to contact them to discuss this aspect of their health and support them in contacting an appropriate NHS agency. Because we are not requesting GP contact details from them, we will be unable to contact their GPs on their behalf.

In the survey, the researcher screened the answers to all surveys within 72 hours of receiving them. There are three survey sections that require screening: Section 3 question 1 (SCOFF) relates to self-harm in relation to disordered eating. It is important to track participant's answers to this question and contact them if they answer YES to inducing vomiting when they feel full. Section 5 asks about diabetes distress. A score of 40 or more indicates a level of diabetes distress that was likely to affect their ability to undertake diabetes self-care activities like taking medication or attending medical appointments. Participants scoring 40 or more were contacted. Section 6 asks about anxiety. A total score of 10 indicates a moderate level of anxiety that is considered high enough to put a person's

health at risk. Participants scoring over 10 or more on the survey were contacted. Additionally, participants were informed in the participant information sheet that if they experience distress, they could choose to skip any questions they would prefer not to answer or they can pause or stop participating at any time and, if they would like support, they can get counselling from signposted resources (e.g., their healthcare providers).

In the main body of the survey, we also included the following statement: “If you have been upset or troubled by any of these questions, please discuss this with your healthcare professional as soon as possible or contact the researchers.'' In addition to this statement, information on sources of support is provided in the participant information sheet in the details at the end of the survey and on the pages that asked about anxiety, diabetes distress, and disordered eating. The contact details of the researcher are also provided in the participant information sheet. As a result, the researcher screened all the responses within 72 hours of receiving survey responses from each participant to check whether there were any significant health needs. Eighty-five women with T2DM were contacted to ask if they were seeking help for this health need, and the researcher encouraged them to discuss their answers with their HCPs and signposted the additional services they might require receiving support.

Data privacy

Confidentiality is an important ethical issue while conducting the study. Participants were informed that their personal information would remain confidential through the use of unique codes that would be used instead of their contact details to protect their identities. These contact details were entered into a separate database not linked to the main survey to ensure the survey dataset remained de-identified. As such, their responses were pseudonymised and they were not identifiable at any point of the research, including when analysing the data or disseminating the findings. All information was stored on a secure database at KCL using an encrypted cloud store (OneDrive). Only the research team have access to participants’ responses. Once the study has been completed, the questionnaires and all person-identifiable information will be destroyed in accordance with the UK data protection law (including General Data Protection Regulation or GDPR).

5.9 Data collection

Expressions of interest

An online survey using Qualtrics^{XM} (Appendix C.1.5) survey software was conducted to collect data through online methods across the UK and Türkiye. Interested participants were directed to a webpage providing additional information (plain language description) and the participant information sheet (Appendix C.1.4) about the research. They were requested to give their consent to participate before proceeding to the survey (Appendix C.1.5). Giving consent involved a 'forced choice' question so that consent could not accidentally be recorded. If they did not consent to participate in the study, the participant was sent directly to an exit page informing them that they could not take part in the study without their consent. Participants were also informed in the participant information sheet that they were free to withdraw up to the end of day 10 following completion of their survey, without having to give a reason. After the specified period, it would no longer be possible to withdraw from the study as the collected data would have already been anonymised and included in the analysis.

Eligibility assessment

After providing consent, the survey began with eligibility screening consisting of four questions. Respondents who completed and met the eligibility criteria were permitted to advance to the study questions, including demographic and clinical questions. Participants were then instructed to complete each of the validated questionnaires. Each questionnaire included instructions on how to complete the survey. Partially completed surveys remained open for two weeks, at which time the survey was then saved and closed. The participants who completed the survey were entered into a prize draw for a chance to win a £50 voucher.

Piloting the survey

The electronic version of the survey was piloted by the researchers with experience in developing online surveys to do a completeness check. It was also piloted by eight lay people to check the survey in terms of logic and flow of the questions, size of the font, time spent on the survey, and clarity of instructions and items. The pilot was carried out over one

month in February 2022. Table 5 illustrates example of the survey amendments. The software for the survey restricts the number of submissions per IP address to two, preventing malicious multiple submissions.

Table 5 Examples of the survey amendments

Items	Before	Amended following piloting
Length of time to complete	Around 15 minutes	Around 20-30 minutes
Page colour and quality	Small font all the same size	Larger fonts, larger size for heading
Question and response category format	Small text boxes at the end of the questionnaire, indicating please write in.	Text boxes appeared if the questions were chosen 'other' and saying things like 'please specify your education level'
Flow of questions	There is no automatic skip to exclude non-relevant questions	Added an automatic skip, e.g., '*when did you last smoke a cigarette'*, if they do not smoke.
Response requirement	No request response	Added 'request response' to be alerted to go back to it if they wish
Instructions	Wording of the introduction page: '*please read the Participant Information Sheet. This includes …*'	Wording of the introduction page changed to: '*please read the Participant Information Sheet which includes …*'
Items of questionnaire	Included similar items of medication intake (6A and 7A-8A in section 7)	Removing items 7A-8A as recommended.
A progress bar	No showing the progress of the survey	Added a progress bar

5.10 Data analysis

All the survey responses, both complete or incomplete, were logged by the Qualtrics^{XM} survey platform and entered into Microsoft Excel as well as downloaded into data files for analysis in the Statistical Package for the Social Sciences (SPSS), version 28. Prior to conducting any statistical analysis, five steps based on Pallant (2016) were deployed: 1) preparing a codebook; 2) creating the data file and data entry; 3) data cleaning and checking; 4) preliminary analysis; and 5) statistical analysis.

1) Preparing a codebook

A codebook provides information about the content, structure, and layout of the data and includes a complete list of data which contains variable names, types of variables, response codes (labelling) related to each variable, assigning numbers to each of the possible responses, and codes used to specify nonresponse and lost data. It explains the data codes what they mean before importing the data into IBM SPSS 28 (Pallant, 2016). Please see an extract from codebook in Table 6.

Table 6 Extract from codebook of the SPSS dataset

SPSS name	Variable	Coding instructions	Data type
Participant ID	Identification number	1 2 3	Scale
Age	Age	Age in years	Scale
Country of residence	Country of residence	1 = UK 2 = Türkiye	Nominal
Country of nationality	County of nationality	1 = UK 2 = Türkiye	Nominal
Duration of diabetes	Diabetes duration	1 = <1 years 2 = 1-5 years 3 = 6-10 years 4 = > 10 years	Ordinal
Sex assigned at the birth	Sex assigned at the birth	2 = Female 1 = Male 0 = Not to prefer	Nominal
Family history	Family history	1 = Yes 0 = No	Nominal
Relationship status	Relationship	1 = Single 2 = Married 3 = In a relationship 4 = Divorced 5 = Widowed 6 = Prefer not to say	Nominal

2) Creating the data file and data entry

First, the data were downloaded from Qualtrics into an Excel file, which was then coded using a coding frame with columns for the participant code, demographic and clinical

characteristics, and questionnaires. Secondly, IBM SPSS 28 was utilised to create a coded dataset file using a coding frame, then both data files were checked in line with variable names (e.g., typos), and duplicated rows removed, or the columns merged or split as needed. An additional Excel file was created for women who were interested in further research and agreed to be contacted, resulting in an anonymised dataset in the Excel and SPSS files. As a result, all the data, including demographic and clinical data and responses of the six validated questionnaires were entered onto the Excel spreadsheet and then transferred to SPSS for further examination.

3) Data cleaning and checking

Data cleaning aims to identify and correct possible errors or at least minimise these errors so that they do not affect the results of the study (van den Broeck, 2005). Data cleaning as a process follows the phases of detecting (e.g., lack or excess of data), diagnosing (clarifying the true nature of worrisome data points), and editing the error data. These processes were conducted both through the 'explore' function of SPSS and manually where necessary. This means that all the variables were checked to see if each was entered as being outside the expected range of their values. After identification of missing values, errors, and true values, the values were corrected, deleted, or left unchanged as appropriate (van den Broeck, 2005).

4) Preliminary analysis

This includes the descriptive statistics, testing normality, and dealing with missing data.

Descriptive statistics

These statistics consist of, but are not limited to, median, means, standard deviations, and distributed percentages. The present subsection includes demographics (such as age, ethnicity) and clinical variables (such as duration of diabetes, medication therapy). Descriptive statistics were reported as frequency, counts (n) and percentages (%) for categorical variables and mean +/- standard deviation (or medians and ranges as appropriate for data distributions) for continuous variables.

Assessing Normality

From the histograms and box plots, it was determined whether the data was normal. In other words, the data was checked for outlier scores that are far from most other values in the dataset. An outlier can affect the results by creating or hiding statistical significance. Various groups were created to identify cases with extreme low or high levels (e.g., family history, education level) through the 'explore' function of SPSS, then tested to determine if the data was normally distributed in order to decide the appropriate statistics test to apply.

Missing data

Missing data can occur in survey research, arising from nonresponse or partial response of the participants due to refusing or failing to answer an item that is too sensitive, or participants not knowing the answer to the item, or cutting off the survey in the middle, and so on (Brick & Kalton, 1996). To minimise any potential bias, the expectation maximisation (EM) approach was selected as a method of dealing with missing data because of its flexibility, usability in a broad range of settings, the possibility of estimating the parameters directly by maximising the complete data log likelihood function (Kong et al., 2013) and its previous application in medical studies (Malan et al., 2020). This imputation method is based on the expectation step, in which the parameters (e.g., variance, means) are estimated. These estimations were then used to create a regression equation to fill in the missing values. An important characteristic of the EM imputation is that a random distribution term for each imputed value is incorporated so as to reflect the uncertainty associated with the imputation when the new dataset with no missing values is generated (Kang, 2013; Malan et al., 2020).

Missing data were replaced with imputed variables using the EM method in SPSS version 28. Overall, 2% of all values were missing, 57.6% of the variables had at least one missing value, and 85% of 92 participants had at least one missing value. All variables in the correlation analysis, excluding the socio-demographic and clinical variables that had no missing data, were included in the imputation model.

Modifying variables for further analysis

This subsection includes the modification of certain variables to facilitate analysis, changing from continuous variables to categorical variables (e.g., age).

5) Statistical analysis

SPSS statistical tests were used to assess the prevalence and correlates of psychosocial factors and self-management behaviours in young women with T2DM, adjusting for age, duration of diabetes, and socio-demographic characteristics. Self-management behaviours were considered a dependent variable, whereas fatigue, stigma, diabetes distress, disordered eating, and anxiety were considered independent variables (Table 7). If there was a skewed distribution in a given variable, then the median (interquartile range) was used to assess central tendency and the Mann-Whitney U test was used to examine differences between the groups. The Pearson correlation coefficient was used to examine how the independent variables were related to the dependent variables. The purposes of this analysis were to determine statistical significance (< 0.5) and effect size (-1 to +1) and directionality (positive or negative) in which each independent variable's relationship to the dependent variables were evaluated. For instance, if the Pearson correlation coefficient is negative, this indicates a negative correlation between variables (e.g., the higher the fatigue level the lower the self-care performance). A correlation of 0 demonstrates no relationship at all, a value of 1 demonstrates a perfect positive correlation, and a value of -1 demonstrates a perfect negative correlation (Pallant, 2016). Determining the strength of the relationship, Cohen (1988, p.79-81) suggests the following guidelines: small r = .10 to .29; medium r = .30 to .49; large r = .50 to 1.0.

Table 7 Analytical characteristics of the PROMs

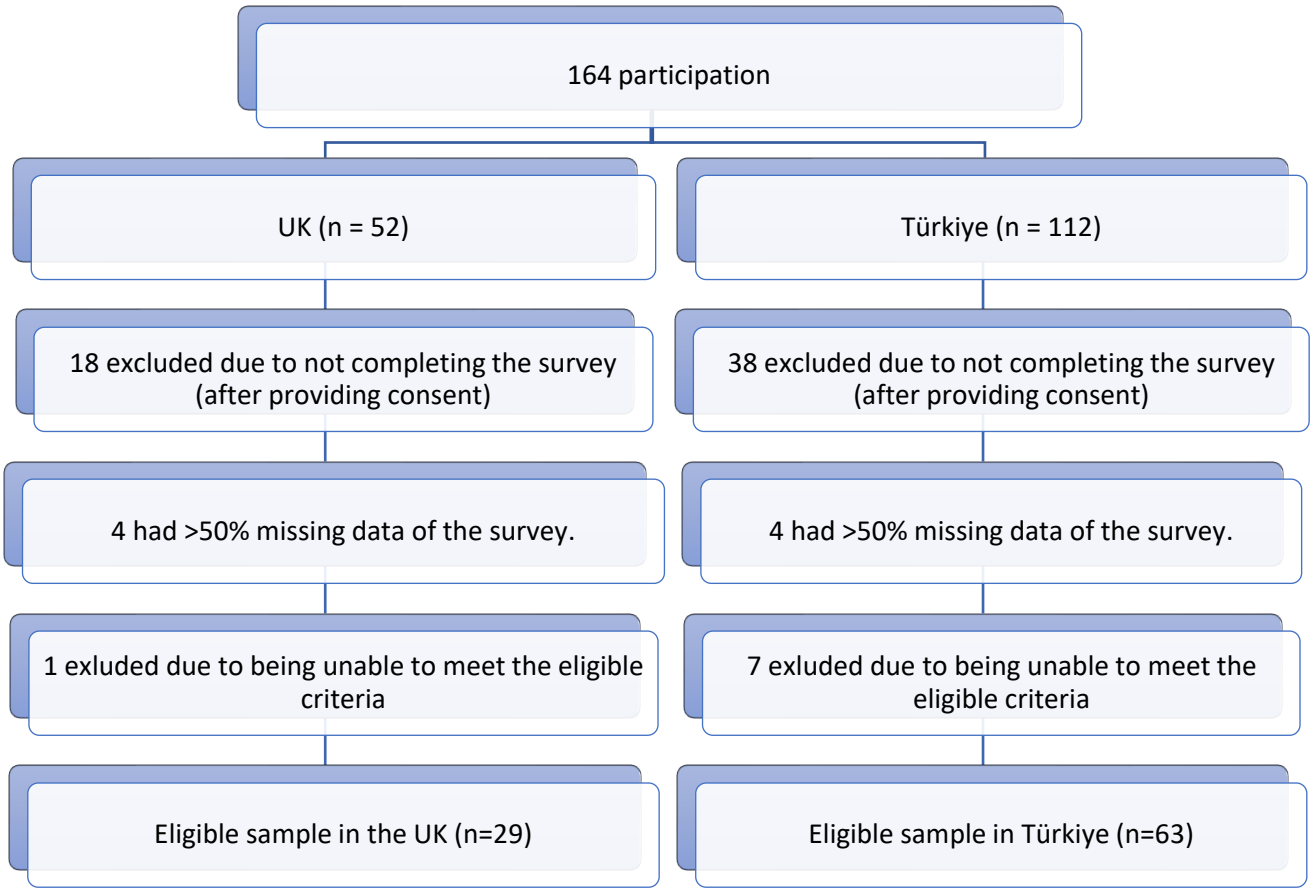
Measure	Domains/subscales	Units	Type of variable	Level of measurement
Summary of Diabetes Self-care Activities (SDSCA)	1)Diet 2)Exercise 3)Foot care	Number of days	Dependent	Continuous
Fatigue Severity Scale (FSS)	Fatigue presence and severity	Likert scale 1 to 7 1 = strongly disagree 7 = strongly agree	Independent	Ordinal
SCOFF (sick, control, one stone, fat, food)	Eating disorder presence	Yes, No answers yes (=1)	Independent	Categorical

		no (= 0)		
Diabetes Distress Scale (DDS)	Diabetes distress subscales: 1) Emotional burden 2)Physician-related distress 3)Regimen-related distress 4)Diabetes related interpersonal distress.	Likert scale 1 to 6 1 = not a problem 6 = a very serious problem	Independent	Ordinal
The Type 2 Diabetes Stigma Assessment Scale (DSAS-2)	Diabetes stigma subscales: 1) Treated differently, 2) Blame and judgment 3) self-stigma	Likert scale 1 to 5 1 = strongly disagree 5 = strongly agree	Independent	Ordinal
Generalised Anxiety Disorder Scale (GAD-7)	Anxiety presence and severity	Likert scale 1 to 4 1 = not at all 4 = nearly every day	Independent	Ordinal

5.11 Results of the cross-sectional study

Data were collected over an eight-month period, commencing in March 2022 and concluding in October 2022. A total of 164 women initiated the survey. Of those women, 56 eligible women left having only completed the consent section of the survey. After checking response completion rates, 8 women were excluded because less than 50% of the survey was completed (only completed some demographic questions). Eight women were excluded due to being unable to meet the eligibility criteria. The final sample was comprised of 92 women, of which 29 women were from the UK, 63 women were from Türkiye. Since the sample size from the UK was too small to make comparisons with the Turkish sample, the data were combined for analysis. The flow of participants through the survey can be found in Figure 11.

Figure 11 Breakdown of the eligible respondents for each country



5.11.1 Participant characteristics

The study population had a mean age of 35.5 years (SD = 7.2; range 19-45 years). All of the participants, with one exception, reported being of female sex at birth. Forth seven percent of the sample (n = 43) had diabetes duration between 1-5 years, with 19 (20.7%) having a diabetes duration < 1 year. A family history of diabetes was reported by 64 (70%) and were married (n = 51, 55%). A total of 60 (65%) were of Turkish ethnicity, and 25% had White ethnicity (n = 23). Most women reported their education status as college degree/diploma (n

= 24, 26%), university/degree (n = 40, 43%), and postgraduate degree (n = 15, 16%). Nearly half of the participants had equal income to their family's basic living needs (n = 47, 51%).

The proportion of women working full-time among women were 39% (n = 36), followed by home duties (n = 22, 24%), then unemployed (n = 16, 20%). Nearly 33% of women (n = 31) had more than 7% (53mmol/mol) HbA1c level, while 29% of women (n = 27) reported not knowing their Hb1Ac levels. In relation to diabetes management, most women (n = 37, 40%) reported taking oral hypoglycaemic tablets, and 21% were taking the insulin and tablets, with one-fifth reporting only using lifestyle changes (n = 18, 20%). The proportions of diabetes complications varied among women as follows: high cholesterol (n = 27, 25%), high blood pressure (n = 19, 17%), and eye issues (n = 17, 16%). Most women reported they had not attended a diabetes education course (n = 70, 76%). A summary of the characteristics of the women is presented in Table 8.

Table 8 Participant characteristics

	Mean	**SD**
Age (years)	35.5	7.2
Sex at birth	**N (Frequency)**	**%**
Female	91	98.7
Prefer not to say	1	1.3
Country of residence n (%)		
UK	29	32%
Türkiye	63	68%
Duration of diabetes n (%)		
<1 year	19	20.7%
1-5 years	43	46.7%
6-10 years	14	15.2%
>10 years	16	17.4%
Family History n (%)		
Yes	64	69.4%
No	28	30.4%
Marital status n (%)		
Single	24	26.1%
Married	51	55.4%
In a relationship	8	8.7%
Divorced	5	5.4%
Prefer not to say	3	3.3%
Ethnicity n (%)		

White British	23	25%
White Turkish	60	65.2%
Asian	2	2.2%
Asian others	1	1.1%
Mixed ethnic group	3	3.3%
Any other ethnic group (from the UK and Türkiye)	3	3.3%
Education n (%)		
Primary school	5	5.4%
Secondary school	8	8.7%
College degree/Diploma	24	26.1%
University/Degree	40	43.5%
Postgraduate degree	15	16.3%
Income status n (%)		
Less than I need to meet mine/my family's basic living needs	30	32.6%
Equal to mine/my family's basic living needs	47	51.1%
More than I need to meet mine/my family's basic living needs	14	15.2%
Missing data	1	1.3%
Employment status n (%)		
Working full-time	36	39.1%
Working part-time	8	8.7%
Home duties	22	23.9%
Unemployed	16	17.4%
Student	5	5.4%
Unable to work	4	4.3%
Other	1	1.1%
HbA1c n (%)		
Less than 6.5% (48mmol/mol)	15	16.3%
Between 6.5% to 7% (48mmol/mol to 53 mmol/mol)	19	20.7%
More than 7% (53 mmol/mol)	31	33.7%
I don't know	27	29.3%
Diabetes Therapy n (%)		
Oral hypoglycaemic tablets	37	40.2%
Insulin and/or other injections for diabetes	11	12%
Insulin and tablets	21	22.8%
Lifestyle	18	19.6%
A Different diabetes management method	5	5.4%
Diabetes Complications n (%)		

Heart	7	6.4%
Blood Circulation	7	6.4%
Stroke	1	0.9%
Nerve	12	10.9%
Eye	17	15.5%
Foot	14	12.7%
High Blood Pressure	19	17.3%
High Cholesterol	27	24.5%
Kidney	6	5.5%
Diabetes education received		
Yes	22	23.9%
No	70	76.1%

5.11.2 Descriptive statistics

Fatigue severity

Fatigue severity, as calculated by the Fatigue Severity Scale (FSS) score (Krupp, 1989), was based on the completion of all nine items (n = 92, 100%). The mean raw score was 4.96 (SD = 1.74), which represented having moderate fatigue (scores 4-4.9), with less than 4 representing no fatigue and 5 or more being severe fatigue. According to the self-report measure, 57% of the total study participants had severe fatigue, and 17.4% had moderate fatigue (Table 9). Internal consistency was high (Cronbach's alpha = 0.95) in this participant sample.

Table 9 Score distribution for Fatigue

Scale	**N (Frequency)**	**%**
FSS (Fatigue) n=92		
No fatigue	23	25
Moderate	16	17.4
Severe	53	57.6
	Mean	**SD**
FSS (Fatigue) n=92	4.96	1.74

Disordered eating scores

Disordered eating behaviours, as estimated by the SCOFF, was assessed in respondents who completed all five items (n = 92). Their mean summed eating behaviours score was 2.99 (SD = 1.19) and ranged from 0-5 out of the maximum possible score of 5. The scores were dichotomised based on Morgon's (1999) recommendation of a score of > 2 as a screening cut-off point (0 = 0-1; 1 = 2-5). Of these, 7.6% (n = 7) had a score of 0-1, indicating no disordered eating behaviours, while the remaining 92.4% (n = 85) had histories of disordered eating behaviours who scored > 2 and more (Table 10). Internal consistency of the SCOFF was low (Cronbach's alpha = 0.46) in this participant sample.

Table 10 Disordered eating scores

Scale	**N (Frequency)**	**%**
SCOFF-5 (n = 92)		
Negative <2	7	7.6
Positive >2	85	92.4
	Mean	**SD**
SCOFF-5 (n = 92)	2.99	1.19

Diabetes-related stigma

Diabetes stigma, as determined by the DSAS-2 scale (Browne et al., 2016), was based on the completion of all 19 items (n = 92). The mean total score obtained in DSAS-2 was 55.68 with a standard deviation (SD) of 16.47, with scores ranging from 19 to 88 points. Three subscale scores for DSAS-2 are presented in Table 11. Of these, the mean score of *treated differently* by others was 14.96 (SD = 4.71), ranging from 6 to 27 in total scores. For the subscale of *blame and judgment*, the mean score was 23.32 (SD = 6.43) and score ranges varied from 7 to 35 in total. The total mean score of *self-stigma* was 17.41 (SD = 7.83), with scores of 6 to 30 in total. A total of 49 (53%) respondents scored more than one SD above the mean total diabetes stigma score, indicating potentially problematic perceived and experiences of diabetes stigma. 46% (n = 42) of women in this study reported the experiences of self-blame

and judgment, 40% (n = 37) were treated differently, and 47% (n = 43) were self-stigmatised. Internal consistency was high (Cronbach's alpha = 0.93) in this participant sample.

Table 11 Diabetes related stigma scores

Scale	**Min**	**Max**	**Mean**	**SD**
DSAS-2 (n = 92)				
Total Diabetes Stigma (n=92)	19	88	55.68	16.47
Treated differently	6	27	14.96	4.71
Blame and judgment	7	35	23.32	6.43
Self-stigma	6	30	17.41	7.83

Diabetes distress level

Level of diabetes distress, as measured by the DDS scale (Polensky et al., 2005), was considered in people answering all 17 questions (n = 92). According to this self-report measure, their mean total raw score was 3.54 (SD = 1.32). Of these, 33.7% (n = 31) had a mean score less than 3, indicating no diabetes distress, while the remaining 65.2% (n = 60) were grouped into moderate or high levels of diabetes distress as a result of getting a mean score of 3 or more (Table 12). The mean score of all subscales was greater than 3, showing moderate to high levels of diabetes distress among women. 69.6% (n = 64) of the total had regimen-related distress and emotional burden, and 57.6% (n = 53) had interpersonal distress, followed by physician-related distress at 54.3% (n = 50). Internal consistency was high (Cronbach's alpha = 0.95) in this participant sample.

Table 12 Diabetes distress score

Scales	**N (Frequency)**	**%**
Diabetes Distress (DDS)		
No distress	31	33.7
Moderate or High	60	65.2
Missing	1	1.1

Emotional burden		
No distress	28	30.4
Moderate or High	64	69.6
Physician-related distress		
No distress	42	45.7
Moderate or High	50	54.3
Regimen-related Distress		
No distress	28	30.4
Moderate or High	64	69.6
Interpersonal Distress		
No distress	39	42.4
Moderate or High	53	57.6
	Mean	**SD**
DDS	3.54	1.32
Emotional burden	3.80	1.37
Physician-related distress	3.26	1.66
Regimen-related distress	3.69	1.47
Interpersonal distress	3.23	1.49

Anxiety severity

Anxiety, as assessed by GAD-7, score was based on the completion of seven items (n = 92). Four categories of the GAD-7 scores are presented in Table 13. Of these, the largest proportion of women (n = 30, 32.6%) had mild anxiety, and a quarter (n = 22, 23.9%) had moderate and severe anxiety, while the smallest (n = 18, 19.6%) proportion were in the category of minimal anxiety (Table 13). Internal consistency was high (Cronbach's alpha = 0.92) in this participant sample.

Table 13 Anxiety severity distribution score

Scales	**N (Frequency)**	**%**
GAD-7 (Anxiety)		
Minimal	18	19.6

Mild	30	32.6
Moderate	22	23.9
Severe	22	23.9

Diabetes self-care activities

Diabetes self-care behaviours were assessed using the SDSCA questionnaire, including five key comments of the diabetes regimen (Table 14). The participants indicated the most commonly performed self-care behaviours was medication taking (n = 92 mean=4.59 per week (p/w); SD = 2.98), while the least performed behaviours were foot care (n = 92 mean = 1.57 (p/w); SD = 2.18), exercise (n = 92, mean = 2.13; SD = 1.87) and glucose monitoring (n=92, mean = 2.12 (p/w); SD = 2.43).

Table 14 Scores of self-care behaviours

Scale (SDSCA)	**N**	**Mean**	**SD**
General Diet	92	3.01	1.97
Specific Diet	92	3.14	1.49
Exercise	92	2.13	1.87
Glucose monitoring	92	2.12	2.43
Medication	91	4.59	2.98
Foot care	92	1.57	2.18

Additionally, the SDSCA included the items regarding smoking status and self-care recommendations from their HCPs. 65.2% of women (n = 60) reported smoking a cigarette and 24.1% (n = 24) have been offered a stop-smoking programme by their HCPs.

Women reported self-care recommendations from HCPs (e.g., diet and exercise). While 11 women (4.4%) stated they had not been given any advice about their diet plan by their HCPs, 20 women (13.5%) had not been given any advice about exercise. Additionally, 30 women (26.8%) stated they had not received any advice about blood glucose testing.

5.11.3 Main findings

The results of analysis identified correlations between psychosocial variables, self-care behaviours, and socio-demographic characteristics as reported in Table 15. Covariate variables were created for two groups of categorical variables. For example, age is categorised as group 1 (18-35 years) and group 2 (36-45 years); diabetes duration as group 1 (0-5 years) and group 2 (more than 5 years); marital status as group 1 (single, widow, divorced), group 2 (married and in a relationship); education level as group 1 (primary, secondary school, college/diploma), group 2 (university, postgraduate); occupation/working as group 1 (employed full time, part time), group 2 (student, unable to work, home duties); HbA1c as group 1 (less than 7%), group 2 (more than 7%). As a result of data analysis, older age was revealed to be associated with greater disordered eating and fatigue. High levels of disordered eating behaviours were associated with older age and higher income, where it was negatively associated with lower education level and a family history of diabetes. Being married or in a relationship demonstrated a small positive correlation with high levels of performed specific diet in the past seven days. Higher HbA1c levels were positively associated with high levels of performed specific diet. High levels of diabetes distress were observed in lower income (r = -.24, p = 0.02). Exercising more exhibited a small association with lower education level (r = .22, p = 0.03). However, there was no association with the other variables (e.g., anxiety and socio-demographic variables).

Table 15 Correlations between measures and socio-demographic characteristics

	Pearson	FSS	SCOFF-5	DSAS-2	DDS	GAD-7	SDSCA general diet	SDSCA specific diet	SDSCA exercise
Age	R	**.213***	**.213***	0.056	0.024	0.024	-0.119	0.097	-0.127
	P value	0.041	0.041	0.593	0.817	0.822	0.258	0.360	0.228
Duration of diabetes	R	0.088	-0.025	-0.183	0.007	-0.027	0.053	-0.079	0.028
	P value	0.406	0.811	0.081	0.946	0.801	0.617	0.456	0.790
Family	R	-0.036	**-.213***	0.064	0.020	-0.060	0.018	0.071	0.032

history	P value	0.732	0.041	0.544	0.849	0.571	0.864	0.504	0.764
Income	R	-0.016	**.230***	0.013	**-.242***	-0.181	0.173	0.116	0.038
	P value	0.880	0.029	0.901	0.021	0.086	0.101	0.275	0.718
Occupation	R	-0.007	-0.027	**-.321****	0.050	-0.078	-0.017	-0.171	-0.140
	P value	0.951	0.797	0.002	0.641	0.460	0.876	0.104	0.185
Diabetes therapy	R	-0.117	-0.038	0.020	-0.043	-0.041	0.030	-0.157	**.236***
	P value	0.282	0.727	0.852	0.691	0.704	0.784	0.146	0.028
Marital status	R	0.039	0.111	-0.089	-0.077	-0.167	-0.015	**.214***	0.062
	P value	0.715	0.302	0.405	0.471	0.118	0.886	0.044	0.565
HbA1c	R	0.005	-0.055	0.043	0.196	0.096	-0.012	**.216***	-0.043
	P value	0.961	0.604	0.686	0.062	0.361	0.908	0.039	0.682
Education college	R	-0.092	**-.345****	0.163	0.068	0.098	0.024	0.015	**.222***
	P value	0.381	0.001	0.121	0.520	0.353	0.823	0.891	0.034

*Correlation is significant at the 0.05 level (2 tailed)

**Correlation is significant at the 0.01 level (2 tailed)

Before the analysis, we tested the model's assumptions; linearity of the relationships between the dependent and independent variables, and the normality of residuals (histograms and normal QQ plot of the residuals). The Mann-Whitney U test, as an independent sample test, was used to compare the differences between two independent groups (e.g., age). This analysis demonstrated the differences between the groups in marital status, education level, and occupation ($p < 0.005$). These variables can affect the dependent variable in some way. To assess the effects of these three predictor variables, multiple linear regression analysis was used, and the following steps were followed: 1) dependent (SDSCA) and independent variables (all psychosocial variables) were included in the first step (Block 1), 2) dependent, independent, and three covariates (marital status, education level, and occupation) were added in the second step (Block 2). Please see Table 16 below.

Table 16 Model summary [c]

Model	R	R square	Adjusted R square	Std. Error of the Estimate
1	.365[a]	.133	.081	1.894
2	.367[b]	.135	.047	1.928

a: Predictors: (Constant), GAD-7, SCOFF-5, FSS-9, DSAS-2, DDS
b: Predictors: (Constant), GAD-7, SCOFF-5, FSS-9, DSAS-2, DDS, marital status, education level, occupation
c: Dependent variable: SDSCA (specific diet).

When the analyses were run, the adjusted R-squared (R^2) was found to be a value of 0.047 which means that the model explains approximately 4% of the fitted data in the regression model. This demonstrated a low proportion of variances in the dependent variable that can be explained by the independent variables. Therefore, the regression analysis was not undertaken as the analysis was underpowered. Only Pearson's correlations were used to test the associations between variables. The results are presented in the following sections.

Relationship between stigma, and disordered eating, diabetes distress, anxiety, and self-care activities

Table 17 shows the results of Pearson correlation analysis and illustrates that high levels of total DSAS-2 scores for diabetes-related stigma and its subscales showed a moderate, positive correlation with high DSS scale scores (total diabetes distress (r = .49, p = 0.000)), emotional related distress (r = .53, p = 0.000), physician related distress (r = .37, p = 0.000), regimen-related distress (r = .39, p = 0.000), interpersonal distress (r = .37, p = 0.000), and anxiety (r = .49, p = 0.000), whereas higher levels of total diabetes-related stigma were negatively correlated with lower numbers of performed foot care activities in the past seven days (r = -.40, p = 0.000). High levels of being treated differently, which is one of the three subscales of the DSAS-2 scale, were positively correlated with high levels of total diabetes distress (r = .50, p = 0.000), emotional burden (r = .48, p = 0.000), physician-related distress (r = .35, p = 0.000), regimen-related distress (r = .41, p = 0.000), interpersonal distress (r = .57, p = 0.000), along with anxiety (r = .46, p = 0.000). Likewise, high levels of blame and judgment and self-stigma, which are the other two subscales of the DSAS-2 scale, were positively correlated with high levels of total diabetes distress and its subscales, anxiety,

excluding disordered eating which was not observed to have any correlation. There was no correlation between concordance with self-management activities and diabetes-related stigma (Table 17).

Table 17 Correlations between total diabetes related stigma along with its three subscales and other variables

	Pearson	DSAS-2 total	Treated differently	Blame and judgment	Self-stigma
SCOFF	R	-0.182	**-.210***	-0.137	-0.140
	p value	0.082	0.044	0.193	0.184
DDS TOTAL	R	**.493****	**.504****	**.425****	**.369****
	p value	0.000	0.000	0.000	0.000
DDS emotional burden	R	**.539****	**.483****	**.454****	**.455****
	P value	0.000	0.000	0.000	0.000
DDS physician-related distress	R	**.371****	**.357****	**.331****	**.283****
	P value	0.000	0.000	0.001	0.006
DDS regimen-related distress	R	**.398****	**.416****	**.367****	**.273****
	P value	0.000	0.000	0.000	0.009
DDS Interpersonal distress	R	**.439****	**.572****	**.342****	**.286****
	P value	0.000	0.000	0.001	0.006
GAD-7	R	**.498****	**.466****	**.452****	**.379****
	P value	0.000	0.000	0.000	0.000
General diet	R	-0.141	-0.114	-0.173	-0.079
	P value	0.180	0.279	0.099	0.452
Specific diet	R	-0.023	-0.041	-0.067	0.035
	P value	0.831	0.700	0.523	0.738
Exercise	R	0.196	0.109	0.193	0.181
	P value	0.061	0.301	0.065	0.085

*Correlation is significant at the 0.05 level (2 tailed)

**Correlation is significant at the 0.01 level (2 tailed)

Relationship between diabetes distress and anxiety, and disordered eating, fatigue, and self-care behaviours

A statistically negative correlation was seen between higher levels of disorder eating behaviours (r = -.34, p = 0.001) and lower total diabetes distress scores (r = -.31, p = 0.002) and anxiety (r = -.27, p = 0.007). Higher DDS scores and each of four subscales, excluding

interpersonal distress, showed significant positive correlations with higher FFS-9 scores (r = .30, p = 0.003). By contrast, high general diet scores (SDSCA scale) revealed medium negative correlations with low levels of total DDS scale scores (r = .33, p = 0.001) and emotion related distress (r = -.21, p = 0.04), physician-related distress (r = -.31, p = 0.002), regimen-related distress (r = -.33, p = 0.001), interpersonal distress (r = -.32, p = 0.001) (Table 18).

Table 18 Correlations between diabetes distress, anxiety, and disordered eating, fatigue, and self-care

	Pearson	DDS total	DDS Emotion	DDS Physician	DDS Regimen	DDS Interpersonal	GAD-7
SCOFF	R	**-.340*** **	**-.317** **	**-.222***	**-.343***	**-.326** **	**-.279** **
	P value	0.001	0.002	0.033	0.001	0.002	0.007
FSS	R	**.309** **	**.337** **	**.237***	**.307** **	0.175	**.327** **
	P value	0.003	0.001	0.023	0.003	0.096	0.001
General diet	R	**-.331** **	**-.211***	**-.313** **	**-.330** **	**-.327** **	-.179
	P value	0.001	0.043	0.002	0.001	0.001	0.088
Specific diet	R	-0.056	-0.038	-0.009	-0.085	-0.067	-.031
	P value	0.599	0.719	0.932	0.420	0.524	0.772
Exercise	R	-0.110	-0.133	-0.048	-0.117	-0.087	-.001
	P value	0.295	0.206	0.651	0.269	0.409	0.992

*Correlation is significant at the 0.05 level (2 tailed)

**Correlation is significant at the 0.01 level (2 tailed)

Correlations of all variables

A statistically significant negative correlation was seen between high levels of disordered eating and low levels of diabetes distress (r = -.34, p < 0.001) and anxiety (r = -.27, p < 0.001). High levels of fatigue showed statistically significant positive correlations with high levels of diabetes distress (r = .30, p < 0.001) and anxiety (r = .32, p < 0.001), whilst by contrast high levels of fatigue were associated with low levels of exercise activities performed in the past seven days (r = -.28, p < 0.05). A statistically positive correlation was revealed between high levels of diabetes-related stigma and high levels of diabetes distress (r = .49, p < 0.001) and anxiety (r = .49, p < 0.001). The DDS scores showed a statistically positive correlation with the GAD-7 scores (r = .63, p < 0.001), but a statistically negative correlation with low levels of following general diet in the past seven days (r = -.33, p < 0.001). Finally, exercising more was

positively correlated with high levels of performed general diet (r = .28, p < 0.001) and specific diet over the past week (r = .22, p < 0.05) (Table 19).

Table 19 Correlations between variables

	1	2	3	4	5	6	7	8
1.SCOFF-5 (Disordered eating)	1.00							
2. FSS-9 (Fatigue)	0.010	1.00						
3. DSAS-2 (Stigma)	-0.182	0.079	1.00					
4.DDS total (DM distress)	**-.340****	**.309****	**.493****	1.00				
5.GAD-7 (Anxiety)	**-.279****	**.327****	**.498****	**.631****	1.00			
6. SDSCA - General diet	-0.019	-0.061	-0.141	**-.331****	-0.179	1.00		
7.SDSCA - Specific diet	0.013	-0.068	-0.023	-0.056	0.031	0.176	1.00	
8. SDSCA-Exercise	-0.040	**-.286****	0.196	-0.110	-0.001	**.282****	**.229***	1.00

*. Correlation is significant at the 0.05 level (2-tailed)

**. Correlation is significant at the 0.01 level (2-tailed)

5.12 Discussion

This study examined the prevalence and correlates of the identified psychosocial health issues and self-management behaviours. Using data from the UK and Türkiye, this is the first cross-sectional study to have examined the prevalence and relationships between psychosocial health issues and self-care activities.

Prevalence of disordered eating and related factors

Disordered eating symptoms were reported by 92.4% of women with T2DM in the current study. The prevalence of disordered eating was higher than that suggested by previous studies, for example, Kenardy et al. (2001) found that 20.9% of women (n = 215, mean age =

58.9) reported binge eating. The findings from this present study revealed that the majority of women experienced a high level of disordered eating. This finding needs further exploration as women of reproductive age living with T2DM may require more attention and support in relation to disordered eating behaviours. Correlation analysis found age, family history, income, and education level to be related to a higher occurrence of disordered eating behaviours. Diabetes distress (r = -.34, p = 0.001), anxiety (r = -.27, p = 0.001), and being treated differently (sub-domain of the DSAS-2 scale) (r = -.21, p = 0.04) were negatively correlated with disordered eating behaviours. These observations are consistent with the findings of previous studies (Yahya et al., 2022; Chevinsky et al., 2020) that have reported an association between impaired health-related quality of life and binge eating behaviours among people with T2DM. Moreover, previous studies (Salvia et al., 2022; Kenardy et al., 2001) found a correlation between the frequency of binge eating and self-management behaviours (e.g., suboptimal HbA1c levels) in people with T2DM. The current study reported no correlation between HbA1c level, self-management, and disordered eating behaviours; however, the conflicting results may be related to the self-management measurement (e.g., HbA1c measurement), disordered eating measurement (SCOFF-5), and small sample size of participants. Further research is needed to clarify these relationships.

Prevalence of diabetes related stigma and related factors

In the present study, 53% of women with T2DM experienced diabetes-related stigma. This finding is consistent with a systematic review by Liu et al. (2017), who reported a 52% prevalence of stigma among people with T2DM. Of the women in this study, 46% reported their experiences of self-blame and judgment [mean = 23.32 (SD = 6.43)], 40% were treated differently [mean = 14.96 (SD = 4.71)], and 47% were self-stigmatised [mean = 17.41 (SD = 7.83)]. Diabetes-related stigma among the women in this study was markedly higher than found by Browne et al. (2016), who reported the prevalence of diabetes-related stigma to be 19.3% amongst people with T2DM (n = 205). In line with a prior study (Browne et al., 2016), correlation analysis found that occupation (r = -.32, p = 0.002), diabetes distress (r = .49, p = 0.000) and anxiety (r = .49, p = 0.000) are related to a higher occurrence of diabetes-related stigma. Unlike a previous study by Puhl et al. (2022), this present study did not find a correlation between self-management activities and diabetes related stigma, which may possibly have been due to the small number of participants and measurement scale (SDSCA).

Existing evidence shows that women with T2DM report diabetes-related stigma, which may affect both physical and mental health. Long-term consequences of stigma among women with T2DM with a large enough sample size are much needed.

Prevalence of diabetes distress and related factors

This study demonstrated that 65.2% of women with T2DM had moderate or high levels of diabetes distress, and 69.9% had regimen related distress, which is concordant with a recent systematic review and meta-analysis where a higher proportion of women were reported (Perrin et al., 2017). The findings from this study showed that diabetes distress is a prominent issue among young women with T2DM. In contrast, Hu et al. (2020) reported the prevalence of diabetes distress among young adults with T2DM in China and found that men had significantly higher diabetes distress than women. The authors suggested that this difference might be because of family responsibilities and stress among men in modern society (Hu et al., 2020). Previous studies have demonstrated that many factors affect diabetes distress such as age, higher self-efficacy, and a healthy diet (Wardian & Sun, 2014). In the present study, income, diet, disordered eating, fatigue, and stigma ($p < 0.001$) were the main factors affecting diabetes distress in young women with T2DM. Age, education level, HbA1c, diabetes duration, and occupation were not associated with diabetes distress, which differs from the findings of previous studies (Perrin et al., 2017).

Prevalence of fatigue and related factors

In the present study, 57% of women with T2DM had severe fatigue. Fatigue among the women with T2DM in this study was considerably higher than previously reported the fatigue levels among women (48%) (Fritschi et al., 2012), suggesting that fatigue is a severe problem in the population in this study. Findings from correlation analysis revealed that high levels of fatigue were statistically related to older age ($r = .21$, $p = 0.04$), high levels of diabetes distress ($r = .30$, $p = 0.003$), anxiety ($r = .32$, $p < 0.001$) and reduced physical activity ($r = -.28$, $p < 0.001$), which are consistent with the literature in various other populations (Kuo et al., 2021; Kelly et al., 2018; Drivsholm et al., 2005). While a correlation was expected between fatigue and HbA1c levels, none was found ($r = .005$, $p = 0.96$); however, these findings are by no means conclusive. In this study, women had multiple choice options for HbA1c levels (see Appendix C.1.5) and a third (29%) of women did not report their Hb1Ac

levels. Thus, women should be asked to self-report their blood glucose levels rather than providing multiple choice options, with the result that a relationship between HbA1C and fatigue may exist (Singh et al., 2016).

Prevalence of anxiety and related factors

According to the GAD-7 scores, 23.9% of young women with T2DM in the current study had moderate or severe anxiety symptoms and 32.7% had mild anxiety. This prevalence of anxiety was higher than found in previous studies conducted by Woon et al. (2020), reporting the rate of anxiety (9%) in people with diabetes, and by Chaturvedi et al. (2019) showing the prevalence of anxiety (18%) in people with T2DM. Correlation analysis found disordered eating ($r = -.27$, $p < 0.001$), fatigue ($r = .32$, $p < 0.001$), diabetes-related stigma ($r = 49$, $p < 0.001$) and diabetes distress ($r = .63$, $p < 0.001$) to be related to the occurrence of anxiety among young women with T2DM. However, there is no correlation between socio-demographic factors, self-management activities, and anxiety in this study, although anxiety symptoms have previously been linked to sub-optimal diabetes management activities in the literature (Woon et al., 2020).

Strengths

There are several strengths of this study. This is the first study to explore the relationships between psychosocial health issues and self-management behaviours among young women with T2DM. This study only focused on women of reproductive age living with T2DM, although previous research has focused on one stage of their life, such as pre-pregnancy care (Scavini et al., 2018). Secondly, this study includes several demographic and clinical variables as potential predictor variables for diabetes self-management behaviours and psychosocial health issues, and the use of valid and reliable tools to measure the dependent and independent variables. Thirdly, the present study used the online survey, thus there is no geographical restrictions within the UK and Türkiye. The results of the present study contributed to the existing knowledge by providing evidence about the prevalence and correlations of psychosocial health issues related to living with T2DM among young women. This informs the provision of targeted interventions to improve the women's health and wellbeing.

Limitations

This study has several limitations. First, this survey was limited by the low completion rate, which likely introduced non-response bias to the findings. Most importantly, the low completion rate limited the opportunity for subgroup analysis based on nationality. The completion rate may have been affected by several factors such as using online survey, which has some disadvantages besides its advantages (such as cost effectiveness, time), women's attitudes towards research/survey, interest, and the time to complete the survey (whether it was a busy daily schedule, etc.). Additionally, due to patient safety issues, the participants were requested to provide their contact details. This can be a particularly challenging factor to participation in a survey, as the survey used had the option to record presurvey and mid-survey attrition (e.g., people who look at or partially complete the survey but do not submit it). It was identified that 56 eligible women left the survey once they reached the section to provide their contact details. While speculative, a potential reason of this attrition may be related to experiences of shame and/or stigma related to living with T2DM resulting in an unwillingness to disclose their condition to others (Sturt, 2022; Browne et al., 2013). Most importantly, it is needed to understand why the completion rate was low, and how women's experiences and belief about T2DM affect their likelihood of responding to online surveys. Although internet access has increased over time, there is also the possibility that some women might have no or only limited internet access, thus may prevent some from participating in the study. Lower completion rates in the web-based survey still could potentially reflect a participant's lack of familiarity with technology, lack of technology related knowledge, or lack of internet access (Wu et al., 2022). There is also some evidence to suggest that online surveys yield a lower completion rate (Manfreda et al., 2008) or that people answering online questions are more likely to drop out before they reach the end of the survey than those answering paper surveys. Furthermore, the survey was only available for completion in English and Turkish. This could be an additional limitation in the UK and Türkiye where potential participants were not able to complete the survey because of language limitations (English or Turkish). As a result, these might have led differences between respondents and non-respondents related to sample characteristics (e.g., age and diabetes duration).

Another limitation is that the use of self-reporting measurements has some shortcomings. Research participants disclose sensitive information such as psychological issues more frequently when responding to self-administrated questionnaires when participating in face-to-face or telephone interviews. However, disclosing sensitive issues on self-administrated questionnaire surveys is enhanced when participants respond anonymously instead of confidentially (Murdoch et al., 2014). In addition to this, they may avoid disclosing honest answers about their experiences, symptoms, circumstance, and lifestyle.

Furthermore, we have used the SCOFF scale to assess disordered eating behaviours. As indicated, the reliability of this scale was low, although it has adequate convergent validity and stable reliability. This is concordant with a previous cross-sectional study exploring eating disorders in males with T2DM, which identified that the internal consistency was 0.47 (Warsi et al., 2020). Therefore, the results based on the use of the SCOFF should be interpreted with caution. Further, this scale might not reflect overall eating behaviours of younger women. Thus, a disordered eating scale related to T2DM is needed. The SDSCA scale also has some limitations, one of which is a poor association with levels of glycaemic control (HbA1c). For example, better self-management (e.g., adjusting diet) should lead to better glycaemic control, but a weak association between these variables raises concerns about the measure's validity (Schimit et al., 2016). Additionally, for self-management measures, a frequency of adherence to certain behaviours over the past week was used, which may cause recall bias as a seven-day recall may not reflect the overall adherence of participants. Further research is needed to address these limitations, such as using a daily record of self-management behaviours. The associations between variables could be reported due to the nature of cross-sectional study. Thus, the present study should be interpreted with a certain degree of caution.

5.13 Implications and recommendations

The findings of this study provide a unique contribution to understanding the correlations between psychosocial variables and self-management activities and provide further implications for future research. Although the study may not be able to provide clear guidelines for use in clinical practice, it has highlighted a set of psychosocial factors that may

be important in understanding self-management behaviours of young women with T2DM. New approaches to managing T2DM in younger ages are urgently needed. These include age- and gender-appropriate engagement of young women, for example, developing interventions or care pathways. This study also showed limitations to the validated scales for this population, thus highlighting the need to develop disordered eating and self-management scales related to T2DM. The present study indicated high levels of psychosocial health issues. These results can be used as a theoretical basis to implement psychosocial assessment for T2DM in younger women. Thus, HCPs could take initiatives to evaluate and affect psychosocial health issues experienced by the younger women with T2DM. The current findings show suboptimal self-management activities by younger women with T2DM who participated in this study. This suggests the need to promote self-management amongst younger women in primary healthcare settings via the use of counselling, education, and behaviour interventions to encourage optimal self-management behaviours.

5.14 Chapter summary

This chapter has presented a cross-sectional study assessing the correlations between identified psychosocial factors and self-management behaviours. These findings show a high level of psychosocial health issues among younger women with T2DM. This chapter also outlined the rationale for a cross-sectional study, data collection methods and data analysis procedures, ethical considerations, and the results of the study. In combination with the findings from the systematic review, qualitative study and quantitative study, these findings could inform future intervention or care pathway development.

The following chapter will discuss an integrated synthesis of the findings from this chapter, along with previous chapters (Chapter 2, systematic review, and Chapter 4, qualitative study) as well as the implications for practice, research, and policy.

Chapter 6 – Discussion

6.1 Chapter overview

This chapter provides the integration and summary of all stages of this study. Incorporated within the chapter are the findings and their contributions to the wider literature, along with the development of an understanding of the healthcare needs of women of reproductive age living with T2DM. Suggestions for enhancing diabetes care for this population to improve their health and wellbeing are also provided. The key findings from this study are discussed with reference to previous relevant literature and theory. This is followed by a review of the overarching strengths and limitations of the thesis methodology and studies conducted. The implications for clinical practice and recommendations for further research are discussed.

6.2 Summary of key findings

This study has provided empirical evidence to draw a holistic picture of the health and healthcare needs of women with T2DM. The systematic review (Celik et al., 2022, Study 1) highlighted reproductive, psychosocial, cardiovascular, sexual, and menopausal health as significant and specific health issues with regard to this population of women. The five major findings of the review are that:

1) HbA1c levels fluctuate through the luteal phase of the menstrual cycle,
2) T2DM increases the risk of early menopause among women,
3) there is suboptimal attendance (and/or availability) of pre-pregnancy care,
4) there is a high prevalence of sexual dysfunction,
5) there are high levels of psychosocial ill-health, including depression symptoms, anxiety, and diabetes distress.

Most studies included were cross-sectional creating an unclear picture as to why women experience such physical and psychosocial challenges and limiting our understanding of their diabetes experiences and healthcare needs. Most importantly, the included studies

were also limited in their research focus around specific ages, reproductive stages, and reproductive events. The review conclusions are: (i) we know some, but not all of, the health risks posed by T2DM at a younger age; (ii) there is a paucity of qualitative studies which would deliver a better understanding of the full range of their experiences, health needs, and potential risks they face; and (iii) there is a notable absence of intervention studies to address the identified health needs. To address this gap in knowledge of women's experiences, a qualitative study was developed and conducted to gain a better understanding of living with T2DM in women of reproductive age. This study identified young women's diabetes perceptions and health needs, emphasising age- and gender-related health issues. It found that living with T2DM was a major disrupting factor to young women's sense of self and identity. T2DM presented a disruption to their pregnancy plans, to their careers and employment, it contributed to shame and self-blame in relation to their lifestyles, and strong perceptions of judgment by having a diagnosis of diabetes at a younger age resulting in a disruption to their engagement in social activities. The perceptions of T2DM related to self and identity in women represented differing emotions and attitudes towards diabetes management. This provided a novel insight into the emotional burden of diabetes management at a younger age where disordered eating behaviours were reported to cope with emotional management. The second main finding is that the focus of diabetes care received did not align with their needs of being younger and female. This represents the lack of awareness of their age- and gender-based concerns, experiences, needs, and wishes by HCPs during their consultations, but rather that consultations were process driven. Their diabetes care is needed to acknowledge and provide for their reproductive health and emotional needs. Women wanted advice and support relating to their reproductive health and their emotional health in diabetes care. Additionally, this qualitative study identifies target components of improved care, suggested by women to improve their health and wellbeing, such as a tailored approach to care based on their emotional needs, age- and gender-based care, and peer support. Thus, this qualitative study concluded that further research is needed in this population which examines the prevalence of psychosocial factors related to living with T2DM and quantifying its consequences in young women with this condition. A more detailed understanding of the psychosocial issues associated with T2DM may aid the targeting and development of effective interventions.

The cross-sectional study was conducted, and it demonstrated the high prevalence of these psychosocial health issues among women. Disordered eating was reported by 92% of participants. The most commonly performed self-care behaviour reported by the women was medication taking, while the least performed behaviours were foot care, exercise, and glucose monitoring. Overall, women reported low or moderate levels of concordance with self-care activities, but also high levels of negative diabetes-related emotions, including stigma, anxiety, diabetes distress, fatigue, and evidence of disordered eating behaviours. The study concludes that psychosocial health issues are very common among young women with T2DM and these impact on concordance with self-care activities. These findings provide greater clarity to the age- and gender-based support required in women's reproductive lifespans and suggest early identification and appropriate timely care of these challenges for younger women in clinical practice. Whilst the findings provide a signal for the high levels of emotional health needs, the study was underpowered, thus the prevalence of evidence should be interpreted with some caution.

Table 20 summarised the key health domains identified in each study.

Table 20 Key outcomes of each study

Study 1: Systematic review	Study 2: Qualitative interviews	Study 3: Cross-sectional study
Aim: Reviewing the health issues faced by women with T2DM during their reproductive years.	Aim: Understanding the experiences and health needs of young women of reproductive age living with T2DM.	Aim: Exploring the prevalence and correlations of identified variables.
Results	Results	Results
1.Diabetes-related modifiable risk factors 1.1) Blood glucose 1.2) Cardiovascular risk 1.3) Neuropathy/nephropathy/ retinopathy 1.4) Diabetes self-management barriers	Theme 1: Perception of self and identity as a younger woman with type 2 diabetes 1.1) Identity disruption Role disruption Identity judged due to type 2 diabetes 1.2) Negative self-perception Self-perception of developing type 2 diabetes Results of negative self-perception 1.3) Fear surrounding fertility and pregnancy 1.4) Emotional burden of diabetes management Diabetes management at younger age Disordered eating	1)Fatigue (FSS-9 scale) According to the self-report FSS-9 measure, 57% of the sample had severe fatigue, and a further 17.4% had moderate fatigue.
2. Reproductive health 2.1) Diabetes care before pregnancy 2.2) Pre-pregnancy care barriers of women 2.3) Pre-pregnancy care expectations of women 2.4) Contraceptive use	Theme 2: Type 2 diabetes care is not orientated to younger women's needs 2.1) Authoritarian approach 2.2) Conflicting agenda 2.3) Lack of empathetic approach	2) Disordered eating behaviours (SCOFF-5) Of this population (n = 92), 7.6% (n = 7) had a score of 0 or 1, indicating no disordered eating behaviours, while the remaining 92.4% (n = 85) had a history of disordered eating behaviours scored at 2 and more.
3. Psychological wellbeing 3.1) Depression symptoms and diabetes	Components of improved care 3.1) Information and awareness	3) Diabetes stigma (DSAS-2 scale) The mean total score obtained for DSAS-2 was

distress 3.2) Perceptions of T2DM 3.3) Emotional concerns about pregnancy	3.2) Tailored approach Need therapeutic approach Age and gender awareness in diabetes care Need follow up in diabetes care 3.3) Supportive connection with other people	55.68 with a standard deviation (SD) of 16.47, with scores ranging from 19 to 88 points. A total of 53% (n = 49) experienced diabetes-related stigma.
4) Sexual function		4) Diabetes distress scale (DDS scale) According to this self-report measure, the mean total raw score was 3.54 (SD = 1.32), indicating moderate or high levels of diabetes distress as a result of the mean score of 3 or more. This means that 65.2% (n = 60) reported moderate or high levels of diabetes distress.
5) Menopause		5) Anxiety scale (GAD-7 Scale) The largest proportion of the women (n = 30, 32.6%) had mild anxiety, and a quarter (n = 22, 23.9%) had severe, while the smallest (n = 18, 19.6%) were in the minimal anxiety category.
6) Sociocultural factors 6.1. Social support 6.2. Cultural norms		6) Self-care activities (SDSCA scale) The participants indicated the most frequently performed self-care behaviours to be medication taking (mean = 4.59; SD = 2.98) while the least performed behaviours were foot care (mean = 1.57; SD = 2.18), exercise (mean = 2.13; SD = 1.87) and glucose monitoring (mean = 2.12; SD = 2.43).

A synthesis of findings from across the studies has been presented in three parts:

1) The impact of living with T2DM on reproductive age women's health and wellbeing includes physical and reproductive health, and psychosocial health issues.
2) Perceived diabetes care omissions/gaps include a lack of attention to women's specific health needs.
3) Suggested areas for future interventions and care pathways.

1) Impact of living with T2DM as a young woman of reproductive age

Diabetes-related complications

The experiences and perceptions of living with T2DM during their reproductive age demonstrate the multidimensional aspects of women's health and wellbeing are impacted, including physical, reproductive, and psychosocial components. One of the significant findings of this thesis is that young women experienced higher cardiovascular events and other diabetes-related complications compared to populations of older women with T2DM, which is supported by previous research (Barker et al., 2022; Hu et al., 2021; Nanayakkara et al., 2020). It has been reported that early onset T2DM has a more adverse cardiovascular risk profile compared with individuals with later onset diabetes (Wilmot & Idris, 2014)). Likewise, Dabelea et al. (2017), exploring the prevalence of and risk factors for complications related to T2DM and T1DM, found young onset T2DM is associated with a higher prevalence of microvascular complications of retinopathy and nephropathy, and macrovascular complications and comorbidities such as hypertension, compared to people with T1DM. Furthermore, the findings evidence that diabetes complications have a major impact on the woman's psychological wellbeing (e.g., fear about the future or lower life expectancy) and that emotions associated with it, in the form of diabetes distress, can remain unresolved.

Reproductive health issues

This thesis provides a novel contribution to identifying young women's reproductive health needs. These include the significant impacts of living with T2DM on the menstrual cycle,

pregnancy, sexual health, and early menopause experiences. In this study, young women with T2DM reported that their experiences of menstrual irregularities led to stress due to the risk of early menopause and showed negative emotional reactions such as shock, denial, and anger. This finding is congruent with previous research among women with premature ovarian failure which reported more anxiety and psychological distress than among women without diabetes (Shuster et al., 2011). Therefore, further research could look at the relationship between reproductive health and psychosexual health factors amongst women with T2DM. In addition, the findings in this thesis illustrate that most women sought information and clarification from HCPs about diabetes related to menopause. Nevertheless, they reported being frequently disappointed by the lack of clarity on menopause, which appeared to feed their negative emotions, such as feeling upset. This thesis concluded that further research is needed to better understand the relationship between early menopause and T2DM which may increase the risk of early development of complications (Ramezani Tehrani & Amiri, 2021).

This study has highlighted that there are significant knowledge deficits among women of reproductive age living with T2DM about diabetes and pregnancy and their future babies' health. This contributed to feeling concerned for the health of their future baby and fear that they may not be able to adequately optimise their blood glucose levels within recommended targets. As illustrated in this study, such thoughts led to a woman terminating her pregnancy. This finding has mirrored the experiences of women with T1DM that reported 23.6% of pregnancy terminations were due to adverse effects on the health of the offspring and the burden of pregnancy on maternal health (Sjöberg et al., 2017). It is also well documented that 40% of women with T2DM had anxiety and depression symptoms in early pregnancy (< 20 gestational weeks) and are more likely to have less optimal glycaemic control at this time (Asbjörnsdottir et al., 2021; Forde et al., 2016; de Wolff et al., 2021; Egerup et al., 2020), resulting in them terminating their pregnancies. Therefore, for women of reproductive age living with T2DM, diabetes education has a role to play in promoting an understanding of reproductive health issues in diabetes. Currently in the UK, all women with T2DM are offered structured education (e.g., DESMOND) (Skinner et al., 2006); however, reproductive health topics were not addressed (Misra et al., 2022b). Women in the qualitative study clearly reported a lack of discussion about reproductive

health topics during their consultations. Furthermore, only 23.9% of women (n = 92) in the cross-sectional study reported they had attended a diabetes education course. The benefits of diabetes education programmes in promoting self-management activities and reducing preventable diabetes complications have been well documented (Hermanns et al., 2020; Winkley et al., 2015; Lawal et al. 2018). This finding is in line with data from other work where fewer than 10% of people with diabetes had attended a diabetes education course, despite such courses being offered to 90% of people with T2DM and 40% of those with T1DM (Hermanns et al., 2020). Reasons for not participating in diabetes education course have been reported as heterogeneous and individual to the person and their circumstances (Lawal et al., 2017; Winkley et al., 2015; Schafer et al., 2014). Therefore, this thesis highlights the urgent need for education strategies which address the wider factors associated with women's reproductive behaviours.

Psychosocial factors

Another significant finding of this thesis is the psychosocial factors identified in the systematic review (study 1) and empirical studies (studies 2 and 3) affecting living with T2DM among younger women. The key psychosocial factors identified were diabetes distress, anxiety, depression symptoms, and stigma. These psychosocial factors overlap with similar previous reviews, for example, a meta-analysis of eight randomised control trials and nine pre-post designs that included diabetes distress as an outcome measure in people with T1DM. In that review, diabetes distress ranged from 20 to 30% amongst the research participants (Sturt et al., 2015). Another meta-analysis of 55 studies demonstrated an overall prevalence of 36% for diabetes distress in people with T2DM (Perrin et al., 2017). Previous studies have highlighted the psychological factors of heterogenous population or other types of diabetes. In addition to confirming this finding, this thesis has added some new insights and perspectives specifically in relation to younger women with T2DM. Specifically, this thesis has presented that experiences of fatigue (57%), stigma (53%), shame (47%), and disordered eating behaviours (92.4%) are commonly reported by younger women with T2DM. The investigation of these psychosocial factors in a cross-sectional study broadened this understanding of living with T2DM.

Disordered eating behaviours

A prominent finding was the high prevalence of disordered eating among younger women with T2DM (92.4% of 92 women) which has not previously been explored. Women in this study reported that their disordered eating behaviours are associated with the complexity of diabetes treatment, and or their negative feelings of living with T2DM at a younger age, resulting in eating large amounts of food when not physically hungry, and then feeling very guilty after overeating. However, there is a lack of understanding of how and why young women of T2DM develop eating disorders. Therefore, to effectively treat this group, there is an urgent need to screen this population for early intervention in disorder eating treatment. Mirroring these findings, a qualitative study conducted in the USA, with a sample of 21 women (mean age 49 years old), explored the perceptions of primary care providers' treatment among adult women with both an eating disorder and T2DM. Women reported the helpful (e.g., adequate diabetes education, non-judgmental attitudes) and unhelpful treatment experiences (e.g., having limited knowledge and understanding of diabetes and binge eating, simplistic advice or judgmental attitudes, feeling of guilt and shame) by their HCPs (Ritholz et al., 2022). Furthermore, eating disorders among those with T1DM include the most commonly reported forms of disturbed eating behaviours, such as binge eating, food restrictions, concerns over shape and weight (Custal et al., 2014; Coleman & Caswell, 2020). For young women with T2DM, there is a paucity of research in the context of T2DM and eating disorders. This study has highlighted that it is vitally important to gain a better understanding the experiences and perceptions of disordered eating behaviours among younger women with T2DM to provide targeted and personalised diabetes care.

Fatigue

Fatigue is a distressing compliant among younger women with T2DM. While also occurring in other medical conditions such as inflammatory bowel disease (Nocerino et al., 2020; Artom et al., 2016), T1DM (Jensen et al., 2017; Goedendorp et al., 2014), chronic heart failure (Williams, 2017; Evangelista et al., 2008), and rheumatoid arthritis (van Hoogmoed et al., 2010), the importance of fatigue may be greater in women with T2DM due to the complex management strategies that must be continuously maintained, impacting the quality of life among this population (Romadlon et al., 2021; Singh et al., 2016). The finding from this thesis further revealed that young women reported high levels of fatigue affecting

their caregiving responsibilities, work performance, sexual life, and daily activities (e.g., exercise). The findings suggest a need for the inclusion of symptom assessment in diabetes education to assist such populations in managing their fatigue symptoms and improving their diabetes self-management.

Role disruption

Living with T2DM strongly affected women's perceptions of self and how they felt they were being perceived by others. A diagnosis of diabetes is considered a major disruption in women's lives, particularly in relation to roles they consider important. Recurrent statements from women illustrated that the disruption from diabetes to their roles (such as carer, mother, wife) negatively impacted their experiences. This included their inability to fulfil the role of childcaring due to tiredness, or to perform their routine activities such as participating in social events with their friends. The perceived disruption following diagnosis is consistent with other studies exploring the experiences of mothers with T1DM. These studies highlighted disruptions to life, with reports of lower levels of general wellbeing, while being more tired than the reference group. Importantly among these groups of women with T1DM, they expressed a greater need to organise their lives after childbirth (Moghadam et al., 2022; Ringholm et al., 2020; Carlsson et al., 2017; Berg et al., 2012; Sparud-Lundin & Berg, 2011). This thesis emphases that T2DM was also perceived as a barrier to making many plans such as their future lives. Many of these feelings were amplified and accelerated by their need for phycological support.

Shame and self-blame

Another important finding is that shame and self-blame for having developed T2DM at younger age were highly salient among women in this thesis (47% and 46% respectively). Having T2DM was associated with shame and failure in relation to their lifestyle, which implied a level of self-blame and negative perceptions of themselves as a woman being of younger age with T2DM. They described their feeling about the other kinds of diabetes they would rather have such as T1DM, as this is not considered self-induced and therefore would not be their own fault. These findings resonate with other conditions such as obesity (Brevis & Bruening, 2018) and HIV/AIDS (Pantelic et al., 2017; Bennett et al., 2015), where shame was characterised by a painful internalised emotion encompassing feelings that the self is

damaged and is accompanied by feelings of desire to disappear, worthlessness, rejection, and isolation (Nebunya & Namuwonge, 2022; Neufeld et al., 2012). A commentary study by Sturt (2022) identified the dangers to health of living with shame because individuals do not believe themselves worthy of good outcomes. This thesis demonstrates that the shame experienced by these women may pose a serious threat to the women themselves, pointing to reduced healthcare service utilisation, resulting in greater negative consequences for their health (Stangl et al., 2019; Earnshaw & Quinn, 2012).

Diabetes related stigma

The findings of this thesis show a high degree of stigma in young women's lives (53%) and describes feeling judged by having a diagnosis of diabetes at a younger age because T2DM was related to their '*wrong*' lifestyle. The experiences of stigma were also stated as being labelled as a woman, through her own failings, has brought the condition upon herself. Furthermore, some women felt judged by HCPs who attributed failings to the women, such as not engaging in appropriate self-management or having an unhealthy lifestyle. Brunton (2022) mirrors these results, reporting that people with both T1DM and T2DM were stigmatised, yet T1DM is different (e.g., misconceptions that T1DM is contagious). Further, due to the aetiology of T2DM, there are misconceptions about it being a self-induced condition. For people with T2DM, negative experiences were underpinned by society's negative biases about T2DM such as '*poor control'* or *'a lack of a sense of responsibility'*. Complicating this is that many individuals with T2DM have comorbid obesity (Himmelstein & Puhl, 2020), and the relative risk of developing T2DM is seven times higher for people with obesity, compared to those with a BMI of 19-25kg/m^2 (Abdullah et al., 2010). Thus, people with T2DM may be vulnerable to weight-related stigma due to their higher body weight or larger body size (Puhl et al., 2020). This thesis highlights that most young women were stigmatised by T2DM being linked with gaining weight or having obesity. However, this thesis also reports a strong sense of confusion amongst women with T2DM and others (such as family or friends) about the underlying causes of diabetes, particularly if the women were not overweight and considered they had a healthy lifestyle. Thus, there is a need to inform both the younger women and public about the reasons for early onset T2DM. Consistent with previous research (Puhl et al., 2020; Browne et al., 2013; Browne et al., 2016; Holmes-Truscott et al., 2018), perceiving and experiencing diabetes stigma has psychological,

physical, behavioural, and social consequences. This thesis has contributed to an understanding of greater internalisation of diabetes stigma among young women with T2DM. This feeling can lead to an unwillingness to disclose their condition, a lower sense of self-value and self-esteem, exclusion from society or smaller social networks and less opportunity to receive social support, along with isolation and feelings of loneliness. Furthermore, considerable evidence has documented diabetes stigma, as well as experiencing judgment about diabetes from HCPs, may lead to lower diabetes self-management (e.g., a lower frequency of haemoglobin checks, or medication intake), self-efficacy, lower quality collaborations with their HCPs, and less frequent clinician-patient communications (Puhl et al., 2020; Holmes-Truscott, 2020; Himmelsmen & Puhl, 2020). This thesis suggests that further research is needed in this population of younger women with T2DM, with a view to examining the long-term outcomes of diabetes-related stigma and self-management and to develop strategies to reduce or prevent its impact.

2) Deficits in diabetes care provided

Communication and engagement

T2DM, consistent with other chronic conditions, requires 'unending work and care' to improve diabetes outcomes and increase health and wellbeing among people living with the condition (Corbin & Strauss, 1988). In this thesis, women often experienced treatment burden owing to the stresses and challenges caused by this complex condition during their reproductive years. Only 34% of participants in study 3 of this thesis reported attaining their long-term blood glucose treatment goals. The factors affecting a person's ability to carry out self-management behaviours include health status, environmental characteristics and the amount and types of resources available, level of knowledge, and access to healthcare systems (Schulden-Green, 2016; Suglo & Evans, 2020). It was earlier discussed in Chapter 4 how communication and support from HCPs may influence women's self-management behaviours, and that the ability to self-manage is a dynamic process that varies from person to person. Age- and gender-based care for women with T2DM is therefore significant. An important finding in this thesis is that many women perceived a need for more support than they received from their HCPs. Additionally, the support that they received was considered

medical treatment rather than listening to and understanding their age- and gender-based health needs or concerns.

Further, this thesis highlighted that some women reported that their HCPs never asked them about their routine diet or lifestyle, and insisted they prescribed more diabetes medications rather than listening to the women's preferences, leading to feelings of being '*patronised*'. Consultations have become process-driven, meaning that 'routine' rather than the productive interactions take place. Most women also expressed the need to be listened to and reported their suboptimal medication intake was a consequence of dissatisfaction with HCP's attitudes and not engaging in a discussion about diabetes management. It has been reported elsewhere that HCPs have an inability to discuss the patients' treatment adherence problems or to take their concerns and experiences seriously. Among those with chronic conditions, this can negatively affect their self-efficacy (Adu et al., 2019; Ebrahimi Belil et al., 2018). A lack of trust in HCPs may also increase the burden of an illness and negatively impact on individuals' self-care behaviours such as medication intake (Kvarnström et al., 2021; Habte et al., 2017; Linetzky et al., 2017; Haskard Zolnierek & DiMatteo, 2009; Parchman et al., 2010). Suboptimal medication intake is a root cause of substantial worsening of diabetes, death, and increased healthcare costs, whilst optimised management is correlated with better clinical outcomes (Parchman et al., 2010).

Empathetic approach

The findings from this thesis also demonstrates that language appeared to have a major impact on the behaviours of women with T2DM. The language used could trigger their negative feelings, such as guilt or a sense of failure. This contributes to continuing emotional distress and a person's lack of confidence in their own ability to manage diabetes and might result in a reduction in their health-attending behaviours (Howick et al., 2018; Dunning et al., 2017; Schulman-Green et al., 2016). Importantly, it is well documented that those with more empathetic HCPs were likely to have a higher sense of self-efficacy compared with those whose HCPs had low empathy (Robinson et al., 2020; Flickinger et al., 2016; Zoffman et al., 2016). This thesis emphasised the importance of listening to and understanding young women's opinions, feelings, and experiences in order to assess their real needs and act accordingly. Further, some women were reluctant to confide in their HCPs due to fear of being judged for failing to manage their diabetes. They perceived they were under attack

from their HCPs when discussing such things as their blood glucose levels being too high. This thesis suggests that such relationships may limit the opportunity to explore the issues encountered by younger women with T2DM and may create a barrier for the women to initiating such discussions. These findings resonate with the previous literature exploring the challenges of expressing emotional issues and help-seeking behaviours when living with a chronic disorder (Aguirre Valesco et al., 2020; Beverly et al., 2012; Ritholz et al., 2015; Uysal &Ozer, 2019). To address the issues surrounding language and how to promote open dialogue, many national and international guidelines have been published to raise greater awareness of the language used when speaking with and about people with diabetes. These guidelines draw attention to the importance of how language is used when communicating with people living with diabetes, as well as contributing to their enhanced mental, emotional, and physical wellbeing. Such guidance is promoted by NHS England (Kar, 2018), Diabetes Australia (Speight et al., 2021), the American Diabetes Association (Dickinson et al., 2017), and the International Diabetes Federation (Snouffer, 2017). A person's engagement in self-care, their relationship with HCPs, and diabetes outcomes may all be improved by HCPs ensuring a person's needs and expectations are met during consultation, while also demonstrating empathy and providing emotional support (Geerling et al., 2022).

Age- and gender-based diabetes care

This thesis highlights a conflict of agendas between women's expectations on reproductive issues and consultation topics of HCPs. Some women expressed that HCPs focused on general aspects of diabetes management such as medication, diet, or the impact of diabetes rather than reproductive issues such as fertility, pregnancy planning, or menopause. Women stated that health topics were not discussed with HCPs according to their age and gender. When discussing their experiences with HCPs, women expressed a desire for them to take the time to discuss their reproductive issues relative to diabetes. They want HCPs to view them a reproductive aged woman, not just a patient with T2DM. Hence, while other studies have previously highlighted system-level deficits related to pre-pregnancy care for women with T2DM (Murphy et al., 2021; Forde et al., 2021; Forde et al., 2020; Gaudio et al., 2021), this thesis has emphasised the system failings in relation to young women's age and gender healthcare needs during their diabetes consultations. In the UK, the Quality and Outcomes Framework (QOF) aims to improve the quality of care delivered by rewarding GP

practices for the care they provide based on a variety of indicators. These indicators target various key clinical care and public health areas and have helped to standardise diabetes care delivery (Hodgson et al., 2022; Forbes et al., 2017; Gunn et al., 2021). Reproductive healthcare, including pre-pregnancy care, contraception or contraception tailored to their pregnancy and contraceptive intentions for women with T2DM have not been incentivised via QOF indicators (NHS, 2021; NICE, 2022). Likewise, currently reproductive health is not routinely addressed in consultations for women with T2DM, nor is it included in the structured education programmes offered to people following diagnosis (Davies et al., 2008). In contrast, it is evident that provision of pre-pregnancy care and advice for women with epilepsy has been included in the QOF since 2011, and an 80% achievement rate has been reported (Taylor et al., 2022; NICE, 2013). Therefore, meeting young women's expectations may result in better care coordination. If the HCPs can gain greater insight into the plight of women's healthcare needs, they will be able to assign the treatment that is more feasible and better aligned with the women's individual circumstances. This could also improve both the quality of care and life of women by increasing self-management behaviours and decreasing diabetes complications and hospital admissions (Natafgi et al., 2022; Catapan et al., 2021).

3) Suggested strategies for future interventions and care pathways

In this thesis, a number of strategies were proposed from recommendations made by women to improve their health and wellbeing living with T2DM during their reproductive years. They highlighted actions such as raising awareness of T2DM at younger age more widely, providing younger women and their families with information and knowledge about diabetes and working towards eliminating the stigmatisation and shame younger women experience due to a diagnosis of T2DM. Women had more existential questions due to having developed diabetes at younger ages, and sought strategies to accommodate diabetes within their daily lives. The lack of knowledge about diabetes led to negative feelings about their diagnosis experiences. Such experiences were distressing for them and contributed to their unwillingness to disclose their conditions to others (e.g., family members or significant others) or led to feelings of failure along with self-blame and shame (as discussed in Chapter 4). Individually and collectively, these may lead to suboptimal

diabetes management behaviours. Therefore, women may benefit from a psychoeducation intervention approach to empower them in relation to their emotional wellbeing and education support, particularly during their early experience of diabetes.

There is a need to emphasise the importance of a tailored diabetes care approach that addresses women's reproductive and psychological needs and provides continuity of care. They also suggested health promotion interventions that project the methods of support, especially peer support, for reducing feelings of isolation and loneliness and sharing coping strategies. Being able to talk to other women in a peer support setting may make them feel relieved and confident, as they perceived conversations with women with T2DM to be of value. Given the high levels of psychosocial need that have been reported by women with T2DM, they also suggested a need for psychological support during this period of life with diabetes, which may increase their health and wellbeing. The data from this study corroborates previous research that reported recommendations to address the unmet health and well-being needs of people living with diabetes (e.g., stigmatisation and shame) (Wylie et al., 2019).

The report of women's health strategies for England is based on women's healthcare and service through their life courses, meaning the different needs at each stage of life, such as menstrual cycle, having children, and going through the menopause (Department of Health & Social Care, 2021) is consistent with women's views in this study. Driving forward the system level changes needed to close the age and gender health gap, this report sets out strategies to boost the health outcomes for all women and girls in five ways:

i) Ensuring women's voices are heard – tackling stigmatisation and ensuring women are listened to by their HCPs,

ii) Improving access to services – ensuring woman can access services that meet their reproductive healthcare needs across their lifespans,

iii) Addressing disparities in outcomes among women – ensuring a woman's age, sexuality, ethnicity, and where she is from does not affect her ability to access service,

iv) Better information and education – enabling HCPs to have the initial and ongoing training they need to treat their patients empathetically and knowledgably, and women and public to easily equip themselves with accurate information about women's health,

v) Greater understanding of how women's health affects their experience in the workplace – normalising taboo topics such as the menopause,

vi) Supporting more research – addressing the lack of research into women's health conditions. The evidence highlighted particular health issues such as menstrual health, fertility, pregnancy, menopause, and mental health (Department of Health & Social Care, 2021), which are consistent with the findings of this thesis.

6.3 Study strengths and limitations

While the findings of this thesis contribute to the wider literature on T2DM in young women of reproductive age and identifies targets for possible interventions and care pathways, some limitations to this thesis's studies need to be acknowledged. The strengths and limitations of each study were described in the discussion section of the published article or chapter section; however, this section will briefly summarise these again, with further considerations to the overarching strengths and limitations of the thesis.

The use of the MRC framework for developing and evaluating complex interventions provides a systematic, robust, and structured approach to enable the researchers to best address the aims and objectives of this thesis, such as understanding the needs of the target population (Craig et al., 2008; Skivington et al., 2021a; Beijenberg et al., 2018). In this study, the MRC framework and its more recent amendments provided a pragmatic and organised yet flexible basis for understanding the health needs of women to enhance their care. This framework highlighted the importance of rooting the development of care pathways and interventions in evidence and theory. As such, this study included a mixed methods systematic review (Chapter 2, study 1) to address gaps in evidence by researching what is known about women living with T2DM from the current literature. These insights were further enhanced by women's subjective experiences and inputs to highlight their healthcare needs (Chapter 4, study 2).

The use of a mixed methods approach strengthens the findings of this study as it has been able to integrate evidence from the qualitative and quantitate studies. First, the qualitative study was conducted to provide an in-depth understanding about women's experiences and healthcare needs and to inform the measures utilised in the quantitative study. Together, the use of qualitative and quantitative studies created confidence in the results, particularly where the findings support each other. In addition, where findings are divergent mixed methods are adopted, emphasising this divergence and allowing further discussion as to why certain differences may be present. Throughout this thesis, standardised guidelines (PRISMA, COREQ, STROBE, GRAMMS) were used to report the research which provides transparency and clarity of the reported methods and findings.

This study is the first transnational study to explore the experiences and healthcare needs of reproductive age women with T2DM in the UK and Türkiye to inform future interventions and care pathways. Despite some differences in the socio-cultural context, the experiences expressed by women across both countries were remarkably similar. These similarities were apparent in their descriptions of their experiences and thus it was decided to analyse the interviews as one whole dataset rather than two separate datasets. Previous diabetes studies involving a sample from countries with more diverse socio-cultural backgrounds have also reported commonalities in needs and experiences of living with diabetes (Chatwin et al., 2022; Due-Christensen et al., 2019; Kofahl et al., 2014; Beran & Golay, 2017). However, while the findings are likely to be transferable to similar populations and healthcare systems, the experiences captured in the study may be less applicable to countries with different availability to healthcare and culture.

The systematic review included all kinds of designs, including qualitative and quantitative studies, and provided a comprehensive synthesis of the literature on women's health and wellbeing. The majority of included studies had a moderate to high quality and a large number of participants included. However, as most of the included studies were of cross-sectional design, this hindered a richer understanding of the experiences of younger women with T2DM. There were few qualitative studies within the reproductive-aged women's healthcare literature. This qualitative study has added to the evidence related to the women's health with T2DM literature overall. The qualitative study of thirty-six women with T2DM included a mixture of age, diabetes duration, country of residence (UK and Türkiye) and ethnicity, largely through the use of a sampling frame to encourage sampling heterogeneity, and maximum variation purposive sampling. Framework Analysis supported synthesis within this diversity. Whilst information power in the qualitative study is achieved at the level of women's reproductive age and diabetes diagnosis, there is much diversity contained within the study population such as culture, duration of diabetes, and specific reproductive health experiences (e.g., pregnancy; pregnancy intentions) that have not achieved information power. Overall, a wide range of views were expressed by the women, indicating that this approach to sampling seemed to be effective, along with identification of consistent reoccurring themes. Development of the interview topic guide was underpinned by the findings of the systematic review (study 1) and guidance from the clinical experiences

of the supervisory team. It was also reviewed by the PPI group, then refined following feedback from this group to ensure that all questions were understandable in both countries. Pilot testing of the interview topic guide was undertaken to ensure the relevance and coverage of the content of the topic guide and to test implementation. However, data obtained through different techniques (video/phone and email) provided varying depths of data, which can be challenging during data analysis. However, combining data from three different sources (video/phone and email) in a single study can provide trustworthy findings. The type and depth of data gathered from the qualitative study (study 2) provides evidence that online interviews have made the process to participate in research more amenable for women who may have felt more embarrassed to disclose their conditions and health issues. However, the need to rely on online recruitment methods has been a limitation in this study. Participants were invited to participate in the study via advertising on the internet, which automatically excludes women without internet access. Furthermore, only few minority groups (e.g., LGBTQ) responded to the study, thus the findings of this study may be limited transferability across all young women living with T2DM.

The strengths of the cross-sectional study were the inclusion of a wide range of validated psychosocial measures to investigate the prevalence and correlates of psychosocial health issues associated with living with T2DM among young women of reproductive age. Another strength is that eight PPI members from the UK and Türkiye have been involved in the planning and design of this study, including identification and prioritisation of these health issues. The results of this study contributed to the existing knowledge by providing evidence on the prevalence and correlations of the identified psychosocial health issues which, to the best of my knowledge, has not previously been investigated in young women with T2DM. The previous studies that attempted to explore the impact of living with T2DM on the relationship among psychosocial aspects and self-management behaviours were limited to heterogenous populations (aged over 18 years and both gender) (Chan et al., 2020; Bo et al., 2020). However, the cross-sectional study has its limitations. This study can only assess the health issues reported at this one point in time. While it was not an aim to assess these health issues over time in these studies, in relation to investigating the experienced health problems, different or fluctuating barriers experienced at different time points may confer more benefits, such as longitudinal studies. Moreover, as the study was not anonymised,

the participants may not have answered accurately, which may be expected in self-reported data collection. Additionally, this study cannot establish a cause-and-effect relationship between exposure and outcome variables. While high anticipated self-stigma was associated with lower levels of self-management behaviours, an assumption can be made that higher self-stigma reduces self-management activities, it could also be possible that lower levels of self-management cause increased stigma. However, this is not clear using a cross-sectional study design, therefore future research should examine these causalities.

Critique of the theories

As stated in Chapter 3, three theories consisting of the Self-efficacy theory (Bandura, 1977), the COM-B model (Michie et al., 2014) and the Corbin and Strauss Model (1988) were chosen to help guide a future complex intervention design process. The application of three theories in order to elucidate the mechanism(s) of action/interventions was an iterative process starting with the findings of a mixed-methods systematic review in Chapter 2, followed by Chapters 4 and 5. Aligned with the MRC framework, the selection of Self-efficacy theory was used to support data analysis and the study findings resonate with the four elements of this theory: mastery and vicarious experiences, verbal encouragement and (re)appraisal of emotional responses. Specifically, mastery experience of this theory was less experienced by young women than other elements, and it enabled an exploration of their health needs, taking account of their pre-existing knowledge and the context in which new knowledge will be acquired and then assimilated in learning. For example, the present study indicated that low confidence in the ability to control eating (mastery experiences) while experiencing negative emotions could be related to disordered eating behaviours (emotional response) by young women with T2DM, which is a novel health issue to this population. This theory therefore was useful to identify novel findings and also to help understand and predict self-care behaviours and improve self-efficacy by providing knowledge and experiences for the mastery of a task, role models for vicarious experiences, verbal persuasion; and support in reducing stress, anxiety and worry (Bandura, 1977). Grounding the findings of this PhD study in the self-efficacy theory was valuable to understand how young women live with and self-manage T2DM, however it does not effectively account for environmental factors (e.g., access to healthcare services) which can

play a role in determining feeling of self-efficacy (Gallagher, 2012; Schunk & DiBenedetto, 2021). The components of the COM-B model, therefore, helped a better understanding of behaviour and environmental factors on women's personal beliefs.

The COM-B model states that an individual needs adequate capability, opportunity, and motivation for a behaviour to take place (such as physical activity), and that a deficit in any of these three areas means the behaviour is unlikely occur (Michie et al., 2014). Its use was therefore beneficial in developing a future intervention which recognised women's capability, opportunity and motivation for change through self-management. Thesis findings aligned with the three components of the COM-B model where they equally distributed with capability being at the same level of importance as motivation and opportunity. For example, chapter 2 (study 1) provided evidence from previous literature supporting the need for knowing how to manage diabetes (capability), social support (opportunity) and HbA1c related to reducing diabetes complications (motivation). Furthermore, themes generated in the qualitative study (study 2) were linked to the COM-B components, for example 'information and awareness' links to capability; 'conflicting agenda' links to opportunity; 'supportive connection with others' links to motivation. In Chapter 4 (study 3), the participants filled out the questionnaires linked to three components of COM-B model at one time point, yet the perceptions of their psychosocial health issues were not elicited directly by the HCPs. In the future, the COM-B model could be incorporated more explicitly in both the development phase and behaviour chance process in order to help the HCPs develop a management plan more tailored their patients' needs. By eliciting the women's perceptions about diabetes related eating disorders for instance, HCPs could then identify the women's capability, opportunity and motivation which are key to improving women's health and wellbeing and subsequently work with them to negotiate a shared set of more helpful T2DM perceptions. As a result, the COM-B model allowed the researcher to explore the findings in more depth owing to interactions described between each of the components of capability, opportunity and motivation. Its use was thus appropriate for understanding of the topic and underpinning any future intervention which requires recognition of the needs of knowledge, skills and support for women with T2DM.

Corbin and Strauss' (1988) work is based upon patients' perceptions of their chronic illness experiences - their concerns and problems about their chronic illness. This model describes

three sets of tasks that are required: medical management, role management and emotional management. The scope of this PhD research was defined by Corbin and Strauss' model of living with a chronic illness (Corbin & Strauss, 1988) as the constructs of this model are inherently patient-centred and focus on the work done by people with chronic condition rather than starting with a list of tasks defined by HCPs. Surprisingly, role and emotional management of this model had more resonance with young women than medical management. Participants in present study highlighted that their HCPs have tended to focus on optimising the medical management of T2DM, however focus of the efforts may need to shift towards an approach that encompasses all of three tasks to help young women to live well with their condition. Role (e.g., as a parent, partner) and emotional management (e.g., disordered eating, feelings of shame and stigma) of living with T2DM were more important to young women as a result of having developed the condition at younger age as well as the emotional burden of diabetes management and role disruptions during their reproductive years. In the support of this model, albeit in an underpowered sample, the cross-sectional study showed high levels of psychosocial health issues experienced by young women. Therefore, this model has supported the identification of mechanisms that may be selected for future intervention targets in order to help young women with T2DM manage their condition, the impact it has on their lives and the disruptions to their roles during reproductive years.

It is important to note that although the Corbin and Strauss's model facilitated a holistic perspective on living with T2DM in this study, this model offers three broad tasks of diabetes management (Schulmen-Green et al., 2012), thus not enabling a better understanding of living with T2DM in young women with reproductive age. To address this, the components of the COM-B model (Michie et al., 2014) and Self-efficacy theory (Bandura, 1977) helped to break down the broad tasks defined by Corbin and Strauss into more specific targets (e.g., beliefs about capabilities and consequences, constructing identity as a woman with T2DM, acquiring relevant knowledge, skills, abilities). As a result, these theories were helpful and appropriate for investigating the research topic which was exploring the impact of T2DM on young women's health and wellbeing in order to inform the future interventions.

Chapter 7 – Conclusion

Previously a condition associated with aging, the prevalence of T2DM in young adults, especially among women, is dramatically increasing. The sharp rise in T2DM prevalence in women suggest that more women of reproductive age encounter diabetes-related health issues, including reproductive and psychological problems during their lifetimes. This condition in women presents a unique challenge to clinical care due to its clinical, biological, and psychological characteristics. Thus, with an ever-increasing prevalence of young women of reproductive age with T2DM, HCPs need to be aware of the challenges of navigating reproductive health concerns along with diabetes care across the lifespan. However, there is a paucity of research that aims to understand the experiences and views of young women living with T2DM to inform and improve their clinical management. Therefore, this thesis has presented an exploration of the experiences and perceptions of living with T2DM among young women of reproductive age. It has also presented the views of women in relation to the diabetes healthcare provided by their HCPs. There are a number of suggestions to improve diabetes care for younger women living with T2DM. This is the first study to comprehensively explore the experiences of and views on living with T2DM during the reproductive years, identifying the health needs of these younger women.

This PhD has provided an original contribution to the body of knowledge on diabetes experiences and diabetes care for young women of reproductive age. Through systematically reviewing the previous literature and qualitative and quantitative studies, the findings in this thesis have identified physical, reproductive, emotional, social, and behavioural factors associated with living with diabetes, including psychosocial factors. This research found that younger women with T2DM are at risk of disordered eating behaviours and other diabetes complications. Women with T2DM have substantial reproductive dysfunction throughout their lifespans, including menstrual cycle issues, fertility, and menopause. Women in this study reported that reproductive healthcare for women with T2DM was not routinely addressed in the clinical setting and women wanted to have age- and gender-based diabetes care. Notably, this study highlighted a lack of integration within the healthcare system in relation to reproductive health in T2DM, suggesting that reproductive health issues should be incorporated into routine diabetes care for all women

of reproductive age. Equally, reproductive health, including menstrual cycle, sexual health, and the menopause needs to be part of the diabetes structured education curriculum.

This thesis has also highlighted important issues in relation to women's perceptions of themselves how they felt they were viewed by others as a woman of reproductive age living with T2DM. Many with T2DM have experienced emotional ill-health and obesity, both of which are stigmatised by society and lead to feelings of shame for the woman. Shame resulted in further emotional distress leading to non-disclosure of diabetes. This further isolated the woman from family, peers, workplace, or healthcare support and impedes their self-care confidence and abilities. This thesis also described the impact of living with diabetes on mood, anxiety, diabetes distress, fatigue, and disordered eating in young women with T2DM. The final study demonstrated high levels of these psychosocial health issues and its impact on self-management activities among women. In particular, disordered eating behaviours were commonly reported in this study. Emotional and phycological health assessment should be part of routine, annual, diabetes reviews and more often when treatment, condition, or life stage transitions occur. Overall, this thesis provided important new insights into the experiences and health needs of young women of reproductive age with T2DM, which may help improve their health and wellbeing as well as enhance diabetes care for this neglected and significant population.

7.1 Implications for clinical practice

The findings of this thesis allow identification of the implications for clinical practice. These implications were identified from the systematic review and empirical studies within this thesis. The findings of this thesis demonstrated the current health issues encountered by young women with T2DM, including the lack of pre-pregnancy care and contraception use, and also highlighted the importance of emotional support to improve their health and wellbeing. There is also a lack of access to emotional and psychological support routinely for young women with T2DM. This thesis indicated that women should receive tailored care based on their age, gender, and emotional needs, highlighting a therapeutic approach in diabetes care. Therefore, there are considerable variations in terms of HCP's knowledge, and the quality of the care and support provided to women. This study demonstrated the

low levels of diabetes education course attendance along with, high levels of psychosocial health issues. These findings demonstrate the need for HCPs to support and communicate effectively with women. Consideration of psychosocial health factor will enable more appropriate management options for women and a better understanding of their health needs. With this in mind, the following clinical implications of the research conducted in this thesis have been identified:

i. Living with T2DM negatively impacts younger women's physical, reproductive, social and phycological wellbeing, and holistic, woman-centred care should be provided to support their healthcare needs and tailored support and care plans.
ii. Non-pharmacological approaches to healthcare support, such as younger women's peer support for T2DM management, should be created and their value recognised for reducing diabetes distress, shame, and stigma, and improving quality of life and self-efficacy, leading to women feeling less isolated and stigmatised.
iii. Women's awareness of diabetes and its complications varied, and they lacked information on living with T2DM and its management. HCPs should ask women about their information needs regarding reproduction and diabetes along with its complications and management, so women can become more self-sufficient and confident in managing diabetes symptoms and complications and seeking help as and when required.
iv. HCPs need to recognise and accept that shame, stigma, and disordered eating behaviours are frequently experienced by young women with T2DM. HCPs have an important role to play in asking questions and being curious, alongside providing relevant support and information to young women of reproductive age.
v. Acknowledging the limited resources available for supporting young women with T2DM in diabetes service, previous research has demonstrated the value of online women wellness programmes. In particular, e-health is rapidly growing in diabetes care and can foster the women's self-efficacy, self-autonomy, self-management activities, and more effective communicative methods with one's clinical team (Celik et al., 2020; Anderson et al., 2021). These findings provide a contribution to this growing area, in advocating the use of the online interventions tailored for the experiences of young women with T2DM to improve their health and wellbeing.

vi. For young women with T2DM, education is needed to provide the necessary knowledge and skills early on to effectively manage their diabetes and encourage behaviours that will improve their clinical outcomes. Reproductive health education should be embedded into women's routine care and incorporated into all structured education programmes for T2DM. This thesis emphasised the presence of emotional distress and stigma/shame of having diabetes at a younger age, highlighting the need for interventions designed to improve the well-being of women with T2DM. The results in this thesis, along with the existing literature on interventions (Winkley et al., 2020; Sturt et al., 2015; Perrin et al., 2017) suggest that psychoeducational interventions, such as cognitive-behaviour therapy (CBT) and counselling, including motivational interviewing, should be offered early on with the aim of preventing the development of the chronic negative emotions (e.g., shame or disordered eating behaviours) along with improving self-management behaviours.

vii. HCPs need a better awareness and education regarding women's health needs when navigating reproductive health and diabetes concerns across their lifespans. Therefore, HCPs should create an opportunity and allocate time to ask young women about their life and concerns and to have a meaningful conversation regarding diabetes assessment and management.

viii. Family members, or friends of young women diagnosed with T2DM as well as the public need to be more informed about the nature of diabetes, complications, and possible impacts on younger women's lives and the support they need.

ix. Women also indicated that their managers and employers were unaware of the nature of diabetes or its potential impact on their health and productivity, suggesting that employers and managers need to provide a supportive environment to disclose their condition and to actively support them in the work environment.

x. As a QOF indicator, reproductive health could provide incentives for incorporating this focus into routine care to deliver quality clinical care in primary care settings. These incentives may include the activities, such as maintaining a register of women aged between 18-45 years living with T2DM, recording a set percentage of women on the register that they are providing advice about reproductive healthcare issues such as pregnancy planning or menopause, and then recording a set percentage of women on the register that have an unplanned pregnancy or fracture.

7.2 Implications for future research

This study has been the first in-depth exploration of living with T2DM in young women of reproductive age, and as such, provides a valuable contribution to the knowledge and understanding the impact of living with T2DM on young women's health and wellbeing. The findings from this thesis have highlighted a number of implications for future research. Hence, the following implications have been made:

i. There is a need to explore the experiences and views of HCPs about diabetes care for young women with T2DM, which were not included in this thesis. As the women highlighted a wide range of health issues related to their diabetes care provided, employing a qualitative study design will provide a deeper understanding about diabetes care provided by HCPs to inform improvements in service delivery for young women with T2DM.

ii. Further research is needed to determine the relationship between women's levels of knowledge about diabetes and its complications and self-management activities and socio-demographic factors. In this study, some women were unaware of diabetes complications and diabetes self-management activities, which could thus lead to more health-related distress and may have impacted on negative coping strategies.

iii. Longitudinal studies are needed to demonstrate the long-term impacts of psychosocial factors on women's health and wellbeing (e.g., glycose level and quality of life) as assessing the women longitudinally, such as at diagnosis, could allow the role of risk and guide the possible implementation of early intervention to reduce emotional comorbidities or chronic disorders (e.g., depression).

iv. Future research will be needed to investigate the causality of psychosocial variables to conceptualise these variables among women.

v. There is a need for a disordered eating scale for T2DM. In this study, the SCOFF-5 was used to assess the level of disordered eating behaviours, although this scale may not directly assess disordered eating related to diabetes itself. A new questionnaire needs to be developed that is reliable and valid to assess disordered eating more accurately.

vi. Further research is needed to discover which method(s) of intervention would be most effective for reducing stigma and shame. This study emphasised the presence

of emotional distress and stigma/shame of having diabetes at younger age, highlighting the need for interventions designed to improve the wellbeing of women with T2DM.

vii. Developing and testing interventions to manage T2DM in young women of reproductive age are urgently needed. This study has identified a notable absence of intervention studies for this population despite these wide-ranging and considerable health burdens.

viii. The experiences of family members or partners are explored to understand the broader impacts of T2DM. This age group population frequently live with their family members or partners, thus exploring the experiences of all family members would lead to the development of the interventions needed to support them.

ix. There is also a need to explore the diabetes experiences among the LGBTQ populations who are significant in general reproductive health-orientated research as only few minority groups (e.g., LGBTQ) responded to the study.

x. Studies in populations of non-white and women (e.g., Black ethnic group) are needed. To provide better diabetes care to these population, there is a need to explore further their experiences during their reproductive years as only a few women from the Black ethnic population responded to the studies (Chapters 4 and 5).

xi. Future research is needed to understand the reasons for the low completion rate at research studies among younger women with T2DM in order to develop online recruitment strategies as the researcher experienced the challenges to recruiting this population.

xii. Further research is needed to examine the impact of T2DM on women's reproductive function across their various life stages. This study identified reproductive health issues such as the risk of early menopause or menstrual disorders among women living with T2DM, however the risk of early menopause and menstrual irregularity is unclear. Thus, in the context of evolving prevalence, treatments, and associated disease patterns of T2DM, exploring the impact of T2DM on reproductive functions may lead to the discovery of its aetiology and possible management methods across reproductive health conditions.

7.3 Dissemination and awards

Data from this study have been submitted in the following local and international conferences and meetings, which are outlined in Table 21, and the plans for further dissemination are presented in Table 22 below.

Table 21 Presentations to date

Year	Type of presentation	Conference
2022	Poster presentation	International Diabetes Federation
2022	Oral presentation	The Research Accelerating Psychosocial Innovations in Diabetes (RAPID) conference
2022	Poster presentation	Psychosocial Aspect of diabetes (PSAD) conference
2022	Oral presentation	Foundation of European Nurses in Diabetes (FEND) conference
2022	Poster presentation	3rd KCL, Postgraduate Research conference (**Best poster award**)
2022	Poster presentation	Diabetes UK
2021	Oral presentation	Foundation of European Nurses in Diabetes (FEND) conference
2021	Oral presentation	Women's Wellness Research Collaborative Roundtable meeting
2021	Oral presentation	Psychosocial Aspect of diabetes (PSAD) conference
2021	Poster presentation	2nd KCL, Postgraduate Research Conference (**Best poster award**).

Table 22 Planned future dissemination

Type of work	Potential conference
Abstract submitted	Diabetes UK 2023
Future papers	**Potential journal**
Title: Relationships among psychosocial factors and diabetes self-care behaviours in younger women with type 2 diabetes: a cross-sectional study	Diabetic Medicine

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Appendix

Appendix A: A mixed-methods systematic review

Appendix A.1.1: Systematic review search strategy example

Database: Ovid MEDLINE(R) ALL <1946 to July 02, 2020>

Search Strategy:

---

1 exp Diabetes Mellitus, Type 2/

2 (MODY or NIDD or T2D or T2DM).tw,ot.

3 (non insulin$ depend$ or noninsulin$ depend$ or non-insulin$ depend$).tw,ot.

4 ((typ? or typ? II or type?2 or type?II) adj3 onset).mp. and diabet$.tw.

5 ((late or adult$ or mature$ or slow or stable$) adj3 onset).mp. and diabet$.tw,ot.

6 1 or 2 or 3 or 4 or 5

7 exp Women/

8 (wom$n* or female*).tw,ot.

9 ((childbear* or reproductiv*) adj2 age*).tw,ot.

10 (sex* or gender differ*).mp.

11 7 or 8 (976222)

12 9 or 10 (1102011)

13 6 and 11 and 12 (2338)

14 limit 13 to (English language and humans and female)

****

Appendix A.1.2: Quality assessment scoring using MMAT (Pluye et al., 2011)

	1.Qualitative				3.Quantitative (non-randomized)				4.Quantitative (descriptive)				5.Mixed methods			Quality score (%)
References	1.1	1.2	1.3	1.4	3.1	3.2	3.3	3.4	4.1	4.2	4.3	4.4	5.1	5.2	5.3	
Alcozer 2000	No	Yes	Yes	Can't tell												50
Lavender et al. 2010	Yes	Yes	Yes	Yes												100
Majeed-Aris et al. 2015	Yes	Yes	Yes	Can't tell												75
Miller & Marolen 2012	Yes	Yes	Yes	Can't tell												75
Miller et al. 2010	Yes	Yes	No	Can't tell												50
Murphy et al. 2010	Yes	Yes	Yes	Can't tell												75
Letherby et al. 2012	Can't tell	No	Yes	No												25
Spence et al. 2010	Yes	Yes	No	Can't tell												50
Forde et al. 2019	Yes	Yes	Yes	Can't tell												75
Earle et al. 2017	Yes	Yes	Yes	No												75
Bal et al. 2015					Yes	Yes	Can't tell	Yes								75
Erol et al. 2002					Yes	Yes	No	Yes								75
Elyasi et al. 2015					Yes	Yes	Yes	Yes								100
Fatemi & Taghavi 2009					Yes	Yes	No	Can't tell								50
Sharifiaghdas et al. 2012					Yes	Yes	No	Yes								75
Nowosielski et al. 2011					Yes	Yes	No	Can't tell								50
Ismail et al. 2014					Yes	Yes	No	Can't tell								50
Yencilek et al. 2009					Yes	No	No	No								25
Kim et al. 2015					Yes	Yes	No	Yes								75
Olmos et al. 2018					Yes	Yes	Can't tell	Yes								75
Egan et al. 2017					Yes	Yes	No	No								50
Garcia et al. 2014					Yes	Yes	Yes	Can't tell								75
Amini et al. 2009					Yes	Yes	No	Yes								75
Conn et al. 2000					Yes	Yes	No	Yes								75
Mirzae & Kazemi 2005					Yes	Yes	No	Yes								75

Zargar et al. 2005					Can't tell	Yes	No	Yes								50
Monterrosa-Castro et al. 2013					Yes	Yes	No	Yes								75
Sekhar et al. 2015					Yes	Can't tell	Yes	Can't tell								50
Gugapriya et al. 2014					Yes	Yes	Yes	Yes								100
Miller 2011									No	Yes	Yes	Yes				75
Montague et al. 2005									No	Yes	Yes	Can't tell				50
Osman et al. 2015									No	No	Can't tell	Yes				25
Scavini et al. 2018									Yes	Can't tell	Can't tell	Can't tell				25
Yacan & Erol 2019									Yes	Yes	Yes	Yes				100
Muruako 2014	Yes	Yes	Yes	Can't tell									Yes	Yes	No	50

Appendix A.2.1: Publication supplementary material

PRISMA – Systematic review checklist (page numbers correspond to manuscript submitted to journal)

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1-2
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	2
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	2
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	2
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	2
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	3

Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	3
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	3
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	3
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	3
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	3

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	3
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	3
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	3
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	3
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	4
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	4-15
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	4-15
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	4
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	4-15
DISCUSSION			

Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	15-16
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	17
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	17
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	17

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

Appendix B: Qualitative study

Appendix B.1.1: Study poster

RADIATE
Reproductive aged women with diabetes type 2

KING'S College LONDON

Are you interested in sharing your experiences of living with type 2 diabetes in reproductive years?

This research is exploring the impact of type 2 diabetes on women's health and well-being during their reproductive years. This study involves individual interview.

If you are;

- ✓ Women aged 18 to 45 years old
- ✓ Diagnosed as type 2 diabetes
- ✓ Able to communicate in English or Turkish

To participate, please get in touch: Aycan Celik or Aya Temple (Researchers in Nursing at King's College London)

*You will also receive **a £20 voucher** at the end of the interviewing as our way of saying thank you.*

Email:
aycan.celik@kcl.ac.uk
Tel: 07434637410
Twitter: @celik_aycn

Email:
ayako.temple@kcl.ac.uk
Tel: 07434 637271
Twitter: @ayatemple

This research has been approved by Psychiatry, Nursing and Midwifery Research Ethics Subcommittees, King's College London

Appendix B.1.2: Participant Information Sheet

INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number: ***HR-20/21-18146***

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of project

Exploring the impact of living with type 2 diabetes on women's health and well-being during their reproductive years: a qualitative study.

Invitation Paragraph

I would like to invite you to participate in this research project which forms part of my **doctoral** research. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the project?

The purpose of the project is to explore the experiences and health needs of women aged 18-45 years living with type 2 diabetes. We will use this information to then develop a web-based program for women with type 2 diabetes during their reproductive years. Thus, we aim to understand the impact of type 2 diabetes on women's health and wellbeing. The purpose of this program is to provide information and support to help women to have knowledge, skills and confidence to manage their diabetes alongside their reproductive and general health.

Why have I been invited to take part?

You are being invited to participate in this project because you have type 2 diabetes and are aged 18-45 years. We would like to understand your experiences of living with type 2 diabetes alongside managing your reproductive health such as pregnancy, hormonal changes, contraception and your general health such as nutrition, physical activity, and mental wellbeing.

What will happen if I take part?

If you choose to take part in the project you will be given a consent form indicating that you have agreed to be a part of this study, and you will be asked to complete a questionnaire which we help us to understand more about you. The questionnaire will include your demographic background (e.g. your age, ethnicity, education) and previous diabetes experiences (e.g. your duration of diabetes, diabetes management method). This questionnaire will help us to make sense of the research results. You can take time to consider your participation in the study and discuss your decision

with family, friends or care team. Taking part will take place in online (e.g. Skype, WhatsApp) or phone according to your preference. We are asking you to speak with one researcher for approximately 60 minutes about what living with diabetes is like for you. This will take place at a time and place suitable for you and the researcher. Speaking with the researcher is called an interview and this will be recorded and afterwards this will be transcribed and given a code, so your name will be removed. All information will be stored securely. With your permission we may play small parts of the interview at the next stage of this study; however, in this case we will not share your name or other information other than the short excerpt of the voice recording.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in anyway. Once you have read the information sheet, please contact us if you have any questions that will help you make a decision about taking part. If you decide to take part, we will ask you to sign a consent form and you will be given a copy of this consent form to keep.

Incentives and payments

We will give you a £20 gift voucher as a thank you for taking part in the interview. If you would like to receive the voucher, please include the postal or email address where you want us to send the voucher. This information will be stored separately from the interview data, in a separate electronic folder and destroyed after all the vouchers have been distributed.

What are the possible risks of taking part?

During the interview, you will be required to recall your experiences of living with type 2 diabetes. For some women this may be emotional. If you feel uncomfortable with any of the questions or topics we can pause or stop the interview. If you feel upset at any stage, feel free to talk to the researcher or your usual diabetes care provider might get a counselling support for you if appropriate.

What are the possible benefits of taking part?

The information that you provide will help us to understand the health issues faced by women with type 2 diabetes during their reproductive years. Your participation will support us to find a new way to help women with type 2 diabetes to manage their own condition. When this web-based program develops in the next years, you may benefit from the required health information for women with type 2 diabetes via the web-based program. We cannot guarantee that you will personally benefit from the research findings but other women like you will benefit in the future.

What if I change my mind about taking part?

You are free withdraw at any point of the project, without having to give a reason. Withdrawing from the project will not affect you in any way. You are able to withdraw your data from the project up until 30 of July 2021, after which withdrawal of your data will no longer be possible due to anonymous of your data.

What will happen to the results of the research study?

The results will be used to help develop a web-based program for women with type 2 diabetes. The results of the study will be submitted to an academic thesis, peer-review publication in academic journals and suitable conferences. No person will be individually identified in any report or publication.

Data handling and confidentiality

Your data will be processed in accordance with the General Data Protection Regulation 2016 (GDPR). King's College London (KCL) is the sponsor for this study based in the United Kingdom. The researcher will be using information from the participants in order to undertake this study and will act as the data controller for this study. This means that the researcher is responsible for looking after participant information and using it properly. KCL will keep identifiable information about participants for 7 years after the study has finished and then will then destroy them permanently.

Your name will be removed and replaced with a code so that all of the information about you can linked by the research team however you will not be identified in any of the information we use during the study or when we share the results. Depersonalized direct quotes will be included in this study. They will be also published in relevant journals and presented as part of the dissemination strategy. No names will appear in any reports that are generated from this study. Only the research team will have accessed to the identifiable information and the entire interview transcripts will be anonymized.

Personal information such as names and contact details and consent forms, will be kept separately from depersonalised data, filed and kept in a locked cabinet in the researcher's office at the King's College London. This cabinet will be situated in a locked room, for which only members of the researcher's team have a key. Only those researchers with direct involvement in this study will have a key to the filing cabinet.

Data Protection Statement

Your data will be processed in accordance with the General Data Protection Regulation 2016 (GDPR). If you would like more information about how your data will be processed in accordance with GDPR please visit the link below:

https://www.kcl.ac.uk/research/support/rgei/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research

Who should I contact for further information?

If you have any questions or require more information about this project, please contact the researchers using the following contact details:

Aycan Celik

PhD student
Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care
King's College London
James Clerk Maxwell Building
57 Waterloo Rd.
London
SE1 8WA
Email: aycan.celik@kcl.ac.uk
Tel: To be confirmed
Twitter: @celik_aycn

Aya Temple

Visiting Research Associate
Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care
King's College London
James Clerk Maxwell Building
57 Waterloo Rd.
London
SE1 8WA
Email: ayako.temple@kcl.ac.uk
Tel: To be confirmed

What if I have further questions, or if something goes wrong?

If this project has harmed you in any way or if you wish to make a complaint about the conduct of the project you can contact King's College London using the details below for further advice and information:

Primary supervisor

Professor Jackie Sturt

Professor of Behaviour medicine in Nursing

Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care

King's College London

James Clerk Maxwell Building

57 Waterloo Rd.

London

SE1 8WA

Email: jackie.sturt@kcl.ac.uk

Thank you for reading this information sheet and for considering taking part in this research.

Appendix B.1.3: Consent form

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: Exploring the impact of living with type 2 diabetes on women's health and well-being during their reproductive years: a qualitative study.

King's College Research Ethics Committee Ref: HR-20/21-18146

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

Please tick

I confirm that I understand that by ticking/initialling each box I am consenting to this element of the study. I understand that it will be assumed that unticked/initialled boxes mean that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element I may be deemed ineligible for the study. ☐

Please tick

1. *I confirm that I have read and understood the information sheet dated 04.05.2021 for the above study. I have had the opportunity to consider the information and asked questions which have been answered to my satisfaction. ☐
2. I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason, up until 30 of July 2021. ☐
3. *I consent to the processing of my personal information for the purposes explained to me in the Information Sheet. I understand that such information will be handled in accordance with the terms of the General Data Protection Regulation. ☐

☐

4. *I understand that my information may be subject to review by responsible individuals from the College for monitoring and audit purposes.

5. I understand that confidentiality and anonymity will be maintained, and it will not be possible to identify me in any research outputs ☐

6. I consent to my data being shared with third parties which include the research team as outlined in the participant information sheet. ☐

7. I agree to be contacted in the future by King's College London researchers who would like to invite me to participate in follow up studies to this project, or in future studies of a similar nature. ☐

8. I agree that the research team may use my data for future research and understand that any such use of identifiable data would be reviewed and approved by a research ethics committee. (In such cases, as with this project, data would/would not be identifiable in any report). ☐

9. I understand that the information I have submitted will be published as a report and I wish to receive a copy of published reports. ☐

10. I consent to my interview being audio recorded. ☐

11. I understand that I must not take part if I fall under the exclusion criteria as detailed in the information sheet and explained to me by the researcher. ☐

_____	_____	_____
Name of Participant	**Date**	**Signature**

_____	_____	_____
Name of Researcher	**Date**	**Signature**

Appendix B.1.4: Demographic questionnaire

DEMOGRAPHIC QUESTIONNAIRE

Study title: Exploring the impact of living with type 2 diabetes on women's health and well-being during their reproductive years: a qualitative study

Participant Name:	
Participant ID Code:	

What is your age? (in year at next birthday)	
How long have you had diabetes? (in years)	
Does anyone else in your family have diabetes? **Yes** ☐ **No** ☐	If **YES**, who?
What is your relationship status? (please tick the box).	☐ Single ☐ Married ☐ In a relationship ☐ Divorced ☐ Widowed
Do you have any children? **Yes** ☐ **No** ☐ **If yes, please tick the box and write in ages.**	If **YES** List ages of children here please ☐ 1 Child and age; _____ ☐ 2 Children and their ages; _____ ☐ 3 Children and their ages; _____ ☐ 4 Children and their ages; _____ ☐ More than 4 children and ages; _____
How do you describe your ethnicity? (please tick the box).	☐ White British ☐ Black Caribbean ☐ White others (Turkish) ☐ Asian ☐ Black African ☐ Asian others ☐ Black Other ☐ Chinese ☐ Mixed ethnic group ☐ Indian

	☐ Any other ethnic group; _____
What is the highest education qualification that you have completed? (Please tick the box)	☐ Primary school ☐ Secondary school ☐ College degree/Diploma ☐ University/Degree ☐ Postgraduate degree ☐ Others (write in) _____
Are you currently working? (Please tick the box)	☐ Employed full-time ☐ Employed part-time ☐ Home duties ☐ Unemployed ☐ Student ☐ Unable to work ☐ Others (write in) _____
How do you manage your diabetes? (Please tick the box(s) or write in)	☐ No treatment ☐ Diet and/or exercise ☐ Insulin and/or other injections for diabetes ☐ Tablets ☐ A Different diabetes management method (please write what treatment is); _____
What was your last HbA1c? (if known) This is the diabetes blood test.	
Has your diabetes caused any of following problems? (Tick as many issues as apply)	**<u>Diabetes issues</u>** ☐ Heart Disease ☐ Leg Ulcers ☐ Numbness or pain in your hand or legs ☐ Problems with eyesight ☐ Kidney problems ☐ Menstrual problems ☐ Polycystic ovary syndrome

	☐ Menopause problems ☐ Anxiety ☐ Depression ☐ Please specify other health issue(s) if you have; _____
What topics do you need help with or would like to learn more about diabetes? (Tick as many issues as apply)	☐ Diet ☐ Exercise ☐ Taking Medications ☐ Knowledge about how to manage diabetes ☐ Dealing with high or low blood sugars ☐ Food and skin care ☐ Preparing pregnancy ☐ Using contraception ☐ Managing with diabetes when I am period ☐ Sexual dysfunction ☐ Dealing with diabetes distress ☐ Knowledge about diabetes and its complications ☐ Knowledge about menopause ☐ Please identify if you have more _____

Thank you for completing this questionnaire and for considering taking part in this research.

Appendix B.1.5: Gatekeeper permission

[Date]

King's College London

Request for Permission to Advertise Research

Dear XXX

My name is Aycan Celik, a doctoral student at King's College London. The research I wish to conduct for my doctoral study involves the exploring the impact of living with type 2 diabetes on women's health and well-being during their reproductive years.

I am writing to ask for your permission to advertise my study in your (publication, account, blog, newsletter) to recruit eligible participants.

I wish conduct one-to-one online interviews with women aged 18-45 years living with type 2 diabetes. Interviews will last nearly 60 minutes and include women's experiences on type 2 diabetes. Your role is just to advertise the study, and then interested participants should contact the researcher directly. All the required documents will be sent by the researcher to the interested participants. I have provided you with a copy of the approval letter which I received from the King's College London Ethics Committee (REMAS).

If you require any further information, please do not hesitate to contact me (Aycan Celik). Thank you for your time and consideration in this matter. Your attention and deliberation on this matter is highly appreciated. With respect I look forward for your reply.

Yours sincerely,

Aycan Celik

Florence Nightingale Faculty of Nursing, Midwifery & Palliative Care
King's College London
Waterloo Road
James Clerk Maxwell Building
London SE1 8WA
Email: aycan.celik@kcl.ac.uk

Principal supervisor

Professor Jackie Sturt
Florence Nightingale Faculty of Nursing, Midwifery & Palliative Care
King's College London
Waterloo Road
James Clerk Maxwell Building
London SE1 8WA
Email: jackie.sturt@kcl.ac.uk

Appendix B.1.6: Framework Analysis

Figure 11 The summary of mapping and interpretation process (Adapted from Neale, 2020)

Table 1 Coding index (example)

Extract from transcripts	Bullet points from data extraction	Reviewing data extract	Codes
I hid my diagnosis from my wider family for a while as I felt that they would watch everything I eat at family get together. Rose	"I hid my diagnosis from my wider family for a while as I felt that they would watch everything"	Disclosure because of social monitoring	Unwilling to disclose
I feel like Type 2 is one that comes with a lot of shame that's heaped on it (Ava)	''Type 2 is one that comes with a lot of shame that's heaped on it''	Feeling shame due to having T2DM	Feeling shame related to having T2DM
But there's also the day to day, sort of, 'you've done this to yourself, you should be like ashamed,' and that can be quite hard. (Ava)	'you've done this to yourself, you should be like ashamed,' and that can be quite hard.	Self-blame for her lifestyle choices Feeling shame	Self-blame
Very embarrassed…Because I'm not overweight, and overweight people would get diabetes. (Oli)	Embarrassed. Because I'm not overweight, and overweight people would get diabetes.	Feeling shame with having diabetes	Shame Comparisons with others
Isolation is an issue as I feel unable engage in the same social activities as my friends. (Jemma)	Isolation is an issue as I feel unable engage in the same social activities as my friends.	Feeling isolation and get away from social life	Feeling isolation Getting away from social life
I am very young. I'm both overweight and have a very high genetic risk, so it's something I talk about quite rarely. Actually, most people don't know other than my close friends, and that's mostly because it's just really quite uncomfortable. (Kath)	I am very young. I'm both overweight and have a very high genetic risk, so it's something I talk about quite rarely.	Unwilling to disclosure from both young and overweight	Unwilling to disclose due to overweight and young age
Well, I had a blood test for 1.5 and it didn't come up with the antibodies... but I want to have it (type 1.5) because that means it's not my fault. (Emily)	I want to have it (type 1.5) because that means it's not my fault	Self-blame and want to have type 1.5	Self-blame with feeling her fault

Table 2 Developing categories

Codes	Categorisation
Shame with being young and lifestyle **Shame with lifestyle** **Shame with having diabetes** **Feeling shame related to having T2DM** **Feeling shame** **Feeling shame because she is young** **Feeling shame with having diabetes due to not being overweight**	Shame
Self-blame **Self-blame with lifestyle** **Self-blame with feeling her fault** **Self-blame with younger age and lifestyle** **Self-blame with gained weight**	Self-blame
Unwilling to disclose **Struggling to understand the reason of diabetes, so unwilling to disclose** **Unwilling to disclose and feeling angry because everyone knows her condition** **Unwilling to disclose because she gets stressed** **Unwilling to disclose due to overweight and young age** **Unwilling to disclose due to social monitoring**	Unwilling to disclose
Comparisons with others	Comparisons with others
Getting away from social life **Getting away from social life due to lots of questions asked** **Feeling isolation**	Exclusion and isolation

Table 3 Subthemes and themes

Links between categories	Subthemes	Final theme
Shame **Self-blame** **Unwilling to disclose** **Comparison with others** **Exclusion and isolation**	**1.1Self-perception of developing type 2 diabetes** -Existential questions “why me” -Comparison with others Self-blame, shame **1.2 Consequences** -Isolation, exclusion, loneliness	1.Negative self-perception

Appendix B.1.7: Field notes

Field notes from data collection

Selected examples

P22 - (27 August 2020)

She sent me an email about being interested in taking part the study. She found the research from the Diabetes UK Forum. After that, I sent the participant information sheet. After she indicated she was willing to participate, I sent the consent form and demographic questionnaire, and requested that they be sent back to me after completing them. I also asked her preferred date, time, and interview method (Skype, Microsoft Teams, Zoom, or phone call). She preferred Zoom because she was an active Zoom user and felt confident with this program. We decided on the date of the interview as the 27th of July by Zoom. I felt excited that I would finally be able to start the data collection, and I hoped that she would be happy to share her experiences with me. I opened the Zoom call early in order to have time to gather my thoughts and focus on what I wanted to achieve. I double checked the recorder, and I was ready to do the interview.

During the interview, it was interesting that she had the different health problems as well as diabetes. I felt she was keen to talk a lot, especially about other conditions rather than her diabetes experiences. She had more comorbidities. However, I should have cut her off a few times with my questions. I needed to be more careful next time, and to ask more prompt questions. I tried my best to concentrate what she was saying, but for a short period of time I may not have heard everything she was saying when I looked at the list of the topics occasionally. Thus, I wondered if I missed anything or if I asked different prompts or if I used any direct questions. Another interesting point was that she had a sedentary lifestyle due to her health condition. After the diagnosis of diabetes, she had to plan a bit more than before. Thus, she felt she had had a positive diabetes experience. The interview lasted 51 minutes, but her partner interrupted the interview. We continued the interview a few seconds later and then finished. She was quite positive.

P34 - (15 September 2020)

She sent me a text message about taking part in the study, which she had found on Instagram. I sent the participant information sheet and she agreed to participate in the interview. She was a farmer who only had limited time to talk. We made an appointment according to her preferred date and time. She was a very good talker and keen to answer all the questions. She had a history of gestational diabetes twice. After her third pregnancy, she was diagnosed with type 2 diabetes.

During the interview, although it was conducted in the Turkish, I tried my best to concentrate on what she was saying as she had some diabetes complications and a history of depression. In addition to her health condition, she had lost three family members because of COVID-19. These affected her more due to having diabetes, as she believed people with diabetes were more vulnerable to the pandemic. Talking about her problems was acknowledging the presence of problems, and she was aware of needing psychological support. The interview lasted 52 minutes, and she was quick to answer the questions that were asked or follow-up on her own discussion.

Appendix B.1.8: Ethical approval

Research Ethics
Office

Franklin Wilkins Building
5.9 Waterloo Bridge Wing
Waterloo Road
London SE1 9NH
Telephone 020 7848 4020/4070/4077
reo@kcl.ac.uk

KING'S College LONDON

Aycan Celik

11 June 2020

Dear Aycan,

Project Title: Exploring the impact of living with type 2 diabetes on women's health and well-being during their reproductive years: a qualitative study
Project Reference:HR-19/20-18146

I am pleased to inform you that full approval for your project has been granted by the PNM Research Ethics Subcommittee .

Important coronavirus update: In light of the COVID-19 pandemic, the College Research Ethics Committee has temporarily suspended all primary data collection involving face to face participant interactions until further notice. **Ethical clearance for this project is granted. However, the clearance outlined in the attached letter is contingent on your adherence to the latest College measures when conducting your research.** Please do not commence data collection until you have carefully reviewed the update and made any necessary project changes:

https://internal.kcl.ac.uk/innovation/research/ethics/applications/COVID-19-Update-for-Researchers

For your information, ethical approval has been granted for 3 years from 11 June 2020. If you need approval beyond this point, you will need to apply for an extension at least two weeks before this. You will be required to explain the reasons for the extension. However, you will not need to submit a full re-application unless the protocol has changed.

Ethical approval is required to cover the data-collection phase of the study. This will be until the date specified in this letter. However, you do not need ethical approval to cover subsequent data analysis or publication of the results.

Please ensure that you follow the guidelines for good research practice as laid out in UKRIO's Code of Practice for research: http://ukrio.org/publications/code-of-practice-for-research/.

If you do not start the project within three months of this letter, please contact the Research Ethics Office.

Please note that you will be required to obtain approval to modify the study.This also encompasses extensions to periods of approval. Please refer to the URL below for further guidance about the process:

https://internal.kcl.ac.uk/innovation/research/ethics/applications/modifications.aspx

Please would you also note that we may, for the purposes of audit, contact you from time to time to ascertain the status of your research.

If you have any query about any aspect of this ethical approval, please contact the Research Ethics Office:

(https://internal.kcl.ac.uk/innovation/research/ethics/contact.aspx)

We wish you every success with this work.

Yours sincerely,

Mr James Patterson
Senior Research Ethics Officer

For and on behalf of

Chair of the PNM Research Ethics Subcommittee

Appendix B.1.9: Submitted report to the development of the Women's Health Strategy for England

HEALTH, AND HEALTHCARE, DEFICITS FOR WOMEN LIVING WITH TYPE 2 AND GESTATIONAL DIABETES

Jackie Sturt, Aycan Celik and Deniz Bozkurt on behalf of cited investigators from the Clinical Diabetes Nursing Research Group, Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care and The Policy Institute, King's College London.

Corresponding author Jackie Sturt jackie.sturt@kcl.ac.uk

GLOSSARY

T2DM Type 2 Diabetes Mellitus; GDM Gestational Diabetes Mellitus; PPC Pre-pregnancy care; HCP Healthcare professional

INTRODUCTION

In this report we provide an executive summary, the background to the current situation and the complicating factors, a brief description of our dataset, participants and research methods. Finally, we present a call for action and eleven specific recommendations to improve care for women living with T2DM and prior GDM.

EXECUTIVE SUMMARY

What have women told us and how?

Here we provide evidence of previously unheard women's voices from a synthesis of eight studies undertaken by our team though reviews and empirical interviews involving 351 women with prior gestational diabetes (GDM) and 19,481 women with type 2 diabetes (T2DM) all aged 16-65 years across reproductive and midlife stages.

Our research has listened to women and they have told us they want:

1) Gender aware diabetes care
2) Knowledge, information and awareness raising around pre-pregnancy care
3) Freedom from shame and stigmatisation associated with their T2DM and GDM diagnosis
4) Emotional and psychological needs to be acknowledged (and met)

What is the current situation?

- The prevalence of diabetes in the UK is expected to increase from 4 to 5.3 million by 2025, 90% have type 2 diabetes. The past 30 years has seen a significant reduction in the age of diagnosis. 40% of the diabetes population are women 18 -45yrs, within their reproductive ages.
- The number of pregnancies in women with T2DM has doubled in the last 15 years. They now represent over 50% of pregnancies in diabetes annually in England and Wales. The infants of women with diabetes have a quadrupled risk of foetal death or stillbirth and double the risks of congenital abnormality. To reduce these risks, NICE publish pre-pregnancy care guidelines with specific recommendations for the management of diabetes and pregnancy.
- Gestational diabetes (GDM) is diabetes first recognised in pregnancy. Whilst in most cases GDM resolves following the birth, it leaves women with a seven-fold risk of developing type 2 diabetes within 10 years. The incidence of GDM is estimated to be in one in every 23

pregnancies in the UK which is between 2-7% of all pregnancies. GDM increases the risk of adverse maternal outcomes and later poorer metabolic outcomes for the offspring.

- Women are transitioning into the menopause with an increased metabolic risk to their health. The menopause brings a reduction in oestrogen and oestradiol hormones increasing body fat which in most cases presents as abdominal fat increasing both weight and waist circumference. This presents cardio-vascular risk for women with existing T2DM as well as being a predictor of a future diagnosis in women at risk.
- Blood Glucose targets are established in T2DM to reduce the risk to life changing complications. We do not understand the relationship between blood glucose fluctuations in response to the menstrual cycle and menopause
- Many with T2DM experience emotional ill-health and obesity, both of which are stigmatised by society and lead to feelings of shame. Women in general report more struggles with their emotional health than men.

What are the complicating factors?

- The shift towards a younger age at diagnosis of Type 2 diabetes is inconsistently reflected in the diabetes and reproductive healthcare provided for women. T2DM is managed in primary care (unlike women with Type 1 diabetes who are mainly cared for by specialists). The T2DM primary care systems are not designed for these younger women living with Type 2 diabetes and in many cases the health professionals have not kept pace with the diabetes-related health implications for this age groups.
- A recent National Pregnancy in Diabetes audit (NPID) reported that at first attendance when pregnant 90% of women with T2DM do not receive NICE recommended care.
- Women with, or at risk of, T2DM are more likely to have pregnancies with no pre-pregnancy health protective measures employed for themselves or their baby. Women are unaware of the risks prior to conceiving, such as stopping diabetes medications harmful to the foetus. Lack of awareness in health professionals and women results in pregnancies that were not planned from a diabetes perspective, thereby increasing the risks to mother and infant.
- The younger age of T2DM diagnosis is, in part, driven by gestational diabetes.
- Menopause is rarely discussed in public, in primary care consultations and in workplaces. Women manage symptoms privately and when they do seek help their menopausal symptoms are often misattributed to depression or low mood or dismissed. Women facing changes in their health have little support in understanding and differentiating whether their symptoms are attributable to their diabetes (which may be new to them) or to the menopause.
- No research has been funded to understand the impact of the menstrual cycle and menopause on blood glucose fluctuations in T2DM
- Emotional distress is compounded by shame leading to non-disclosure of diabetes. This further isolates the woman from family, peer, workplace or health care support and impedes their self-care confidence and abilities. There are many underexploited intervention points.

What do we do about this?

1. **Provide gender-aware care by**

- Training for health professionals around the specific impacts of diabetes on reproductive health for women living with, or at risk of, diabetes
- Awareness raising to the public around the specific impacts of diabetes on reproductive health for women living with, or at risk of, diabetes
- Use of check list and alerts on electronic medical records
- Reproductive health, sexual health and menopause needs to be part of diabetes structured education curriculum
- Systematising regular post-partum and annual follow up following GDM

2. **Raise awareness and increase knowledge in relation to pre-pregnancy care by**
- Healthcare systems need to systematically integrate contraception and pregnancy planning discussions into routine diabetes care
- Regular and ongoing information and follow up about future diabetes risk for women with prior GDM

3. **Achieve freedom from shame and stigmatisation associated with their T2DM and GDM diagnosis by**
- Research is needed to understand stigma and shame and its association to gender. Interventions to reduce HIV-related shame and stigma can offer guidance in this area
- Awareness raising for health professionals is required to develop better understanding of how shame and stigma impact on diabetes self-care and prevention behaviours

4. **Emotional and psychological needs to be acknowledged (and met)**
- Emotional health assessment should be part of routine, annual, diabetes reviews and more often when treatment, condition or life stage transitions occur
- Emotional support during and following diagnosis of T2DM and GDM

1.0 BACKGROUND INFORMATION

Globally women continue to be less likely than men to receive adequate healthcare.[4] In the UK this is true for women living with T2DM. Currently the education programmes designed to support people newly diagnosed with diabetes exclude women's health specific content while male health is attended to. Diabetes is a chronic, progressive, multisystem condition that can have devastating consequences if not appropriately cared for. In the UK there are almost 4 million people living with diabetes of which 90% have T2DM, and almost half are women.[5] The predicted prevalence of diabetes in the UK is expected to increase to 5.3 million by 2025, representing an increase from 8.6% to 9.7% of the total population.[6] There has been a shift towards a younger age at diagnosis of T2DM and now 40% of women in the UK living with this form of diabetes are aged between 18 and 45 years: therefore, within their reproductive years.[1] Our research group has identified areas of unmet need requiring women-focussed healthcare.

1.1 <u>Diabetes pre-pregnancy care</u>: Inadequate diabetes care before pregnancy, (pre-pregnancy care (PPC)), increases the risk of adverse pregnancy outcomes in women with pre-existing diabetes.[7,8] Compared to women without diabetes, the infants of women with diabetes have: a quadrupled risk of fetal death or stillbirth [9,10] and double the risks of congenital abnormality.[9,11] The number of pregnancies in women with T2DM continues to rise, having doubled in the last 15 years, and this group now accounts for more than 50% of pregnancies in women with pre-existing diabetes (n=4,460

annually) in England and Wales.[12] Concerningly, these adverse outcomes are increasing with no progress being made since the Confidential Enquiry into Maternal and Child Health (CEMACH)[13] and the proportion of stillbirths and neonatal deaths is now higher in women with T2DM compared to those with Type 1 diabetes. [12,9] NICE diabetes PPC guidelines have specific recommendations however a recent National Pregnancy in Diabetes audit (NPID) reported that at first attendance when pregnant 90% of women with T2DM do not receive this recommended care.[14,12] Furthermore, the NPID audit reported that in women with T2DM:

- 26% of pregnancies resulted in large for gestational age babies
- 50% of women gave birth by caesarean section
- 15% of infants are admitted to neonatal care

Many women with T2DM are unaware of these risks prior to conceiving, resulting in pregnancies that were not planned from a diabetes perspective, thereby increasing the risks to mother and infant.[12] The shift towards a younger age at diagnosis of Type 2 diabetes is inconsistently reflected in the diabetes and reproductive healthcare provided for women. T2DM is largely treated and managed in primary care by general practitioners and practice nurses (unlike women with Type 1 diabetes who are mainly cared for by specialists). The primary care health systems are not designed for these younger women living with Type 2 diabetes and in many cases the health professionals have not kept pace with the diabetes implications for this age groups. Women with, or at risk of, T2DM are more likely to have pregnancies with no pre-pregnancy health protective measures employed for themselves or their baby. These include no discussion around contraception or pregnancy intentions, no/inadequate doses of folic acid prior to conception and continuance of diabetes medications which are not approved for use during pregnancy and no discussion around blood glucose goals.

1.2 Gestational diabetes: Gestational diabetes (GDM) is diabetes first recognised in pregnancy. The incidence of GDM is estimated to be in one in every 23 pregnancies in the UK, with 2-7% of all pregnancies are affected by GDM which increases the risk of adverse maternal outcomes. Whilst in most cases GDM resolves following the birth, it leaves these women with a seven-fold risk of developing type 2 diabetes within the following 10 years.[3] Additionally, the children of mothers with GDM have an increased risk of metabolic and cardiovascular complications later in life.[15] Both GDM and T2DM are concerning because while they are distinct conditions, they are both associated with adverse outcomes for the woman and the baby. Negative consequences include the higher rate of births of large babies, caesarean sections, neonatal care admission, long-term metabolic effects on the infant; and for women with GDM a risk of GDM in subsequent pregnancies plus an increased risk of future T2DM. The rise in GDM prevalence is, in part, driving the rise in earlier diagnosis of T2DM.

1.3 Menopause: Women at the other end of the reproductive lifecycle are transitioning into the menopause with an increased risk to their health. Menopause signals a major change in hormonal regulation with multiple physiological effects for women. The menopause brings a reduction in oestrogen and oestradiol hormones increasing body fat which in most cases presents as abdominal fat. This increased weight and waist circumference is a cardio-vascular risk for women with existing T2DM as well as being a predictor of a future diagnosis. For women with T2DM towards the end of their reproductive life, they face a double stigma. Menopause is rarely discussed in public, in primary care consultations and in workplaces. Women manage symptoms privately and when they do seek help their menopausal symptoms are often misattributed to depression or low mood or dismissed. Women facing changes in their health have little support in understanding and differentiating whether their symptoms are attributable to their diabetes (which may be new to them) or to the menopause.

1.4 Menstrual cycle: No research has been undertaken to understand the impact of the menstrual cycle on blood glucose fluctuations in T2DM.

1.5 Emotional health and diabetes: Women in general report more struggles with their emotional health. Many with T2DM experience emotional ill-health and obesity, both of which are stigmatised by society and lead to feelings of shame for the woman. Shame results in further emotional distress leading to non-disclosure of diabetes. This further isolates the woman from family, peer, workplace or health care support and impedes their self-care confidence and abilities. There are many underexploited intervention points as women seek health care during their lives where women's' diabetes-related reproductive, sexual and menopausal health continue to be overlooked.

2.0 RESEARCH METHODS AND PARTICIPANTS

Our research methods have used both empirical methods and literature reviews to understand what women experience, what they need and what they want to live well with diabetes across the different phases of their life. Our research focuses on women aged between 16 years as they enter young womanhood and 65 years when most women conclude their menopausal phase of life. Women in our research live with T2DM, GDM or are at heightened risk of it due to a prior diagnosis of GDM. Our systematic literature reviews in T2DM have analysed the evidence from 39 published studies.[16,17] These studies involved 19,346 women meeting the age criteria of our interest and 83 HCPs working with this population. In GDM we have reviewed 16 published studies involving 302 women.[18] Our empirical studies have all been qualitative interview or focus group studies where we heard directly from the women themselves. We have interviewed 135 women with T2DM and 22 HCPs.[19-22] In gestational diabetes we have heard from 50 women .[23,24] These women have given us approx. 180 hours of their time to tell us their stories. To present their voices we have looked across our eight data sets and published papers to identify where these women's voices were most in accord with each other

3.0 CALL FOR ACTION

We identify four key calls for action for:

a) Gender aware diabetes care
b) Knowledge, information and awareness raising around pre-pregnancy care
c) Freedom from shame and stigmatisation associated with their T2DM and GDM diagnosis
d) Emotional and psychological needs to be acknowledged (and met)

3.1 Gender- aware T2DM care

Women felt that HCPs did not consider their reproductive stage of life and did not take their needs seriously.

Across our studies, women reported that reference to their gender and life stage during care was absent. Health professionals omitted to asked them about contraception, pregnancy planning, fertility, menstrual cycle and blood glucose fluctuations, their sexual health or menopause. Women report a conflict of agendas between women's expectations on reproductive issues and consultation topics of HCPs .[19,18,23,16,22] Women perceived HCPs as not understanding them, which led to loss of trust, feelings of alienations, and not disclosing potentially important clinical information.

The women described that HCPs focused on general aspects of diabetes management such as medication or diet on the impact of diabetes rather than reproductive issues. Women felt that HCPs did not take their care seriously because they neglected to pass on important information such as communicating the importance of taking folic acid to protect their baby's health or the change from tablets to insulin injections to manage their diabetes.[19,16] One women voiced: "*I didn't really get any help, no, because they never asked me if I was trying for a baby, I was never asked, did I want to get pregnant*".[19] Women also felt that HCPs did not consider their reproductive needs. Many women repeated this same point *''specifically reproductive topics, for example fertility, menopause, or sexual health, do need to be discussed more prominently when a diagnosis is made''*.

Our published reviews research found important age-related differences in risk of cardio-vascular disease and other diabetes complications between pre-menopausal and post-menopausal women with T2DM [16] with pre-menopausal women being at higher risk. Younger women with T2DM had seven-fold higher rate of obesity (BMI>30 kg/m2) than women with T1DM and also increased rates of hypertension or microalbuminuria associated with cardiovascular outcomes and diabetes. Our interview studies identified no evidence that these major risk topics were discussed with women at the appropriate age or menopausal status. However, women reported that when offered midlife-focussed care it enhanced their health outcomes and lifestyle behaviours by encompassing increased exercise, healthy eating, improved diabetes management self-efficacy, adequate sleep, and reduced distress.[20,21]

3.1.1 Specific recommendations: Incorporating gender awareness in diabetes care by:

- Training for health professionals around the specific impacts of diabetes on reproductive health for women living with, or at risk of, diabetes
- Awareness raising to the public around the specific impacts of diabetes on reproductive health for women living with, or at risk of, diabetes
- Use of check list and alerts on electronic medical records
- Reproductive health, sexual health and menopause needs to be part of diabetes structured education curriculum
- Systematising regular post-partum and annual follow up following GDM

3.2. Knowledge and information about diabetes and pregnancy

90% of women with Type 2 diabetes are not adequately prepared for pregnancy

Women with GDM often feel abandoned after the birth of their child

Our research [17,19,16] concluded that adverse pregnancy outcomes could be reduced through provision of appropriate pre-pregnancy care (PPC) to women living with T2DM. There is limited knowledge and awareness regarding PPC among women living with T2DM in the UK. PPC was not included in their education about living with T2DM and was rarely raised in follow-up care. When PPC was addressed, women felt that the information provided was uninformative and they did not connect with their current pregnancy planning or contraceptive use. The desire to become pregnant was more important

than their diabetes and they felt confused by/about planning a pregnancy, or what was meant by planning for pregnancy in terms of their diabetes.

HCPs have a responsibility towards PPC for women with T2DM. However, many HCPs in primary care expressed that it was not considered as part of routine T2DM care, therefore they did not address the reproductive intensions of the women. The information was delivered in ad hoc way where there is no systematic identification of women with diabetes. HCPs stated the lack of systematic records, meaning that reproductive issues were not followed up in next appointments. Thus, the lack of systematic pre-pregnancy care records decreased its visibility as a part of diabetes care, with limited capacity for surveillance through clinical audits to assess clinical performance. Furthermore, pre-pregnancy care was not adequately addressed in HCPs professional education, and hence they were unaware of and ill-prepared to deliver it. HCPs felt that they did not have the time or resources to address pregnancy in diabetes nor were they familiar with PPC requirements. Some HCPs also expressed a limited awareness of current guidance whereas others had a limited understanding of the specific requirements or sought them out if they were unsure about care recommendations, rather than to proactively inform their practice. The NHS is currently failing to deliver effective PPC to women with T2DM, increasing the risks for adverse pregnancy outcomes and inflating NHS care and treatment costs.

3.2.1 Specific recommendation

- Healthcare systems need to systematically integrate contraception and pregnancy planning discussions into routine diabetes care
- Regular and ongoing information and follow up about future diabetes risk for women with prior GDM

3.3. Reducing stigma and shame to improve access to care

Women with T2DM and GDM say they feel judged and blamed by others for their diabetes

Our research across ages groups and diabetes types found women reporting being labelled a person who, through overeating, being inactive or being overweight has brought the condition upon themselves.[23,17,16,22] Women experienced stigmatisation for having a condition traditionally associated with overweight and older age. Women with GDM often feel guilty and blame themselves for their diagnosis, worrying that they have put their baby at risk. This is compounded by the stigma and judgement they perceive from others, which increases emotional stress both during and after pregnancy, sometimes impacting self-care and engagement with postpartum diabetes screening.

Women were reticent to disclose their condition to others, including family members and health professionals. Key reasons alongside fear of judgement included not wanting to answer a lot of questions about diabetes or not wanting to deal with public misconceptions. Women shared their feeling of being stigmatised by cultural beliefs, such as they thought they would be infertile and consequently this results in difficult partner relationships and unwillingness to disclose their condition. Some women also stated that T2DM is perceived to be a less serious condition compared to T1DM or thought that diabetes is only serious when insulin is required, and interpreted this as they were less important than women with T1DM. [19,22] Many felt self-blame and shame on what they have done

''wrong'' with their lifestyle and stated, *'it is my own fault, this did not have to happen, this should have been completely avoidable, so I did not tell many people''*. These negative perceptions affected their health-seeking behaviours with a tendency towards disengagement when communicating with HCPs about their reproductive intentions.[19] An unwillingness to disclose also is associated with lower levels of self-care such as skipping or delaying medications as well as a reduced sense of autonomy with high levels of external controls and judgmental interactions. [23]

Social stigmatisation and shame affect the overall wellness of women with diabetes by limiting their access to diabetes programs provided by healthcare. Midlife women with T2DM, whilst ambitious and enthusiastic about participating in a gender and age focused programme, shame prevented them from attending the peer elements which may have enhanced their confidence and self-esteem. [21,22] Younger women in our studies counselled other women not to disclose their pregnancy intentions to health professionals due to their own negative and stigmatising experiences of doing so.[19]

3.3.1 Specific recommendations

- Research is needed to understand stigma and shame and its association to gender. Interventions to reduce HIV-related shame and stigma can offer guidance in this area
- Awareness raising for health professionals is required to develop better understanding of how shame and stigma impact on diabetes self-care and prevention behaviours

3.4 Psychological needs

"I think society generally will just say, 'Well, if you're under 40 and you've been diagnosed with Type 2 diabetes, that must be because of your own fault'

Women described the impact of living with diabetes on mood, anxiety, depression symptoms, diabetes distress and disordered eating in both T2DM and GDM.[16,23,17,20-22] Sources of worry for 40% of research samples in our published reviews were worrying about the future and fear of diabetes complications, and guilt and anxiety when they did not adhere to self-care goals. Many women reported that stress made their diabetes worse and thus they needed emotional care to overcome diabetes challenges across their whole of the adult life course . Many women also voiced strong emotional concerns about their fertility, believing that diabetes would reduce their fertility, resulting in ambivalence toward contraception and increasing their risk of an unplanned pregnancy. [19,17,16,22] Women worry about the health of a future baby and their ability to control their diabetes to protect their baby. Women experienced palpable anxiety with HCPs during or after the birth of their baby. The intense concern expressed by HCPs for the baby's health led to heighted sense of fear and anxiety in the woman during labour.[23] As a result, women with T2DM had emotional concerns regarding pregnancy and their future baby. To maximise the health of the baby, women with GDM are not given time to accept and adapt to their diagnosis; they are required to make immediate lifestyle changes and often take medication or insulin very quickly. This reduces feelings of control and can exacerbate emotional stress.

3.4.1 Specific recommendation

- Emotional health assessment should be part of routine, annual, diabetes reviews and more often when treatment, condition or life stage transitions occur
- Emotional support during and following diagnosis of T2DM and GDM

4.0 CONCLUSION

Gestational and Type 2 diabetes are a significant health risk for a large proportion of women navigating co-occurring sexual, reproductive and menopausal health needs respectively. These needs are under the radar of health professionals providing their care. Some of this, but not all, can be attributed to a lack of evidence. We suggest 8 calls for action which would improve the health, safety and wellbeing of women living with diabetes at crucial stages in their reproductive health life cycle.

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Appendix B.2: Publication supplementary materials

Appendix B.2.1: Supplementary file 1 – Sampling Frame

Variable	Aim	Rationale
Country of residence	Recruit ≥15 participants per county band UK Türkiye	Sensitive understanding of a diverse range of backgrounds
Age ranges	Recruit ≥10 participants per age band as below 18-25 years 26-35 years 36-45 years	Aim for information power across experiences by age.
Duration of diabetes	Recruit ≥7 participants per diabetes duration band as below < 1years 1-5 years 6-10 years >10 years	Understanding the needs of women who represent different duration along the diabetes, and so the full spectrum of needs can be determined.

Appendix B.2.2: Supplementary file 2 – Interview topic guide

Introductions:

1.Tell me about your experience of living with type 2 diabetes?

Prompts:

- What is that like for you?
- How does diabetes affect you on a day-to-day basis?
- When you were diagnosed with diabetes, what was that like for you?

2. How has the way you live your life changed since your diagnosis?

Prompts:

- Diet, exercise, medications, symptoms, working, cultural effects, feelings, future?
- What do you think has been your biggest challenge to manage diabetes over the past years? How do you feel about these challenges?
- Any other challenges?

3. In what way do you think your diabetes impacts on other aspects of your health?

Prompts:

- How does diabetes impact your physical health?
- What about the impact on your mood and well-being (mood – emotion)?
- In what way does diabetes impact your social life relationship/employment/interacting with others (relationships – social life)?

4. Tell me about any impacts living with diabetes has on your reproductive health (e.g., hormones – pregnancy planning – pregnancy – sexual health).

Prompts:

- Menstrual cycle experiences since diagnosis of diabetes?
- Diabetes care experiences before/after or during pregnancy?
- Your experiences of contraception after diagnosis of diabetes?
- Your sexual health or sexual fulfilment (sexual health)?
- Menopause and diabetes? How? Why?

5. What you have been told about the complications of diabetes such as eyes, or feet for example?

Prompts:

- What about your heart, eyes, kidneys, feet?
- How do you feel when you think about diabetes complications?
- What do you think would be helpful to you?
- In your opinion what would be the best way to share this information with women like you who have been told they have diabetes? – From whom, how, when, in what way?

6. What do you think would be the best way to help women who like you live with diabetes at a younger age?

Prompts:

- What do you think would be helpful? supporters, education?

- How, in what way? (Online – in person – individual – group – app etc.)

7. What things/area of care do you need help with or would like to learn more about diabetes? Prompts:

- Diet, exercise, taking medication, knowledge about how to manage diabetes, managing diabetes during menstrual cycle, contraception use, dealing with high or low blood sugars.
- What is it about that you would like to know?

8. Is there anything you would like to add about what is like for you to live with diabetes?

Thank you for taking part.

Appendix B.2.3: Supplementary file 3 – COREQ Checklist

Manuscript: 'No one ever asks about something that actually is relevant to my life': A qualitative study of diabetes and diabetes care experiences of young women with type 2 diabetes during their reproductive years

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:
Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

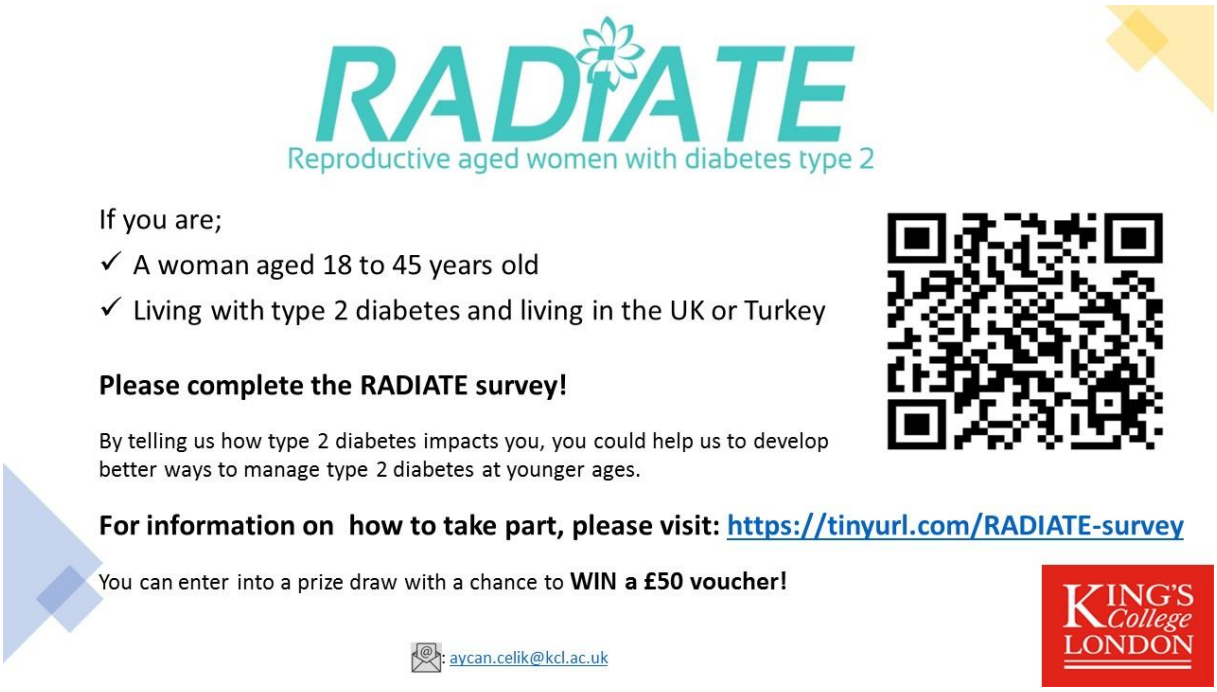
No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	Page 5
2. Credentials	What were the researcher's credentials? E.g., PhD, MD	Page 5
3. Occupation	What was their occupation at the time of the study?	Page 5
4. Gender	Was the researcher male or female?	Page 5
5. Experience and training	What experience or training did the researcher have?	Page 5
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Page 5 .
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g., personal goals, reasons for doing the research	Page 4-5
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Page 4-5

Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g., grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Page 3
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Page 4
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Page 4
12. Sample size	How many participants were in the study?	Page 5
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Page 5
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Page 4
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	Page 4
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Page 4
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Supplementary file 2 and page 4
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No, inferred on page 4
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Page 4

20. Field notes	Were field notes made during and/or after the interview or focus group?	Page 5
21. Duration	What was the duration of the interviews or focus group?	Page 5
22. Data saturation	Was data saturation discussed?	Page 4, 11
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No, inferred on page 5
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	Page 5
25. Description of the coding tree	Did authors provide a description of the coding tree?	Page 5
26. Derivation of themes	Were themes identified in advance or derived from the data?	Page 3, 5
27. Software	What software, if applicable, was used to manage the data?	Page 5
28. Participant checking	Did participants provide feedback on the findings?	No, inferred on page 5
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Page 5 to 9
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes, there was. Page 5 to 11
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes, there were. From page 5 to 9
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Discussion of major and minor themes From page 5 to 11

Appendix C: Cross-sectional study

Appendix C.1.1: Study Poster



Appendix C.1.2: Gatekeeper permission

GATEKEEPER LETTER

Ethical Clearance Reference Number:

Title of Project: Exploring the relationship between psychosocial factors and diabetes self-care behaviours in younger women with type 2 diabetes: a cross-sectional study

Dear [Gatekeeper Name],

My name is Aycan Celik, a doctoral student at King's College London. The research I wish to conduct for my doctoral study involves the developing a better psychosocial understanding of living with type 2 diabetes in women with reproductive age.

I'm writing to ask your permission to post the research advertisement in your (social media, publication, account, blog, newsletter, etc.) to recruit eligible participants. The research advert you post will help to recruit interested respondents to participate in the study. Only after the members agree and are happy to take part, they will be asked to fill-in a questionnaire. All answers and results from the research will be kept strictly confidential and anonymised before the results are published in a journal. I have provided you with a copy of the approval letter which I received from the King's College London Ethics Committee (REMAS).

If you require any further information, please do not hesitate to contact me (Aycan Celik). Thank you for your time and consideration in this matter. Your attention and deliberation on this matter is highly appreciated. With respect I look forward for your reply.

Yours sincerely,

Aycan Celik
Florence Nightingale Faculty of Nursing, Midwifery & Palliative Care
King's College London
Waterloo Road
James Clerk Maxwell Building
London SE1 8WA
Email: aycan.celik@kcl.ac.uk

Principal supervisor

Professor Jackie Sturt

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Appendix C.1.3: Ethical Approval

Research Ethics
Office

Franklin Wilkins Building
5.9 Waterloo Bridge Wing
Waterloo Road
London SE1 9NH
Telephone 020 7848 4020/4070/4077
rec@kcl.ac.uk

KING'S College LONDON

Aycan Celik

01/02/2022

Dear Aycan

Reference Number: HR/DP-21/22-26924
Study Title: Exploring the relationship between psychosocial factors and diabetes self-care behaviors in younger women with type 2 diabetes: a cross-sectional study

Review Outcome: Approval with Provisos

Ethical Clearance

Thank you for submitting your application for the above project. I am pleased to inform you that your application has now been approved with the provisos indicated at the end of this letter. All changes must be made before data collection commences. The Committee does not need to see evidence of these changes, however supervisors are responsible for ensuring that students implement any requested changes before data collection commences.

Important COVID-19 update: Please consult the latest College guidance (linked below) and ensure you have completed the risk assessment procedure prior to any data collection involving face-to-face participant interactions.

https://internal.kcl.ac.uk/innovation/research/ethics/applications/COVID-19-Update-for-Researchers

Please ensure that you follow all relevant guidance as laid out in the King's College London Guidelines on Good Practice in Academic Research (http://www.kcl.ac.uk/college/policyzone/index.php?id=247).

For your information, ethical approval has been granted for 3 years from 1 February 2022. If you need approval beyond this point, you will need to apply for an extension at least two weeks before this. You will be required to explain the reasons for the extension. However, you will not need to submit a full re-application unless the protocol has changed. You will not be sent a reminder when it is due to lapse.

Ethical approval is required to cover the data-collection phase of the study. This will be until the date specified in this letter. However, you do not need ethical approval to cover subsequent data analysis or publication of the results.

Please ensure that you follow the guidelines for good research practice as laid out in UKRIO's Code of Practice for research: http://ukrio.org/publications/code-of-practice-for-research/.

If you do not start the project within three months of this letter please contact the Research Ethics Office.

Please note that you will be required to obtain approval to modify the study. This also encompasses extensions to periods of approval. Please refer to the URL below for further guidance about the process:

https://internal.kcl.ac.uk/innovation/research/ethics/applications/modifications.aspx

Data Protection Registration

As you have indicated in Section E that personal data will be processed as part of this research project, this letter also confirms that you have also met your requirements for registering this processing activity with King's College London. This is required in line with the College's role as a Data Controller, in accordance with the UK General Data Protection Regulation (UK GDPR).

Please note it is the responsibility of the researcher(s) to ensure compliance with other aspects of the UK GDPR, more information about this can be found here: https://internal.kcl.ac.uk/innovation/research/Research-Governance/how-does-uk-data-protection-law-affect-research/how-does-uk-dp-law-affect-research

You are required to adhere to all research data/records management and storage procedures agreed to as part of your application. This will be expected even after the completion of the study.

If there are any changes to the project that will impact on how you will you collect, manage or otherwise use your data, these must also be reflected in a modification request as outlined above.

Please would you also note that we may, for the purposes of audit, contact you from time to time to ascertain the status of your research.

If you have any query about any aspect of this ethical approval, please contact your panel/committee administrator in the first instance (https://internal.kcl.ac.uk/innovation/research/ethics/contact.aspx)

We wish you every success with this work.

Yours sincerely,

Dr Alexander Miller Tate
Research Ethics Facilitator

For and on behalf of

Chair

Health Faculties (Blue) Research Ethics Subcommittee

Cc: Supervisor

Review Reference: HR/DP-21/22-26924

26924

Feedback requiring substantial consideration
N/A

Minor feedback related to application

Cover Letter

C6 – Please ensure that gatekeepers, especially those in positions of influence, will not be able to identify which individuals eventually participate and which do not, and reassure participants of this fact via the information sheet. If you cannot meet this proviso, please contact the Research Ethics Office.

Research Governance & Data Protection Feedback

N/A

Feedback related to recruitment documents

N/A

Advice and Comments (do not have to be adhered to, but may help to improve the research)

N/A

Appendix C.1.4: Participant Information Sheet

INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number: HR/DP-21/22-26924

Title of project

Exploring the relationship between psychosocial factors and diabetes self-care behaviours in younger women with type 2 diabetes: a cross-sectional study

Invitation Paragraph

I would like to invite you to participate in this research project which forms part of my PhD research. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the project?

The purpose of the study is to explore how emotional health impacts on how diabetes is managed. We know a lot about this in older adults with type 2 diabetes, but we know little about this in younger women. We know from interviewing over 30 women of reproductive age with type 2 diabetes that their needs and experiences are different. Understanding more about diabetes distress, anxiety, fatigue, stigma, and disordered eating in younger women will help healthcare professionals improve the diabetes care they give to younger women with type 2 diabetes and better understand women's health priorities and needs.

Why have I been invited to take part?

You are being invited to take part in this study because you are female, have type 2 diabetes, are aged between 18-45 years and live in the United Kingdom or Turkey and are able to read and understand English or Turkish.

Please note that you cannot participate in this study If you have type 1 diabetes, gestational diabetes, the other types of diabetes, or currently have any investigation, treatment or therapy for a psychiatric illness.

What will happen if I take part?

You will first be presented with information about the study, which you can read at your own pace, and then asked if you have understood this information and consent to taking part. If you have decided to give consent in order to take part in the project, you will be asked to complete the short screening questions about your type 2 diabetes diagnosis, your age ranges, country of residence, any psychiatric illness. You will then be asked to provide your name, an email address and phone number, so that we can contact you to signpost if needed any sources of support or should you contact us directly. The name, email address and phone numbers will not be linked to your survey answers and your contact details will be stored separately to the research data.

Following the screening questions, if eligible, you will be asked to complete about your demographics (e.g., age, education), your diabetes health (e.g., how long you have had diabetes and diabetes complications) your emotional health (e.g., diabetes related distress,

anxiety, and fatigue) and your self-care activities (e.g., taking medication, attending appointments). The survey will take you approximately 20-30 minutes to complete. After you have completed the survey, you will be redirected to a separate site to tick a box for the future research interest. This is optional and your contact details will be stored separately to the research data.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in any way. Once you have read the information sheet, please contact us if you have any questions that will help you make a decision about taking part. If you decide to take part, we will ask you to complete an online consent form. To do this you will be asked to indicate that you have read and understand the information provided and that you consent to your data being used for the purposes explained.

Incentives

The participants who complete the survey will be entered into a prize draw for a chance to win a £50 voucher.

What are the possible risks of taking part?

There is no anticipated risk in taking part the study. While answering the questions, you will be required to recall your experiences of living with type 2 diabetes. Some of the questions relate to sensitive issues such as anxiety and stress. You are not asked to provide any details – the questions simply have multiple choice response options. This is unlikely, however, if you feel upset or distress while answering the questions, you can choose to skip any questions you wish not to answer or you can pause or stop the participating at any time. You can contact the researcher about your concerns if you want. Also, information sources of support is provided in detail below, at the end of the survey and on the pages that ask about particularly difficult issues. If you feel that taking part in the research has had a negative impact on you, please discuss this with your usual diabetes provider, general practitioner (GP) immediately and you can also find the support from:

The Samaritans: 116 123

Diabetes UK: 0345 123 2399

What are the possible benefits of taking part?

The information that you provide will help us to understand the health issues faced by women with type 2 diabetes during their reproductive years. Your participation will support us to find the new interventions/care pathways to help younger women with type 2 diabetes to manage their own condition. We cannot guarantee that you will personally benefit from the research findings but other women like you will benefit in the future.

Data handling and confidentiality

Your data will be processed under the terms of UK data protection law (including the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018). Please note that your data will remain strictly confidential and pseudonymise. This means that only the researchers will be aware of your identity if you provide this to us, for example should you need to contact us directly, or we contact you if/when required (for example, for any

healthcare support and/or withdrawing your data if you request this up to day 10 from completing the survey). Your answers will nevertheless be treated confidentially and the information you provide will not allow you to be identified in any research outputs/publications. You will be invited to provide your contact details (name, email address and phone number) to signpost if needed any sources of support, and to express your interest to be contacted for further research. These contact details will be entered into a separate database not linked to the main survey to ensure the survey dataset remained de-identified. Your personal information will be destroyed once the study has been completed. Your data will be held securely, and your personal information will remain confidential through a unique ID code, known only the research team. As such, your responses will be pseudonymised and you will not be identifiable at any point of the research, including when analysing the data or disseminating the finding. Please note that your data will remain strictly confidential and pseudonymous which means you cannot be identifiable through your responses. All information will be stored on a secure database at King's College London with encrypted cloud store (OneDrive). Only the research team will have access to participants' responses.

Data Protection Statement

King's College London (KCL) is the sponsor for this study. Your personal data (name, email address and phone number) for the purpose of the research outline above in this information sheet will be processed under the terms of UK data protection law (including the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018). KCL will keep survey responses for 7 years after the study has finished and will then destroy them permanently.

If you would like more information about how your data will be processed under the terms of UK data protection laws, please visit the link below:

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

What if I change my mind about taking part?

You are free withdraw at any point of the project, without having to give a reason. Withdrawing from the project will not affect you in any way. You are able to withdraw your data from the project until end of day 10 from completing the survey, without having to give a reason by contacting me (aycan.celik@kcl.ac.uk), after which withdrawal of your data will no longer be possible because on day 11 following survey completion your data will be anonymised and will be included in the analysis.

What will happen to the results of the project?

The results of the study will be summarised in my PhD thesis, along with submitting in appropriate peer-reviewed journals, relevant conferences, and meeting. It will be used to develop training for health professionals and develop new types of health care support.

Who should I contact for further information?

If you have any questions or require more information about this project, please contact me using the following contact details:

Aycan Celik, aycan.celik@kcl.ac.uk ; Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care, King's College London, James Clerk Maxwell Building, 57 Waterloo Rd. London SE1 8WA.

What if I have further questions, or if something goes wrong?

If this project has harmed you in any way or if you wish to make a complaint about the conduct of the project you can contact King's College London using the details below for further advice and information: The chair, King's College London, the Health Faculties Research Ethics Subcommittee: *rec@kcl.ac.uk*

Primary supervisor

Professor Jackie Sturt

Professor of Behaviour Medicine in Nursing

Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care

King's College London

James Clerk Maxwell Building 3.21

57 Waterloo Rd.

London

SE1 8WA

Email: jackie.sturt@kcl.ac.uk

Thank you for reading this information sheet and for considering taking part in this research.

Sources of support: This information will be provided again at the end of the Survey. If you are experiencing distress and would like to receive support, please contact the following resources:

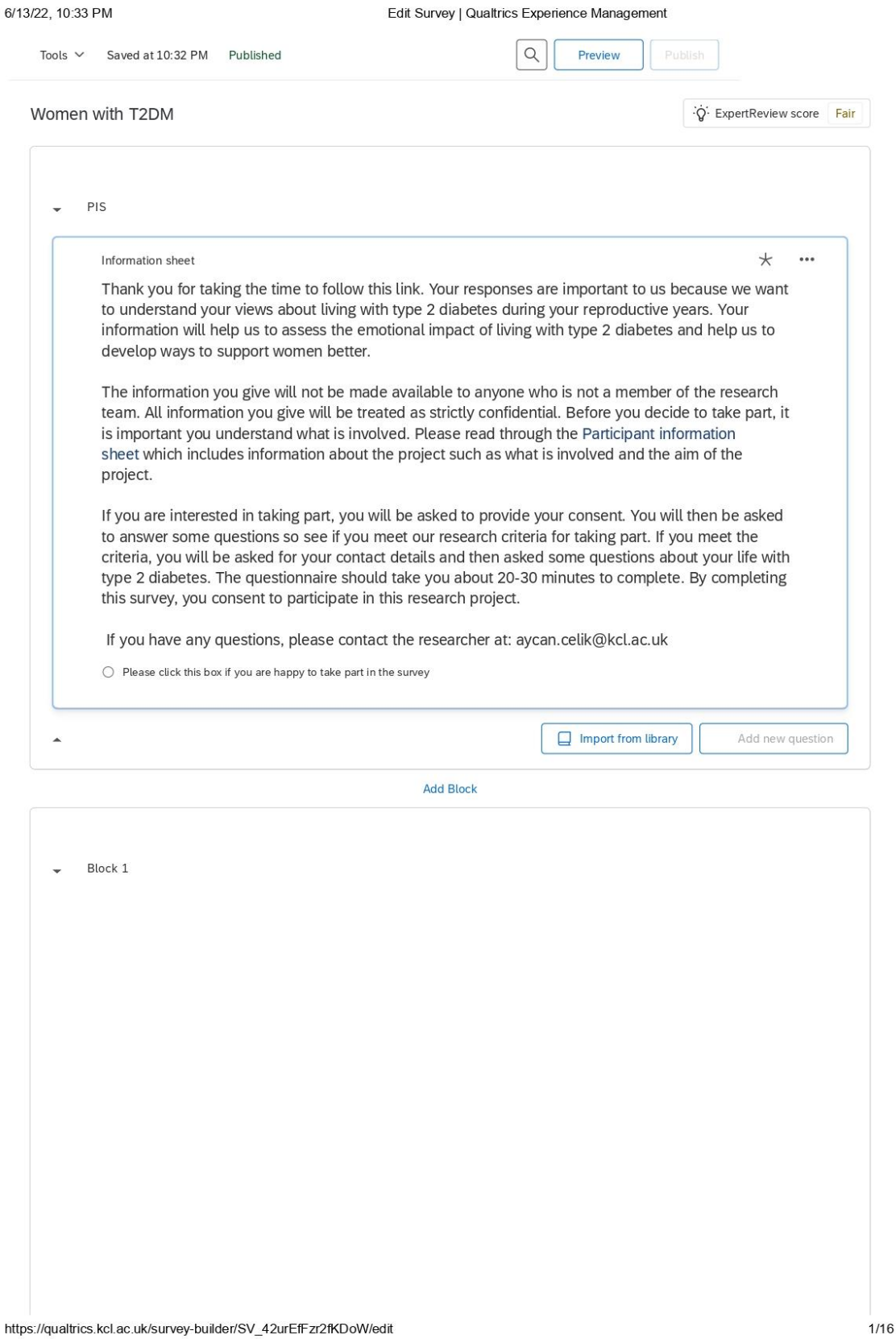
-Your usual diabetes provider: They provide a medical diabetes examination, health care, diabetes symptom management and when necessary, your diabetes provider can refer you to Mental Health Service for further examination, support, and care if needed.

-Doctor (General practitioner, GP): Your doctor provides a medical examination, health care, symptom management and when necessary, your doctor can refer you to Mental Health Service for further examination, support, and care if needed.

-Diabetes UK: Diabetes UK has trained counsellors who provide a free and confidential talk about uneasy emotions. You can get in touch with their highly trained advisors for support, advice or just a chat. You can call their helpline on 0345 123 2399, Monday to Friday, 9am to 6pm. https://www.diabetes.org.uk/about_us/contact_us

-Samaritans: It’s a 24-hour service that provide confidential telephone support for adults who have difficulties with their emotions. Helpline 116 123 (UK).

Appendix C.1.5: Study questionnaire (Qualtrics^{XM} preview)



Consent form *

Thank you for considering taking part in this research. You should only complete this form after you have read and understood the Participant Information Sheet. To consent to participate, you must agree to each of the statements listed below, by clicking the boxes to acknowledge that you have read and understood the information provided and freely agree to take part in this research project.

- [ ] I understand that by clicking each box I am consenting to this element of the study. I understand that it will be assumed that unclicked boxes mean that I do not consent to take part of the study. I understand that by not giving consent for any one element I may be deemed ineligible for this study.
- [ ] I confirm that I have read and understood the above information. I have had the opportunity to consider the information and had my questions responded to satisfactorily.
- [ ] I consent to the processing of my data and personal information if any for the purposes explained to me in the Information sheet. I understand that such information will be treated in accordance with the terms of the UK Data Protection Act 2018.
- [ ] I understand that the information that I provided for this study will be kept confidential.
- [ ] I understand that it will not be possible to identify me in any research reports.
- [ ] I consent voluntarily to be a participant in this study and understand that I can choose not to answer questions and I can withdraw from the study at any time without providing an explanation, and that I can ask for my data to be removed / deleted up to 10 days after I have submitted the survey by contacting the research team.
- [ ] I understand that data may be looked at by the research team at King's College London. I give permission for the research team to have access to my data and contact me if they think I may need any sources of support.
- [ ] I have read the above statements and give my consent to be a participant in this study.

Page Break

Q11

Eligibility Criteria

Q1 *

I am a woman diagnosed with type 2 diabetes.

- ○ Yes
- ○ No

Q2 *

I am aged between 18-45 years.

- ○ Yes
- ○ No

Q3 *

I live in the UK or Turkey.

- ○ Yes
- ○ No

Q4 *

I am not currently having any investigation, treatment or therapy for a psychiatric illness.

- ○ Yes
- ○ No

Page Break

Q17

Thanks for your interest to participate in this survey, you are eligible to take part.

Page Break

Contact details

Please provide your name, email address and mobile number below, so that we can contact you if needed any source of support OR should you need to contact us directly.

Your name	
Your email adress	
Your phone number	

Page Break

Demographic data

This section will ask some basic questions about yourself. Please click/write the appropriate box.

Q1 *

What is your age in years?

Q2 *

Country of residence?

- ○ UK
- ○ Turkey

Q3 *

Country of nationality?

- UK
- Turkey

Q4 *

How long have you had type 2 diabetes? (in years) (please click the box).

- < 1 year
- 1-5 years
- 6-10 years
- >10 years

Q5 *

What sex were you assigned at birth, on your original birth certificate? (We would like to gain a fuller picture as to the healthcare needs of ALL younger women living with type 2 diabetes to enable better and more informed care to be provided and to further equality).

- Female
- Male
- Prefer not to answer

Q6 *

Does anyone else in your family have diabetes? (please click the box).

- Yes
- No

Q7 *

What is your relationship status? (please click the box).

- Single
- Married
- In a relationship
- Divorced
- Widowed
- Prefer not to say

Q8 *

How do you describe your ethnicity? (please click the box).

- White British
- White others
- Turkish
- Asian
- Asian others
- Chinese
- Indian
- Black Caribbean
- Black African
- Black Other
- Mixed ethnic group
- Any other ethnic group

Q61

Display this question

If How do you describe your ethnicity? (please click the box). Any other ethnic group Is Selected

Please specify your ethnic group

Page Break

Q9 *

What is the highest education qualification that you have completed? (Please click the box)

- Primary school
- Secondary school
- College degree/Diploma
- University/Degree
- Postgraduate degree
- Other

Q59

Display this question

If What is the highest education qualification that you have completed? (Please click the box) Other Is Selected

Please specify your education qualification

Page Break

Q10 *

How do you describe your household's income status?

- ○ Less than I need to meet mine/my family's basic living needs
- ○ Equal to mine/my family's basic living needs
- ○ More than I need to meet mine/my family's basic living needs

Q11 *

Are you currently working? (Please click the box)

- ○ Working full-time
- ○ Working part-time
- ○ Home duties
- ○ Unemployed
- ○ Student
- ○ Unable to work
- ○ Other

Q60

Display this question

If Are you currently working? (Please click the box) Other Is Selected

Please specify your working position

Page Break

Q12 *

What was your last long-term blood glucose test result (also called HbA1c or A1C)?

- ○ Less than 6.5% (48mmol/mol)
- ○ Between 6.5% to 7% (48mmol/mol to 53 mmol/mol)
- ○ More than 7% (53 mmol/mol)
- ○ I don't know

13 *

How would you best describe the diabetes therapy your doctor prescribed?

- ○ Oral hypoglycaemic tablets
- ○ Insulin and/or other injections for diabetes
- ○ Insulin and tablets
- ○ Lifestyle
- ○ A Different diabetes management method

Q62

Display this question

If How would you best describe the diabetes therapy your doctor prescribed? A Different diabetes management method Is Selected

Please specify your diabetes management method

Q14 *

Has your diabetes caused any of following health problems? (Click as many issues as apply)

- [ ] Heart
- [ ] Blood circulation
- [ ] Stroke
- [ ] Nerve damage
- [ ] Eye problems
- [ ] Foot problems
- [ ] High blood pressure
- [ ] High cholesterol
- [ ] Kidney disease
- [ ] Please specify other health issue(s) if you have

Q15 *

Have you ever attended a diabetes education course?

- ○ Yes
- ○ No

Page Break

Section 2

Section 2 is about the fatigue/tiredness level you feel.

Fatigue

This section consists of answering a short questionnaire that requires the participant to rate your own level of fatigue/tiredness. You are asked to read each statement and click a statement from strongly disagree to strongly agree, depending on how appropriate you felt the statement applied to you over the preceding week. A low value indicates that the statement is not very appropriate whereas a high value indicates agreement.

Q16

During the past week, I have found that:

	Agreement score						
	Strongly disagree	Disagree	Somewhat disagree	Neutral	Somewhat agree	Agree	Strongly agree
1. My motivation is lower when I am fatigued.	○	○	○	○	○	○	○
2. Exercise brings on my fatigue.	○	○	○	○	○	○	○
3. I am easily fatigued.	○	○	○	○	○	○	○
4. Fatigue interferes with my physical functioning.	○	○	○	○	○	○	○
5. Fatigue causes frequent problems for me.	○	○	○	○	○	○	○
6. My fatigue prevents sustained physical functioning.	○	○	○	○	○	○	○
7. Fatigue interferes with carrying out certain duties and responsibilities.	○	○	○	○	○	○	○
8. Fatigue is among my three most disabling symptoms.	○	○	○	○	○	○	○
9. Fatigue interferes with my work, family, or social life.	○	○	○	○	○	○	○

Page Break

Section 3

Section 3 is about issues with eating.

Q17

The following statements describe your eating habits related to type 2 diabetes. Select the appropriate response that best describes yourself using Yes or No. If you have been upset or troubled by any of the questions, please discuss this with your healthcare professionals as soon as possible or contact the researchers.

	Yes	No
1. Do you make yourself sick because you feel uncomfortably full?	○	○
2. Do you worry you have lost control over how much you eat?	○	○
3. Have you recently lost more than one stone (14 lb) in a 3-month period?	○	○
4. Do you believe yourself to be fat when others say you are too thin?	○	○
5. Would you say that food dominates your life?	○	○

Page Break

Q18

Section 4 is about Type 2 Diabetes Stigma.

Q18

The following statements are about stigma and type 2 diabetes. Some statements refer to your personal experiences, and some are about your views on society in general. Use the response options to indicate how much you agree or disagree with each statement. We are interested in what is true for YOU.

	Strongly disagree	Disagree	Unsure	Agree	Strongly agree
1. Some people think I cannot fulfil my responsibilities (e.g. work, family) because I have type 2 diabetes)	○	○	○	○	○
2. Because of my type 2 diabetes, health professionals have made negative judgments about me	○	○	○	○	○
3. Because I have type 2 diabetes, some people assume I must be overweight, or have been in the past.	○	○	○	○	○
4. Some people treat me like I'm "sick" or "ill" because I have type 2 diabetes	○	○	○	○	○
5. There is blame and shame surrounding type 2 diabetes	○	○	○	○	○
6. I feel embarrassed because of my type 2 diabetes	○	○	○	○	○
7. I have been discriminated against in the workplace because of my type 2 diabetes	○	○	○	○	○
8. Health professionals think that people with type 2 diabetes don't know how to take care of themselves	○	○	○	○	○
9. I'm ashamed of having type 2 diabetes	○	○	○	○	○
10. Some people see me as a lesser person because I have type 2 diabetes	○	○	○	○	○
11. Because I have type 2 diabetes, I feel like I am not good enough	○	○	○	○	○
12. There is a negative stigma about type 2 diabetes being a 'lifestyle disease'	○	○	○	○	○
13. Having type 2 diabetes makes me feel like a failure	○	○	○	○	○
14. Some people exclude me from social occasions that involve food / drink they think I shouldn't have	○	○	○	○	○
15. I feel guilty for having type 2 diabetes	○	○	○	○	○
16. I have been told that I brought my type 2 diabetes on myself	○	○	○	○	○
17. I have been rejected by others (e.g. friends, colleagues, romantic partners) because of my type 2 diabetes	○	○	○	○	○
18. I blame myself for having type 2 diabetes	○	○	○	○	○
19. Because I have type 2 diabetes, some people judge me for my food choices	○	○	○	○	○

Page Break

Q19

Section 5 is about diabetes distress.

Q19

Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 17 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 17 items may have distressed or bothered you DURING THE PAST MONTH and select the appropriate statement.

Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you will circle "Not a problem". If it is very bothersome to you, you might circle "A very serious problem". If you have been upset or troubled by any of the questions about your diabetes distress, please discuss this with your healthcare professionals as soon as possible or contact the researchers.

	Not a problem	A slight problem	A moderate problem	Somewhat serious problem	A serious problem	A very serious problem
1. Feeling that diabetes is taking up too much of my mental and physical energy every day.	○	○	○	○	○	○
2. Feeling that my doctor doesn't know enough about diabetes and diabetes care.	○	○	○	○	○	○
3. Feeling angry, scared and/or depressed when I think about living with diabetes.	○	○	○	○	○	○
4. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.	○	○	○	○	○	○
5. Feeling that I am not testing my blood sugars frequently enough.	○	○	○	○	○	○
6. Feeling that I am often failing with my diabetes routine.	○	○	○	○	○	○
7. Feeling that friends or family are not supportive enough of self-care efforts (e.g., planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).	○	○	○	○	○	○
8. Feeling that diabetes controls my life.	○	○	○	○	○	○
9. Feeling that my doctor doesn't take my concerns seriously enough.	○	○	○	○	○	○
10. Not feeling confident in my day-to-day ability to manage diabetes.	○	○	○	○	○	○
11. Feeling that I will end up with serious long-term complications, no matter what I do.	○	○	○	○	○	○
12. Feeling that I am not sticking closely enough to a good meal plan.	○	○	○	○	○	○
13. Feeling that friends or family don't appreciate how difficult living with diabetes can be.	○	○	○	○	○	○
14. Feeling overwhelmed by the demands of living with diabetes.	○	○	○	○	○	○
15. Feeling that I don't have a doctor who I can see regularly enough about my diabetes.	○	○	○	○	○	○
16. Not feeling motivated to keep up my diabetes self-management.	○	○	○	○	○	○
17. Feeling that friends or family don't give me the emotional support that I would like.	○	○	○	○	○	○

Page Break

Q20

Section 6 is about how anxious you feel.

Q20

Below is a list of common symptoms of anxiety. Please carefully read each item in the list. Indicate how much you have been bothered by that symptom during the past month, including today. If you have been upset or troubled by any of the questions about your anxiety, please discuss this with your healthcare professionals as soon as possible or contact the researchers.

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

Page Break

Q21

Section 7 is about your diabetes self-care.

Q21

The questions below ask about your diabetes self-care activities during the past seven days. If you were sick during the past seven days, please think back to the last seven days when you were not sick.

Diet

	0	1	2	3	4	5	6	7
How many of the last SEVEN DAYS have you followed a healthful eating plan?	○	○	○	○	○	○	○	○
On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?	○	○	○	○	○	○	○	○
On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?	○	○	○	○	○	○	○	○
On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products?	○	○	○	○	○	○	○	○

Exercise

Exercise

	0	1	2	3	4	5	6	7
On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking).	○	○	○	○	○	○	○	○
On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?	○	○	○	○	○	○	○	○

Blood sugar testing

Blood Sugar Testing

	0	1	2	3	4	5	6	7
On how many of the last SEVEN DAYS did you test your blood sugar?	○	○	○	○	○	○	○	○

Food care

Foot Care

	0	1	2	3	4	5	6	7
On how many of the last SEVEN DAYS did you check your feet?	○	○	○	○	○	○	○	○
On how many of the last SEVEN DAYS did you inspect the inside of your shoes?	○	○	○	○	○	○	○	○

Q52

Smoking: Have you smoked a cigarette—even one puff—during the past SEVEN DAYS?

- ○ No
- ○ Yes, If yes, how many cigarettes did you smoke on an average day?

Page Break

Q53 ✳

Self-Care Recommendations:

1A. Which of the following has your healthcare team (doctor, nurse, dietitian, or diabetes educator) advised you to do? Please click all that apply.

- [ ] Follow a low-fat eating plan
- [ ] Follow a complex carbohydrate diet
- [ ] Reduce the number of calories you eat to lose weight
- [ ] Eat lots of food high in dietary fiber
- [ ] Eat lots (at least 5 servings per day) of fruits and vegetables
- [ ] Eat very few sweets (for example, desserts, non-diet sodas, candy bars)
- [ ] Other (specify)
- [ ] I have not been given any advice about my diet by my healthcare team

2A ✳

2A. Which of the following has your healthcare team (doctor, nurse, dietitian, or diabetes educator) advised you to do? Please check all that apply.

- [ ] Get low level exercise (such as walking) on a daily basis
- [ ] Exercise continuously for a least 20 minutes at least 3 times a week
- [ ] Fit exercise into your daily routine (for example, take stairs instead of elevators, park a block away and walk, etc.)
- [ ] Engage in a specific amount, type, duration, and level of exercise
- [ ] Other (specify)
- [ ] I have not been given any advice about exercise by my healthcare team

3A ✳

3A. Which of the following has your healthcare team (doctor, nurse, dietitian, or diabetes educator) advised you to do? Please check all that apply.

- [ ] Test your blood sugar using a drop of blood from your finger and a colour chart
- [ ] Test your blood sugar using a machine to read the results
- [ ] Test your urine for sugar
- [ ] Other (specify)
- [ ] I have not been given any advice about my blood or urine sugar level by my healthcare team

4A ✳

4A. Which of the following medications for your diabetes has your doctor prescribed? Please check all that apply.

- [ ] An insulin injection with injection 1 or 2 times a day
- [ ] An insulin injection with injection 3 or more times a day
- [ ] Diabetes pills to control my blood sugar level
- [ ] Other (specify)
- [ ] I have not been prescribed either insulin or pills for my diabetes

Page Break

5A

Diet

	0	1	2	3	4	5	6	7
5A. On how many of the last SEVEN DAYS did you space carbohydrates evenly through the day?	○	○	○	○	○	○	○	○

6A

Medications

	0	1	2	3	4	5	6	7
6A. On how many of the last SEVEN DAYS, did you take your recommended diabetes medication?	○	○	○	○	○	○	○	○

9A

Foot Care

	0	1	2	3	4	5	6	7
9A. On how many of the last SEVEN DAYS did you wash your feet?	○	○	○	○	○	○	○	○
10A. On how many of the last SEVEN DAYS did you soak your feet?	○	○	○	○	○	○	○	○
11A. On how many of the last SEVEN DAYS did you dry between your toes after washing?	○	○	○	○	○	○	○	○

Page Break

12A

12A. At your last doctor's visit, did anyone ask about your smoking status?

- ○ Yes
- ○ No

13A

13A. If you smoke, at your last doctor's visit, did anyone counsel you about stopping smoking or offer to refer you to a stop-smoking program?

- ○ Yes
- ○ No
- ○ Do not smoke

14A

Display this question

If 13A. If you smoke, at your last doctor's visit, did anyone counsel you about stopping smoking or... Yes Is Selected

Or 13A. If you smoke, at your last doctor's visit, did anyone counsel you about stopping smoking or... No Is Selected

14A. When did you last smoke a cigarette?

- ○ More than two years ago, or never smoked
- ○ One to two years ago
- ○ Four to twelve months ago
- ○ One to three months ago
- ○ Within the last month
- ○ Today

Page Break

Q65

Would you also be interested in our future research?

In our future research, we aim to develop the interventions/care pathways for women with type 2 diabetes to improve health and wellbeing and also to inform healthcare professionals about younger women's health needs.

If you would like to be contacted about future research projects as well, please click the box below.

- ○ Yes
- ○ No

Page Break

Import from library Add new question

Add Block

End of Survey

Thank you for your time spent completing this survey.

Your responses have been recorded.

Sources of support

Email: aycan.celik@kcl.ac.uk

KING'S College LONDON

Appendix C 1.6: Newsletter

WELCOME TO YOUR RADIATE STUDY PARTICIPANT NEWSLETTER

THANK YOU, FOR YOUR PARTICIPATION

We would like to thank you for the time you spent talking with one of our research team about your experiences of living with diabetes.

The chance to make an impact on women's health and wellbeing, while sharing your ideas about diabetes is a milestone for you and other women with diabetes.

We are grateful for your generous time and please feel free to get in touch with any issues, comments, or concerns.

STUDY UPDATE

- Thirty-six women with type 2 diabetes (T2DM) shared their experiences, perspectives and health needs about living with diabetes.
- Data analysis of these interviews is almost complete, and we are looking forward to sharing all the data with you.
- These valuable findings will be disseminated at diabetes conferences, articles and other meetings.
- Our findings show that future strategies are needed to improve women's health and wellbeing.

STUDY UPDATE: Summary of women interviewed

		Total (N: 36)
Country of residence		
	UK	23 participants
	Turkey	13 participants
Age		
	Mean	37 years
	Range	20-45 years
Gender		
	Female	36 participants
Ethnicity		
	White	20 participants
	Asian	13 participants
	Black	2 participants
	Mixed	1 participant
Family History of T2DM		
	Yes	29 participants
	No	7 participants
Duration of diabetes		
	<1 year	5 participants
	1-5 years	15 participants
	6-10 years	9 participants
	>10 years	7 participants

Summary of important health topics that you told us about

Health Topics	Sub-topics
1.Emotions of living with diabetes	• Diabetes related distress • Positive attitudes/thoughts for living with diabetes • Emotional response at the time of diagnosis - Changing and adapting • Disordered eating
2.Physical wellbeing	• Diabetes symptom burden (e.g. Fatigue, Yeast and Urinary tract infection) • Experiencing T2DM complications (Cardiovascular problems, Eye and kidney problems, Nerve damage)
3.Reproductive Health	• Periods and diabetes • Early menopause – an emerging silent impact of T2DM • Sexual wellbeing • The perceptions of women about pregnancy
4.Sociocultural impacts of living with T2DM	• Stigmatisation • Social monitoring and pressure • Social gatherings and events and cultural norms • Family and friend support • Social awareness and support and environment

Summary of important health topics (continued)

Health Topics	Sub-topics
5. Factors influencing diabetes self-management practices at a younger age	• Knowledge/Being in control: • Women's previous experiences of diabetes education • Daily life responsibilities (multitasking) • Perceived burden of self-care • Perceived impact of diabetes on work • Social support & culture • Impact of pandemic on diabetes management
6. Women's voices about diabetes care provided	• (Non)Person centre care – Just listening! • Perceived emotional care skills of Healthcare providers (HCPs) • HCP interaction • Context of diabetes care • Health topics that women want to discuss with health professionals – leaving a door open to discuss that conversation
7. Suggestions for diabetes management ideas	• Need for raising diabetes awareness at younger age • Education and training about T2DM and its risk factors • The necessity for holistic care • Methods of support • Social media, m-health, e-health • Continuity of care

NEW OPPORTUNITIES

Calling all women with T2DM aged 18-45 years

- In the next stage of our study we want to understand which of these health topics is a priority for women living with T2DM.
- Would you be willing to offer us advise on our ongoing research with a wider group of women living with T2DM?
- The information you advised will help us:

✓ to improve the diabetes management for women with T2DM

✓ to better understand women's health priorities and needs.

✓ to undertake the research that is relevant to women with T2DM.

Let's work together to find the top priority women's health needs

Participation is voluntary.

Taking part will take place in online (Zoom, Teams) or phone according to your preference.

You can take part in one-to-one OR a group with between 2-4 other women with T2DM according to your preference.

The meeting will not be audio-recorded.

There will be a few topics that we would specifically like to cover, and we would like to ask everyone's opinion about them.

NEXT STEPS

- Attend two online meetings (one-to-one OR a small group of other women)
- Share and discuss your views and opinion about women's top priority health needs

If you choose to help us design the next phase of our study or if you have any questions, please get in touch:

Aycan Celik (PhD researcher at King's College London)

Email: aycan.celik@kcl.ac.uk

Twitter: celik_aycn

Appendix C.1.7: Ranking Health Topics Identified in Study 2 (Qualitative Interviews)

IDENTIFICATION OF PRIORITY HEALTH TOPICS

What is this study about?

Prioritising women's health needs when living with type 2 diabetes during reproductive years.

What is known about women's health needs with type 2 diabetes?

The numbers of young women living with type 2 diabetes is rising sharply, accounting for 60 million women all around the word. Likewise, in the UK, nearly 121,000 young adults are living with type 2 diabetes, especially women are more likely to have it. The health needs of women of reproductive age living with type 2 diabetes are under-researched. Therefore, we have interviewed with 36 women with type 2 diabetes aged between 20 to 45 years old. We have found a wide range of health concerns experienced by our participants. These are presented in table 1 below.

Table 1: Health topics - Summary of important health topics that you told us about

Health topics	Sub-health topics
1.Emotions of living with diabetes	• Diabetes related distress • Positive attitudes/thoughts for living with diabetes • Emotional response at the time of diagnosis - Changing and adapting • Disordered eating
2.Physical wellbeing	• Diabetes symptom burden (e.g. Fatigue, Yeast and Urinary tract infection, weight gain) • Experiencing T2DM complications (Cardiovascular problems, Eye and kidney problems, Nerve damage)
3.Reproductive Health	• Periods and diabetes • Early menopause • Sexual wellbeing • The perceptions of women about pregnancy
4.Sociocultural impacts of living with	• Stigmatisation • Social monitoring and pressure

T2DM	• Social gatherings and events and cultural norms • Family and friend support • Social awareness and support and environment
5. Factors influencing diabetes self-management practices at a younger age	• Knowledge/Being in control: • Women's previous experiences of diabetes education • Daily life responsibilities (multitasking) • Perceived burden of self-care • Perceived impact of diabetes on work • Social support & culture • Impact of pandemic on diabetes management
6. Women's voices about diabetes care provided	• (Non)Person centre care – Just listening! • Perceived emotional care skills of Healthcare providers (HCPs) • HCP interaction • Context of diabetes care • Health topics that women want to discuss with health professionals – leaving a door open to discuss that conversation
7. Suggestions for diabetes management ideas	• Need for raising diabetes awareness at younger age • Education and training about T2DM and its risk factors • The necessity for holistic care • Methods of support • Social media, m-health, e-health • Continuity of care

Why do we want to prioritise these health issues?

- To inform healthcare providers.

- To spread knowledge to the wider population with younger women with type 2 diabetes.
- To adapt care and education support to better meet the physical and emotional needs of younger women.
- To provide effective management of type 2 diabetes at younger age.
- To improve women's health and wellbeing during their reproductive ages.
- To undertake the research that is relevant to younger women with type 2 diabetes.

Deciding on priorities

Please consider the health topics below. We want you to choose the 8 health topics that are most important to you. Rank them from 1-8 with 1 being the most important (greatest priority) and 8 being the least important (or lower priority) to you. We will ask 10 women to undertake this same activity.

Table 2: Health topics

Choose and rank 8	**Health topics**	**How participants described this topic.**
	Diabetes related distress (includes feeling overwhelmed by diabetes demands, anger, frustration, Fear for the future and complications)	*For me it was really, you know, difficult for me to go for injections or for the medicine because I wanted to manage it like without it, which is not possible I understand. I am worrying about what will happen to me.* *It (diabetes) affects my mood badly. It makes me very angry, irritable.''*
	Anxiety	*I do get anxious about, um, you know, like feet and amputations and all that kind of thing. I don't want to be that person.* *Living with diabetes is very difficult. You feel anxiety, stress…*
	Depression	*As a diabetic you are more likely to suffer from some sort of depression because of the hormonal balance*

		imbalance on the sugar level that you have internally that can fluctuate with your mood… *I used to take depression pills before… I am not currently using it, but I need it. My diabetes was under control with the depression medicine.*
	Knowledge and emotional support at the time of diagnosis	*I was very tearful at home and I didn't know what to do. I couldn't quote. I was finding ways to cope with it.* *It was quite an emotional rollercoaster during that time.*
	Disordered eating	*So I can go weeks and weeks and weeks of eating really well, and then have weeks of just like really dysfunctional binge eating, and that's been the case for decades.* *I feel like I'm addicted to carbs, rice. It mainly rice that's my problem.*
	Fatigue	*I struggle with tiredness daily.* *I don't have the previous energy anymore… I get tired very quickly.*
	Stigma	*There is almost a label attached to the diagnosis, that you don't look after yourself and eating the wrong things, which really is not the case.* *I think there's something that comes with diabetes, like I said, type 2, the kind of assumptions of like laziness.*
	Yeast infection & Urinary tract infect	*I had this issue of getting yeast infection and that my doctor told me that it's because of diabetes… I had it like twice or thrice. It means you know the effects of itching and smell and everything I faced it* *I found that I was having regular vaginal infections.*
	Headache	*My blood sugar levels fluctuate and in I sometimes have intense headaches; this affected my performance at work and now I work part time.*
	Swelling	*Diabetes caused swelling in me… My fingers, toes, sometimes my face are very swollen.* *My feet swell when I stand a little bit.*
	Weight gain	*After looking at symptoms did explain a lot, like gaining*

		weight for no reason, mood swings feeling tired a lot. *I'm aware that I've gained weight, and if I say to people, 'oh, I've also got type 2 diabetes now', I feel that I'd be judged because they would feel that, 'well it's obvious because you can see that she gained weight'.*
	Sleep problems	*I cannot sleep at night, it is difficult. I wake up at night and feel my hand and foot burning.* *It causes sleep problems when blood sugar is high.*
	Memory and concentration difficulties	*I also some days suffer with what I call brain fog find it difficult to concentrate on things, which when caring for my husband and sorting meds is hard work.* *I don't know, how can I explain? I sometimes forget something, I forget often…Exactly, I think it is due to my diabetes.*
	Cardiovascular issues	*I know that when my sugars are really high that my breathing is affected and my heart rate goes up, where I'm sort of struggling.* *I had a heart problem a few months after I was diagnosed with diabetes.*
	Eye problems	*There was a decrease in my vision. I said a curtain was coming down on my vision… He (doctor) said it might be because of diabetes.* *It (diabetes) just influenced my eyes. It affected my sight. I'm using glasses.*
	Kidney problems	*I already had stones in my kidneys. Inflammation occurred due to the high blood sugar level.*
	Nerve damage (Hand and Feet issues)	*My feet and knees got pain. I felt like a needle was sticking. I have suffered for a year, now I'm a little bit better.* *Yeah, it's a bit like tinkling in my hands… it's normally when I wake up in the morning, I found that my hands are all numb.*
	Menstrual cycle	*More irregular periods…It started almost a year ago and it causes me immense worry…I worry about my periods.*

		There were some irregularities since DM being confirmed, I had diabetes. I notice.
	Menopause	*Menopause, I am a bit young, but I mean it's quite useful, I suppose knowledge to have about, you know, what to expect.* *More recently, it has been erratic. I have partially put it down to being peri-menopausal…*
	Sexual function	*The only indirect affect is the depression which restricted my interest in sexual fulfilment.* *I think sometimes feeling tired and not being in the mood. That is happening.*
	Pre-pregnancy	*I wasn't really aware of the dangers/downside of high blood sugar and the affect on the pregnancy.* *I would like to know more how diabetes can affect pregnancy.*
	Pregnancy	*Having diabetes in pregnancy was worrying as I worried about the health of my baby. I ended up having a "dreaded" c section*. *Because I'm diabetic, does the body react differently in anyway? Is it a risk to baby? You know, the fact of having diabetes, does that present a risk for babies? I don't know.*
	Knowledge/information needs about diabetes management (diet, exercise, medication intake)	*I would like to get information about what are the side effects of these medications or not.* *I would like to learn what foods are okay to eat, actually, because I'm just doing that on my own at the moment.* *I'd like to know everything about diabetes. I would like to get information about how beneficial it will be to use my medicines regularly, how insulin is used, how beneficial exercise is, and which organs it will harm.*

Thank you so much for taking part in this prioritisation. We will share the findings with you by February 2021.

Appendix C.1.6: STROBE Checklist

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses
Results		

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
Outcome data	15*	Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at

http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.